STATEMENT OF DR ARCHIBALD D McINTYRE
B4

i. On re-reading paras 8.122 to 8.138 I am reminded of the happenings at that time but as I have indicated elsewhere my memory does not permit me to comment in detail or chronologically. This section of the preliminary report covers most of the questions I am being asked and what I read in these paragraphs is in keeping with what I remember of it.

ii. As can be seen from various papers sent to me the scientist members of the various expert committees were largely drawn from English Universities and other scientist orientated units. Much of the guidance given by DHSS and SHHD was based on the recommendations of these bodies. Either Dr Bell or I attended many of the expert advisory committee meetings which were held in London and reported back on progress and highlighted the problems involved in reaching difficult decisions.

iii. The paragraph numbers used in this statement are referable to the paragraph numbers used in the Inquiry's witness statement request schedule.

4. I presume that the statement "We would therefore be in a strong position to make decisions about the need to buy from one of the five US pharmaceutical companies" means that depending on the evaluation a decision could be reached about the need to buy from the USA. DHSS really took the lead in this area. My colleague Dr Covell later produced a note of an Expert Advisory Group on AIDS meeting which he attended (on 29th January 1985) where screening tests were discussed. He noted that "It may turn out that overseas tests may be produced quicker and could be more reliable" (SGH.002.7296).

5. I think it is likely that the issue of testing for HTLVIII was discussed between 13 August 1984, when Dr Ed Harris was invited to consider the need for the formation of a working group of the Advisory Committee on the National Blood Transfusion Service and the first meeting on 27 November 1984, but I imagine that the meeting of 27 November 1984 would be the first time where this issue was

discussed in a formal forum. My former colleague Dr Bell attended meetings of the CBLA Central Committee for Research and Development in 1984 and it is clear from notes that he prepared following these meetings that the issue of surrogate testing for HTLVIII was discussed but discounted (SGH.007.0734 and SGH.007.0761). There was also discussion at one of the SNBTS Directors' meetings, on 11 September 1984, of the fact that Dr Tedder had acquired a significant quantity of reagents from the USA and was establishing anti-HTLVIII assays (minutes at SGH.001.0445).

8. I do not know who was involved in these discussions; this would seem to be a DHSS issue (by which I mean that this was being led by DHSS, who would have known which scientists etc. were involved). With regard to the assessments I can only assume that the intention was to judge the efficacy of the various tests and compare the commercial tests with the one being developed in the NHS. A sensitive test was essential to avoid false positives or false negatives. Telling a person he was infected had family, social and employment implications. It is normal practice to evaluate a new test. This is particularly important in an area such as this where the test was not being carried out solely for the patient's own benefit but to ensure that the blood which was transfused into others would not pass on disease. The test had to be accurate. Any scientific test should be as near 100% accurate as possible. In the case of testing for HTLV III a test giving a significant number of false negatives could mean that infected blood would not be detected and could be given to a patient. If there was a significant number of false positives it would mean that some donors could be classified as HIV positive with all the stigma this causes. Therefore to suggest that any test is better than no test could have serious implications. To evaluate a test it has to be carried out on a large number of specimens in laboratory conditions. I do not know what scale the evaluation was to be carried out on; this was a scientific/technical issue which would have been considered by the people carrying out the evaluation.

9. I do not know whether it is correct that the assessment of commercial products from the USA was not to include the Middlesex Hospital/Chester Beatty test. There is a reference to the UK evaluation panel in a briefing minute to the Scottish Health Minister (SGH.002.7226 at paragraph 10) which talks about the

"English test" being included in these evaluations; I think this reference must be to the MH/CB test. In any event I do not imagine that the Middlesex Hospital test could have been excluded from evaluation entirely, because we couldn't possibly have used a domestic test which had not been properly evaluated.

10. I do not know why the English Ministers were not told about the evaluation programme in January 1985. The Scottish Ministers were advised in March 1985 (SGH.002.7226) and indicated their assent to the adoption of a phased policy of introduction, which would take into account the evaluation of the tests available, the need for ready access to testing facilities outwith the transfusion service and a recognition of the considerable requirement for additional testing, monitoring and counselling of donors with positive tests (SGH.002.7224 and SGH.002.7225). This briefing would have been contributed to by the relevant SHHD medical advisers and officials. Whitehall Ministers and the Scottish Ministers were nearly always told about major developments at around the same time.

11. I do not know who the parties referred to in the memo were. I imagine that the background to the memo was simply that evaluation required to be undertaken in order that advice could be provided to Ministers. It was simply necessary. I do not know which manufacturers were to be subjected to evaluation. I imagine that the intention was that the DHSS would carry out the evaluation, because they were taking the lead in this area. I imagine that SHHD would have been told that it was considered necessary for there to be a programme of evaluation. We knew that evaluation was important and there would have been no objection in principle.

15. As you can imagine there was a great rush to develop a test and to get there first. I believe that there was a move to bring across from the USA some tests which did not have FDA approval and hence I believe could not be marketed there but could possibly be introduced in UK. There was some concern that this might happen and I think that in their discussions it was suggested that to counteract that only those tests with FDA approval could be used. (By 'their', I mean DHSS in the widest sense as their Scientific and Technical Branch would be involved and possibly also the licensing branch. We were kept informed of developments). To be

fair to all concerned this ruling would probably have to apply to UK companies. Hence the suggestion that this stipulation might not be in Wellcome's interest.

DHF.001.9098 is the draft letter to go to those developing tests and telling them about the proposed evaluation. While addressed primarily to companies outside the UK there is no reason to believe it was excluding the UK companies. I assume the letter originated from the administrative side of DHSS. DHF.001.9105 (which I assume was a minute from higher up the DHSS administrative chain giving approval to the draft and stating specifically "All kit/tests from any source including Middx Hospital and Wellcome will have to be tested to the same level and protocol.") gives approval on 17 January 1985. However, then Scientific and Technical Branch appear to have jumped in in DHF.001.9143 saying in effect 'hold on' - "Before the letter goes out.....". This all feels logical but is no more than my attempt to elucidate the thinking of DHSS colleagues after a lapse of 25 + years and my comments should be read in light of this caveat. DHF.001.9143 was written on 21.1.85 from the Scientific and Technical Branch of DHSS and was particularly concerned with facilities for carrying out the test. I seem to remember that STB was based in a different building but that is really irrelevant. In this minute the STB officer said he would speak to X when he returned from holiday.

It would seem quite clear that the policy was decided as stated in the minute of 17.1.85.

17. I do not know whether EAGA members were aware, at the first meeting on 29 January 1985, that the decision to carry out the evaluation had already been made and that letters had been sent to all manufacturers. I would not have expected the decision as to whether evaluation was necessary to be left to EAGA, because their focus was not specifically on testing – they were looking at HIV/AIDS from many different angles. The question of evaluation is really for the scientific and technical people within DHSS. I note from the SNBTS Directors' meeting minutes of 20 June 1985 (SGF.001.0203) that SNBTS decided to await the results of the evaluation.

19. I do not know what was meant by "I think we would regard the commercialisation of the BTS test as quite separate from the evaluation programme that we were setting up", but it may have had something to do with the desire to keep the development of UK tests and the evaluation process separate. I imagine there was a desire to avoid a conflict of interest. This was why it was decided that the Middlesex Hospital was not the appropriate venue for the evaluation to be carried out, and why PHLS were eventually invited to conduct the evaluation.

21. I do not know anything about the "secret meeting". I do not know whether it took place.

22. The evaluation exercise was not run in parallel with the introduction of testing because it is necessary to ensure that a test is good before it is put into practice. The evaluation process was to determine the accuracy of the tests and which one or ones were to be preferred. This is how we ended up with a choice of 2 tests.

23. Dr Bell who was one of my group did most of the day to day work in relation to blood transfusion and attended most of the meetings in SHHD and DHSS on this matter. He worked very closely with Dr Alison Smithies who was a Senior Medical Officer at DHSS and was engaged for a large part of her time in this area of work. Dr Bell kept me and other relevant staff in SHHD informed about what was happening either in discussion or by one of his detailed aide memoire notes (this was his general practice; I am not referring to specific notes that I can recall in this context however three examples which are related to the introduction of HIV testing are contained within SHHD blood policy files which have been delivered to the Inquiry: SGH.007.0734; SGH.007.0761 and SGH.002.7301. Dr Alison Smithies was the key DHSS medical officer. In addition to Dr Alison Smithies, Drs Ed Harris and Mike Abrams (both DCMOs) were also involved as was Dr Diana Walford initially, before handing over to Dr Smithies. The SHHD medical officers dealt with their medical colleagues in DHSS and left their administrative colleagues to liaise with the DHSS administrators.

26. I believe that SNBTS did abandon its own evaluation altogether to await the DHSS evaluations (see SGH.002.7260 and SGH.002.7301). The DHSS evaluation

may have been more advanced than the SNBTS evaluation. This issue was discussed at the SNBTS Co-ordinating Group meeting on 19 February 1985 (SNB.003.9171). At this meeting concern was expressed as to the number of false positives produced by the then current generation of tests and in fact the Directors were writing a letter to the Lancet advising that antibody testing should not be introduced at present given the unreliability of the current generation of tests. The Directors decided, after full discussion, not to pursue a proposed evaluation by the West of Scotland BTS. From this minute it would appear that the decision to await the results of the DHSS evaluations was made by the Transfusion Directors. I cannot recall being involved in any discussions between SHHD and SNBTS regarding this matter. It was also agreed at this meeting that no Transfusion Centre in Scotland would commence routine HTLVIII antibody testing unilaterally.

31. It was agreed that HTLVIII screening had to be introduced on a national basis and the date of 14 October 1985 was selected. Testing for HIV was a very sensitive matter, with particular reference to homosexual and especially bisexual spread. Also, false positives occurred and confirmatory tests were essential but very specialised (at least in the early days). Although the first stage of the evaluation programme was completed on 30 July 1985 the second stage still required to be undertaken. This was an assessment of the test in a regional transfusion centre setting and this was necessary because laboratory evaluation of the test only gives you part of the picture; you need to see how the test works in practice. The evaluation would only have dealt with blood samples and not identifiable people. I am reminded by reference to the papers (SGH.002.6950, SGH.002.7012 and SGH.002.7029) that Dr Forrester and I took steps to ensure that funding for the essential confirmatory tests was made available to the reference centres in Edinburgh and Glasgow. The arrangement of alternative testing facilities was the responsibility of the health boards and SHHD ensured that Chief Administrative Medical Officers of the Health Boards were aware of the need to provide such

facilities (see SGH.002.6995 and SGH.002.6997).

Statement of Truth

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

Signed .....

Dated 18-3-11