STATEMENT OF DR GRAHAM ALEXANDER SCOTT
B4

(i) This witness statement relates to the request received by the Scottish Government Legal Directorate on 18 March 2011. I am anxious to assist the Inquiry but I'm afraid that my recollection of the events described in the witness statement schedule is not good, and I am unable to provide helpful responses in relation to matters of detail. I do not recall being substantively involved in the events which the Inquiry wishes to look into, although I would have had a general awareness at the time.

(ii) The paragraph numbers used in this statement relate to the paragraph numbers in the Inquiry's witness statement schedule.

4. I do not know what was meant by 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." I don't think it was necessarily intended that commercial tests from the USA would only be brought into the UK in the event that the Middlesex/Wellcome test provided unsatisfactory for UK requirements. One of the 2 tests recommended following the DHSS evaluation was in fact a commercial US test (the Organon test).

5. I do not recall whether the Advisory Committee on the National Blood Transfusion Service Working Group was the first forum in which the introduction of donor screening for HTLVIII was discussed. I have been shown papers which relate to meetings of the CBLA Central Committee for Research and Development in Blood Transfusion which suggest that the possibility of surrogate testing for HTLVIII was discussed at some point (SGH.007.0734 and SGH.007.0761), but I believe the idea was rejected.

8. I do not know when the discussions referred to took place, nor who was involved. I certainly do not recall having been involved. The assessment would have been intended to test the efficacy of the tests which were being developed. At the end of the evaluation process, 2 tests were recommended for use within the

blood transfusion setting. The Blood Transfusion Services were heavily involved in the process. An evaluation process such as this is completely standard in circumstances where a new testing process is being introduced. There is absolutely no point in using tests which have high rates of false positives or false negatives; to use such a test would distort the true picture and would in any event simply be dangerous. A test is only of value if it is accurate and the purpose of the evaluation would therefore have been to determine which tests provided as few false positive/negative results as possible. I do not know what scale the assessment was intended to be carried out on.

9. I do not know whether it is correct that the assessment to be done on the commercial products from the USA was not to include the Middlesex Hospital/Chester Beatty RIA. I do not imagine that the Middlesex Hospital test would ever have been used without having been evaluated, because all tests proposed for use would require to be equally thoroughly 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 on 21 March 1985 that DHSS Ministers had agreed, in principle, that all blood donations should be screened and that a UK Evaluation Panel had been set up (SGH.002.7226). A briefing paper such as this would have been the product of much internal discussion, as the official submitting the briefing would wish to ensure that it was definitive. I do not know whether the proposed meeting between DHSS and which is referred to in SGH.002.7302 took place. I certainly do not recall being in attendance.

11. I do not know who the parties referred to in the memo were. I do not know what the background to this memo was, however this memo is exactly the sort of thing I would expect to see. I would expect that in order for the various tests to be evaluated, the manufacturers would be asked for information to substantiate performance claims etc. I do not know which manufacturers were intended to be subjected to the evaluation programme. I do not know who was intended to carry out the evaluation although I imagine that SNBTS would have been invited to participate in some way, perhaps by provision of information as to their capability to introduce the various methods. SHHD may also have been asked to participate,

although I do not recall this happening. John Cash was SHHD's Adviser in Blood Transfusion matters at that time, as well as being the National Medical Director of SNBTS.

15. I cannot explain the discrepancy between the two responses, nor advise what was decided.

17. I do not know whether the 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 imagine that the decision as to whether an evaluation was necessary was made by DHSS because they were operating at a level above EAGA, which was simply an advisory body, although an important one. I do not doubt that EAGA would have supported the principle that an evaluation process was required, however as an advisory body they did not have executive powers to make that decision, and I do not believe that they would have had a budget for setting up an evaluation process such as this.

19. I do not know what is meant by the phrase "I think we could regard the commercialisation of the BTS test as quite separate from the evaluation programme that we are setting up", although to my mind those two processes must necessarily be kept separate because they are two completely different things – commercialisation is a process aiming to offer a product for sale, which is of a different nature to a process aiming to evaluate the quality of products.

21. I do not know what the "secret meeting" was, whether it took place or who attended. Seeing reference to the term "secret meeting" did not ring any bells with me at all.

22. The evaluation exercise was not run in parallel with the introduction of testing because it simply wouldn't have been the correct thing to do to introduce a test before it had been evaluated (because of the risk of false results etc). I also do not imagine that the Regional Transfusion Centres would have accepted that they should use tests before they could be satisfied as to whether or not the test was up to the required standard.

23. I do not know any other DHSS personnel who might have been involved with the introduction of HTLVIII screening. The only name I recall is Dr Smithies'.

26. I do not know whether the SNBTS abandoned its own evaluations altogether to await the DHSS evaluations. I was not involved in any discussions which resulted in SNBTS abandoning its own evaluation.

31. HTLVIII screening was not introduced in Scotland until 14 October 1985 because, in the first place, it had been decided that the test should be introduced simultaneously across the UK. In the second place, there was the outstanding issue of the arrangement of alternative testing facilities. These were to be arranged by Health Boards, and I issued advice to Health Board Chief Administrative Medical Officers on 14 August 1985 to ensure that they made the necessary arrangements (SGH.002.6995 and SGH.002.6997). Circulars such as this were more often issued in the name of the Chief Medical Officer and I imagine that Dr Reid, the then CMO, may have been out of the country when this circular was issued. The Scottish Minister for Health had been particularly concerned to ensure that alternative facilities were available, as is shown by his response to the minute of 21 March 1985 (his response is found at SGH.002.7225 and the Secretary of State for Scotland's response is at SGH.002.7224). It was also only the first stage of the process which had been completed by 30 July 1985; the test still had to be evaluated under field conditions. Everyone was possessed of the need to introduce the test as soon as possible, preferably on a UK basis as Ministers would have expected this and it was sensible to deal with an issue of such national public health importance on a co-ordinated basis. It goes without saying that introduction of testing had to be done properly. However, had England eventually not been in a position to introduce the test on the date agreed upon, I imagine that at that stage Scotland might have considered a delay to allow England to catch up unacceptable and may have

introduced the test unilaterally on the date planned.

Statement of Truth

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

Signed .....

Dated .....5/18/11.....