THE PENROSE INQUIRY

WITNESS STATEMENT OF DR IAIN S MACDONALD

C2 – SURROGATE TESTING FOR HEPATITIS C

1. My name is Iain Smith Macdonald CB. My date of birth is [redacted]. I attach a copy of my curriculum vitae as Annex A to this statement.

2. My background was in public health medicine. Before the major reorganisation of the NHS in 1974, public health responsibilities rested with local authorities which were required to appoint a Medical Officer of Health and additional medical staff as required. Prior to joining the Scottish Home and Health Department, I was Deputy Medical Officer of Health to two Lancashire county boroughs.

3. I joined the Scottish Home and Health Department as a Medical Officer in 1964. Between that year and my retirement from the post of CMO at the end of 1988 there were two periods during which I was involved in matters relevant the Inquiry's terms of reference. It may be helpful if I offer some background comments on how the medical staffing on SHHD was organised and how it operated. Thereafter I will attempt to describe my rather different involvements in blood transfusion matters.

The Medical Staff in SHHD.

4. Until 1974 SHHD had one Deputy Chief Medical Officer, to whom Principal Medical Officers reported. Each Principal Medical Officer headed a group of perhaps 3 or 4 Senior Medical Officers and Medical Officers and each PMO group had a defined remit. In 1974 a second DCMO post was created and I was appointed to that post. Responsibilities at that level had therefore to be divided so that some PMOs reported to one DCMO and some to the other. The PMO group with responsibility for blood transfusion did not report to me, although our liaison arrangements, to which I will refer in paragraph 5 below, ensured that I had some awareness in broad terms of major developments. In 1985, when I was appointed CMO, SHHD reverted to the arrangement prior to 1974 and had only one DCMO. As Chief Medical Officer from 1985 to 1988 I had a total medical staff of perhaps 20 to 25 individuals.

5. Two practices in SHHD were intended to keep the CMO and DCMO(s) aware of the work in which medical staff were engaged and of any special or difficult situations that might be arising. These practices were helpful in identifying occasions when more than one member of the medical staff might have become involved in similar or overlapping matters. Thus adequate liaison and sensible handling could be ensured. The two practices were:

(1) A meeting was held every Monday morning chaired by the CMO, or in his absence by a DCMO, and attended by the PMOs heading each of our groups. In addition to keeping CMO and DCMO(s) informed this gave PMOs an opportunity to learn about activities in other groups that might have relevance to their interests. These were quite informal meetings and notes were not made.

(2) SMOs and MOs wrote a monthly report indicating briefly the activities in which they had been engaged during the month. These were passed to their PMOs and by them to the CMO and DCMO(s). It was then open to CMO and DCMO(s) to ask for more information on any particular matter. Unfortunately these reports cannot now be found.

6. The remits of the PMO groups were, as a general rule, in sufficiently broad terms to ensure that any issue likely to arise would belong to one or other of these groups. Nevertheless, CMO or a DCMO might decide to take the lead on a particular issue, with support from the relevant PMO group, because it had some unusual significance. For example, when CMO I chose to take the lead in trying to introduce measures to limit the spread of HIV by the shared use of injecting equipment. I did this because the spread of HIV/Aids was a major epidemiological occurrence of a kind rarely seen over the centuries and we knew that in Scotland we had a serious situation on our hands arising from the sharing of needles and syringes. It was also a sensitive matter requiring agreement at a senior level in SHHD, the consent of Ministers and the cooperation of police and others. Dr Scott, as DCMO, took the lead on medical staffing and training because of its vital importance to the NHS, and the levels at which it was handled by medical professional bodies and universities.

7. Medical staff were related to administrative colleagues as advisers. The medical staffing structure outlined briefly above matched the administrative structure fairly closely. This facilitated the development of working relationships. While the administrative staff were ultimately accountable for expenditure the advice of medical staff would be taken into account whenever appropriate. The consideration given to the question of introducing surrogate testing for NANBH, which will be addressed in more detail below, provides an example of how this arrangement works in practice. If departmental medical staff had been persuaded, after consulting colleagues with relevant expertise, that surrogate testing for NANBH was a reliable procedure which would give few false results (positive or negative) and be free from adverse effects they would have advised administrators accordingly and it would have been highly likely that funding would have been provided. In the event departmental medical staff were not sufficiently persuaded and advice reflected this. It is of course important not to see this in over simplistic terms. Such situations seldom present as a straightforward differentiation between black and white. Various shades of grey are more likely to be encountered.

My First Responsibility for Blood Transfusion Matters.

8 As an MO/SMO I had responsibility between 1965 and 1973 for the Department's medical interest in blood transfusion. The position of the blood transfusion service in Scotland was still as described in paragraph 5.5 of the Inquiry's Preliminary Report. The Scottish National Blood Transfusion Association was responsible for the operation of the service and had its own secretary and treasurer. The Department's medical officer held a position (unpaid of course) with the curious title of Medical Secretary. I believe that I spent about a third of my time on blood transfusion matters. The head of an administrative branch in the Department also spent a significant amount of his time on blood transfusion matters.

9. During this period I chaired quarterly meetings in St Andrew's House of the five Regional Directors of the SNBTA. I also attended, along with one of the Directors from Scotland, similar meetings at two monthly intervals in London, attended by Regional Directors in England, Wales , and Northern Ireland, chaired by

Dr (later Sir) William Maycock, Consultant Adviser to the Department of Health and Social Security.

10. As a civil servant, issues relating to blood transfusion arising within or referred to SHHD would be passed to me for medical advice or opinion. As Medical Secretary within SHHD I also had a medical and to some extent an administrative role in that organisation and made fairly frequent visits to the various regions..

11. A major issue that straddled the interests of SHHD and the SNBTA was the future arrangements for protein fractionation and the production of blood products. These future arrangements had to take into account the intended rebuilding of the Royal Infirmary of Edinburgh, and the intention that protein fractionation and the production of blood products would be divided between a new centre in Edinburgh and facilities in or near London.

12. On the first point, the Blood Products Unit in Scotland was originally in the Royal Infirmary of Edinburgh. In the 1960s there was an intention, which eventually did not materialise, to rebuild the Royal Infirmary on its existing site in Lauriston Place. Later in the 1960s the view was taken that it would not be appropriate to embed a production facility with uncertain future space requirements in a major teaching hospital. A site for a new purpose built BPU was found at Liberton, where the new centre was built.

13. On the second point, at the end of 1965, when I took over the blood transfusion responsibility, my predecessor told me that it had already been agreed that one-third of the fractionation work for Great Britain would be undertaken in Edinburgh and two-thirds at Elstree. There are references in paragraphs 5.6-5.15 and 5.93-5.96 of the Inquiry's Preliminary Report to a series of meetings between the senior staff involved in protein fractionation and blood products in England and in Scotland, between February 1965 and March 1973. These were intended to coordinate and monitor progress. A brief account of matters discussed is provided in document SNF.001.2412. I was present at most of those meetings. My recollection is that there were useful exchanges on technical matters but little progress was made towards settling production targets. Paragraph 5.13 states correctly that "total production targets were not resolved". In relation to production targets, the English

view would have been of much greater significance in relation to UK needs than the Scottish one because of the much larger quantity of plasma to be expected from the English transfusion centres. Throughout my involvement with the SNBTA, the practicalities of implementing this were never considered in detail, but it remained an intention to be fulfilled at some later date. In the event that never happened in the way envisaged.

14. During my period of involvement with the SNBTA, rapid progress was made in developing preparations for the treatment of haemophilia. Towards the end of that period, in 1973, the concept of prophylactic treatment and home treatment became realistic possibilities and were being advocated with enthusiasm. It began to be apparent that Factor VIII requirements could become the dominant factor in determining plasma requirements and hence the priorities for a blood transfusion service that depended on voluntary donors.

My Concern with Blood Transfusion as CMO.

15. As I explained in paragraph 4, while I was one of two DCMOs from 1974 until 1985 the PMO group with responsibility for blood transfusion did not report to me. When I became CMO from 1 December 1985 blood transfusion was of course part of my overall responsibility for medical matters within SHHD. However, the day to day concern with blood transfusion, including the impact on it of HIV and Hepatitis C infections was left in the hands of experienced colleagues whom I knew well as competent and conscientious individuals who had been undertaking this for several years. Before addressing the questions about the non-introduction of surrogate testing for Non-A, Non-B hepatitis im the Schedule requesting this statement I would like to draw particular attention to Dr Forrester's minute of 1 December 1986 to Dr McIntyre giving an account of a meeting on 24 November 1986 of the UK Working Party on Transfusion-Associated Hepatitis (SGH.002.8137). This is a masterly summary of the pros and cons of surrogate testing and has a bearing on most of the questions raised in the Schedule. That working party's advice went of course to DHSS as well as to SHHD.

Questions on the non-introduction of surrogate testing for Non-A Non-B Hepatitis.

Consideration given by the Scottish Home and Health Department in the 1980s as to whether surrogate testing of blood donors for non-A, non-B hepatitis (NANBH) should be introduced

16. As explained in paragraph 4 I did not have responsibility for blood transfusion matters in the early 1980s, before I became CMO on 1 December 1985. Dr Scott (the other DCMO at that time) had responsibility for blood issues. Thereafter, although blood transfusion was of course part of my overall responsibility the day to day concern with this was undertaken by experienced colleagues. The immediate involvement of Dr McIntyre (PMO) and Dr Forrester (SMO) has been noted in the Preliminary Report.

The research into surrogate testing for NANBH in the 1980s funded by the SHHD

17. Research fell under the aegis of the Chief Scientist Office, which had its own staffing and budget. As part of SHHD there was liaison, as may have been appropriate, between the CSO and other parts of SHHD. I would not, as a matter of routine, have had personal involvement in relation to applications for funding of research and I am not aware of research into surrogate testing for NANBH that may have been funded by the CSO as part of SHHD. .

Why the Biomedical Research Committee at their meeting of 25 September 1987 rejected the research proposals by Drs Gillon and McClelland for Scottish participation in the UK multi-centre study into surrogate testing

18. I did not attend meetings of the Biomedical Research Committee and have no knowledge of the proposal which was declined at the meeting of 25 September 1987. CSO may be able to explain why the application was rejected. Dr McIntyre or Dr Forrester may also have some knowledge of this.

The response by SHHD to each of the requests by the SNBTS for funding to introduce surrogate testing

19. I have now seen the relevant PES documents. I did not see them at the times when they were submitted to SHHD. It would however have been quite exceptional for them to have been shown to me, or for me to have been involved in considering them. Paragraph 9.36 of the Preliminary Report suggests that Dr Scott may have been involved and may be able to contribute a comment.

The response by SHHD to the recommendation of the SNBTS directors (agreed at their meeting of 3 March 1987, SGH.001.6653) that surrogate testing should be introduced with effect from April 1988

20. This was in fact a meeting of the SNBTS Directors and Haemophilia Directors rather than SNBTS Directors alone. It was chaired by Dr Forrester, who would no doubt have reported back on what had been agreed. The Departmental response was negative, which is not at all surprising in the light of Dr Forrester's account of the meeting of the UK Working Party on Transfusion-Associated Hepatitis on 24 November 1986 (SGH.002.8137). This note also indicated a lack of enthusiasm within DHSS, confirmed at paragraph 9.35 of the Preliminary Report.

The extent to which the cost of surrogate testing was taken Into account by SHHD in considering whether to finance such testing

21. I cannot answer this question from my own knowledge. Cost is always a factor that has to be taken into account, but never without regard to any other relevant considerations. In this instance the other relevant considerations were the doubt and uncertainties described by Dr Forrester in his account of the meeting of the UK Working Party on Transfusion-Associated Hepatitis on 24 November 1986 (SGH.002.8137).

Why surrogate testing of blood donors for NANBH was not introduced in Scotland?

22. I cannot add anything to what is recorded in the minutes referred to in the Preliminary Report. Essentially, there was too much uncertainty about various aspects of surrogate testing to justify introducing it.

The main discussions between SHHD and the Department of Health and Social Security (DHSS) on research into surrogate testing and whether surrogate testing of blood donors should be introduced?

23. There were obviously exchanges between individual medical officers in these two departments but I do not know what might be covered by the reference to 'main discussions'.

If surrogate testing for NANBH had been introduced in Scotland, the extent to which the incidence of post-transfusion NANBH/hepatitis C is likely to have been reduced.

24. In the light of the unresolved uncertainties this question is unanswerable.

Statement of Truth

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

Signed Iain S Macdonald

Dated 17 August 2011