THE PENROSE INQUIRY

SUPPLEMENTARY STATEMENT OF DR IAIN S MACDONALD

C2 – SURROGATE TESTING FOR HEPATITIS C.

1. This statement is in response to a request from the Inquiry for a further statement on surrogate testing for hepatitis c (C2). My original C2 statement explains my involvements in blood transfusion matters during different periods. In paragraphs 3 and 4 I explained that as an MO and SMO I had a direct involvement in the affairs of the SNBTA from the end of 1965 until I became a Deputy CMO in 1974. As a DCMO I did not have responsibility for blood transfusion matters. When I became CMO on 1 December 1985 blood transfusion was of course part of my overall responsibilities but, as I explained in paragraph 15, I left the immediate responsibility with colleagues who were already involved.

2. In paragraphs 16 to 24 I answered questions posed by the Inquiry in requesting that earlier statement. Many of these were about whether or not I had seen or was aware of specified documents, and did not call for extended responses. The questions posed in requesting this supplementary statement are of a different character and seem to call for more extensive answers. In attempting to offer a constructive response I therefore propose to refer to information derived from written material already known to the Inquiry, and to knowledge acquired from my contacts with the blood transfusion service.

3. Queries (1) and (2) are about the benefits that might have flowed from a large scale prospective study, perhaps along the lines of the US TTV and NIH studies, including the follow up of recipients, in the UK in the early 1980s or at some point thereafter. The study proposed by Dr McClelland in 1981 included a wish 'to obtain information as to whether the screening of blood donors by ALT might be of value in the UK'.(PEN.017.0942 and PEN.017.0950) While such a study would have provided additional information about NANBH in the UK it seems doubtful whether sufficient new information could have been obtained in time to influence the decisions that

had to be made by blood transfusion services. The US TTV study commenced in July 1974, but in reporting on an interim analysis in 1978 caution was advised in interpreting the data 'since the number of patients analyzed to date is small'. (PEN.017.0870)

4. Other considerations have also to be taken into account. A blood transfusion service has a duty of care towards donors as well as towards recipients, and must maintain an acceptable balance between these two duties. All of the available information shows that surrogate testing will yield varying but appreciable numbers of false positive and false negative results. Each of these sets of false results creates problems. There are comments, mostly cryptic, in the literature and records available to the Inquiry which recognise that false positive results arising from surrogate testing of donors would create problems that require consideration.

5. Examples of such comments are:
   - '*Other considerations must be taken into account if widespread ALT testing of blood is to be considered....Advising donors of the implications of the ALT level would pose a special problem....*' N Eng J Med (1981) (LIT.001.0753)
   - An assessment in the JAMA referred to findings having '*important implications for blood transfusion services, raising many difficult ethical and practical issues*' (1981) (LIT.001.1817)
   - *'The manifold effects of ALT testing must be thoroughly considered before there is wide-spread adoption of such an interim measure....'* N Eng J Med (1981) (LIT.001.1630)
   - Dr R Mitchell (SNBTS) is recorded as saying that surrogate testing would '*...cause some anxiety to donors and their families when we cannot offer anything more than the argument that NANBH may exist...*' (1983) (LIT.001.1837)
   - Barbara and Tedder said that '*The additional question of appropriate advice to donors would also be enormous. Such considerations also led the American Association of Blood Banks to advise against routine ALT*

screening of donors.' Clinics in Haematology. (1984) (LIT.001.3739) The American Association of Blood Banks however decided in 1986, with some difficulty, to change its position. (PEN.016.0312)

6. Query (3) is concerned with the conclusions of Drs Dow and Follett in their report 'NANBH in the West of Scotland' and asked if sufficient emphasis had been placed on the likely prevalence and seriousness of post transfusion NANBH. This report was based on a study carried out between 1.9.80 and 31.8.83. Dr Dow has already given oral evidence to the Inquiry and this issue appears to have been clarified in the course of that evidence (18 March 2011, p151 et seq.).

7. Query (4) asks if in the second half of the 1980s SHHD medical officers placed sufficient weight on the likely prevalence and seriousness of post-transfusion NANBH, and if their views in that regard influenced their opinion on whether surrogate testing of blood donors should be involved. Dr Forrester's extensive note of 12.6.86 (SGH002.8142) on transmission of NANBH by blood and blood products began by saying that the information in the note is mostly derived from Dr Dow's thesis, but he goes on the say in paragraph 5 that *'The condition is not as a rule serious, and most cases detected have not even been jaundiced. There may however be a tendency for it to become chronic and the long-term outlook is inevitably not yet known.'* Dr Forrester seems therefore to be taking account of the facts that many cases are non-icteric and that some go on have more serious consequences. His later note of 26.1.87 (SGH.003.1657) was a short paragraph intended for internal departmental purposes and was limited in its scope. In the note dated 9.2.87 (SGH.001.2261) of Dr Forrester's report to the Meeting of Haemophilia and SNBT Directors he mentions *'some risk of cirrhosis of the liver in the long term'*. The context in which his note to CMO (me) of 30.8.88 (SGH.002.4672) was written is not clear. I may have raised a query about some unidentified document, but what he said was probably perfectly fair in the circumstances – whatever they were. In his minute of 6.4.87 (SGH.002.8127) Dr McIntyre is reporting a situation as it existed and does not appear to be endorsing views expressed elsewhere or expressing a view of his own on the characteristics of

NANBH. While the views of SHHD medical officers may have contributed to their opinions on whether surrogate testing of blood donors should be introduced, these views do appear to have been properly balanced.

8. Query (5) asks about the possible consequences if surrogate testing of donors had been introduced in Scotland. I do not think that we have sufficient information to attempt to answer query (5)(a). The same probably applied to query (5)(b), although, as the supply of blood came under stress in attempting to secure sufficient plasma for fractionation, any loss would have been unfortunate. Query (5)(c) raises an interesting point. As virtually all of the plasma that could be secured from donated blood was being contributed to large pools for fractionation a few donations that slipped through as false negatives could do damage out of all proportion to the actual number of such donations.

9. Finally, it is of some interest to note the increasing pressure perceived by SNBTS from about mid-1986 to introduce surrogate testing. A major source of this pressure was that moves were afoot elsewhere in the world, including particularly among commercial producers in USA, to introduce surrogate testing. The existence of these commercial producers cast a long shadow over fractionation activities within the NHS.

Statement of Truth

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

Signed ..... Alan S Macdonald .....
Dated ..... 23 September 2011 .....