SNBTS DOCUMENT REQUEST No:

2010/00033

Penrose Inquiry

C1 Witness Statement

Final Draft

Prison Donations

Schedule

Issue in respect of which a statement is sought

Hepatitis C

The acceptance of blood from 'higher risk' donors, in particular:

a) **prisoners; and**

b) **donors who had a history of jaundice, and who were negative for Hepatitis B when the existence of Non-A Non-B Hepatitis was known and its presence could not be excluded**

Matters to be included in the statement

Penal institutions

(1) The total amount of blood collected annually from penal institutions by each Blood Transfusion Service ("BTS") in Scotland between 1975 and the cessation of the practice around 1984. **(I have no recollection of these figures but have reason to believe they could be made available from SNBTS)**

(2) (In order to place the preceding information in context), the total amount of blood collected annually by each BTS region in Scotland between 1974 and 1991. **(I have no recollection of these figures but believe they could be obtained from SNBTS. I**

would advise that placing these annual figures in context with those above should be done with some caution. More appropriate data may be available from SNBTS which would allow a better view of the way prison donations supported the supply of red cells in the early 1980s, at critical but short periods throughout the year.)

(3) When the practice of collecting blood from penal institutions stopped in each region in Scotland. (Dr Anne Welch (SNBTS) has kindly advised me that the following dates are the occasions of the last prison donor sessions: Aberdeen: 28/7/83, Belfast: 26/10.83, Dundee: 2/8/83, Edinburgh: 7/4/80, Glasgow: 25/3/84, Inverness:24/2/83)

(4) Why the practice stopped. (It may be helpful to acquire Information from those Regional Centre Directors (Dr Mitchell, Urbaniak, McClelland and Brookes) who are still alive. But it can be assumed that it had much to do with the comments of the MCA Inspectors (though this issue was not raised at the Glasgow, Inverness, Aberdeen or Northern Ireland inspections); the lively/heated discussions of the Directors at their meeting on the 29 March 1983, when no consensus was achieved; and subsequent regional reflections on ways of sustaining supplies without prison sessions. What is more certain, however, is that these dates do not derive from a national (SNBTS Directors) management decision because such decisions required consensus or an instruction from SHHD; neither was forthcoming. What we did do, as did the MCS Inspectors, was seek guidance from DHSS. None came.

My father was a prison chaplain and on several occasions I visited HM Armley Prison. I judged the health of many paid donors seen by me in 1969 in plasma collection centres in Los Angeles was much worse than that of inmates of the Leeds HM prison in 1983. As I recall the problem of drug addiction in UK prisons in 1983 was not the problem it is now.

Whilst arguably not relevant, it may be worth pointing out that MCA Inspectors did not seek to impose a ban on prison donors used by commercial plasma collection agencies in the US which supplied plasma for coagulation factor

concentrates destined for the UK. It is my understanding that prison donors were not excluded in the US until 1990 (I have a reference for this if required).

(5) The consideration given between 1975 and 1984 by those in the Scottish National Blood Transfusion Service ("SNBTS") to whether blood collected from prisons carried a higher risk of hepatitis including, in particular, non-A non-B hepatitis ("NANB hepatitis"), and whether the practice of collecting blood from penal institutions should continue. **(As far as I can recall this topic was not discussed by the SNBTS Directors until the matter was raised by the Medicines Inspector in 1982. Furthermore, to the best of my recollection, the news on the 29 March 1983 that Edinburgh had abandoned prison donor session in 1980 came as a complete surprise to me and all other SNBTS Directors.)**

(6) Whether the cessation of the practice of collecting blood from penal institutions led to any difficulties in maintaining a sufficient supply of blood in Scotland. **(None that I recall but I would advise that each former living Regional Centre Director should be consulted. Certainly I am aware that on a number of occasions after 1983 surgical procedures were postponed due to blood shortages in the West of Scotland. SNBTS has access to documents which will confirm this. Whether these shortages had anything to do with abandoning prison donor session is not known to me, but it is worth pointing out that the annual blood collection figures per million of population in the West was significantly below all other regions in Scotland throughout the 1980s Thus supply difficulties for red cell was a not an infrequent anxiety for colleagues in the West where poverty and deprivation were significant challenges those responsible for the blood collection programmes. It is almost certain that this was never a problem for Edinburgh or any other SNBTS region)**

(7) Whether the witness was aware of the evidence produced by the NBTS for England and Wales around July 1974 that the incidence of hepatitis B in donors from prisons was approximately five times greater than the incidence in donations from the general public (SGH.001.7095). If so, what, if anything, did the witness do in response to that

information? **(I cannot recall whether I was aware of this evidence or the work published work from the West of Scotland BTS – SGH.002.9831 and SNB. 008.0002) If it was discussed by the SNBTS Directors then I would imagine it was would have been raised by Dr John Wallace (RTD West of Scotland) in 1974/75 and by Dr Mitchell in 1981/82. I must confess I do not recall having ever given the matter on prison donors any consideration until the it was raised by the MI in 1982/3.**

(8) Whether the witness was aware of the letter dated 6 January 1975 by J Garrott Allen (Stanford) to Dr William Maycock (Blood Products Laboratory) warning of the increased risk of hepatitis, including NANB Hepatitis, from the blood of prisoners (SGH.004.6061). If so, what, if anything did the witness do in response to the concerns raised in that letter? **(As far as I can recall, I was not aware of this letter and first discovered its existence when reading Douglas Starr's book in 2007.)**

(9) Whether the witness was aware of the letter dated 1 May 1975 by H Yellowlees, Chief Medical Officer, England and Wales, to all Regional Medical Officers on the subject of blood donation and hepatitis (SGH.003.0187) and whether the witness agreed with the advice contained in that letter i.e. that it was not necessary to discontinue the collection of blood from prisons provided that all donations were tested for hepatitis B using a sensitive test. What was the sensitivity of the tests used to screen for hepatitis B at that time? **(As far as I can recall, I was not aware of this communication, but SNBTS may have access to copies of Directors' Meetings which reveal the contrary. I have long forgotten details of the absolute sensitivity of the HBsAg donation tests in 1975 but am quite certain this information can be made available from SNBTS).**

(10) Why the SNBTS continued to collect blood from penal institutions following the Medicines Inspectorate's adverse comments on that practice in March/May 1982 (SGF.001.0086, SGF.001.0351 and SNB.008.7582). **(As far as I recall there were 4 reasons: 1. there was bemusement that no mention of this difficulty had been made in the MI reports for Aberdeen Glasgow and Inverness. 2. There was a**

strong view that this could have significant adverse effects on red cell supplies at certain times of the year – notably in the West. 3. Without SNBTS Directors' consensus, there was no national management process for considering issues related to the location of blood collection sessions in the regions. Throughout the UK: this issue were strictly left to the RTDs and their teams and the priority was maintenance of supply. This management practice and the operational priorities enjoyed SHHD/DOH support. 4. There was uncertainty, at the time, with regard to the locus of the Medicines Inspectors regarding donor session issues (a view shared by SHHD).

(11) At their meeting on 29 March 1983 (SGH.001.0002), why the SNBTS Directors were unable to agree on future policy in respect of collecting blood from penal institutions. **(See above)**

(12) At the meeting at the National Institute for Biological Standards and Control on 9 February 1984 to discuss the infectious hazards of blood donors (SNF.001.3109) Dr McClelland advised that certain policies had been adopted in Scotland to minimise the risk of transmission of infection. The main strategies were stated to include the avoidance of high risk communities, such as prisons. When was the strategy referred to at the meeting of avoiding high risk communities such as prisons adopted and implemented and why? Was it adopted and implemented in each of the Scottish regions at the same time and, if not, why not? **(I have no recollection of this NIBSC meeting and therefore unable to comment whether the Minute accurately reflects what Dr McClelland said. Certainly there was no SNBTS policy in place in February 1984, regarding Prison Blood Donor Sessions.)**

(13) The report in July 1984 by Drs Follett and Dow on their three year research project, "Non-A, non-B hepatitis in the West of Scotland" (SGF.001.2060) noted (a) that screening of blood from prisoners detected 10 times more donations with grossly elevated ALT levels compared to other donors and (b) that the vast majority of drug abusers with elevated ALT levels admitted being heroin addicts and a considerable proportion were prisoners. The Report noted that these findings had discouraged the

SNBTS from visiting prisons to obtain blood for transfusion purposes. To whom, and when, were these findings communicated? (I.e. that (a) screening of blood from prisoners detected 10 times more donations with grossly elevated ALT levels compared to other donors and (b) that the vast majority of drug abusers with elevated ALT levels admitted being heroin addicts and a considerable proportion were prisoners). What action was taken, by whom and when, in reliance on these findings? **(As far as I can recall, the SNBTS Directors had first sight of Dr Dow's studies in May 1986. Thus the presentation of this work to the Directors was not related to prison donor sessions (indeed by then the last SNBTS prison donor sessions had taken place two years earlier) but the debate around surrogate testing. It is my understanding that SNBTS is in a position to provide the relevant documents which will confirm this.)**

(14) The extent to which, if at all, between 1975 and 1984, the SNBTS discussed with officials from the SHHD the practice of collecting blood from penal institutions, the increased risks of hepatitis, including NANB hepatitis, from prison donations and whether the practice of collecting blood from such institutions should continue. **(SHHD officials were present on all occasions the SNBTS Directors discussed this topic. This included the initial verbal briefing immediately after the inspections in the Dundee and Edinburgh centres and every occasion when it was discussed at the SNBTS Directors' Meetings. SHHD were also aware that we had sought advice/guidance from DHSS)**

Donors with a history of jaundice or hepatitis

(15) Whether the SNBTS accepted the recommendation in the 2nd report of Dr Maycock's Advisory Group on the Testing for the Presence of Hepatitis B Surface Antigen (1975) (SGH.003.0079) that blood from donors with a history of jaundice or hepatitis could be accepted if the donor tested negative for hepatitis B surface antigen. If so, why that recommendation was accepted given that such donors may have suffered from jaundice or hepatitis as a result of NANB hepatitis, which possibility could

not be excluded by testing. **(I do not recall this topic being discussed by the SNBTS Directors in 1975 but I do recall, soon after I was appointed NMD, expressing my concern to Dr Ed Harris (DCMO, London) that the criteria for the selection of blood donors in the UK was left in the hands of junior DHSS civil servants who had little knowledge of blood transfusion practice nor were in touch with international experts.)**

(16) The consideration given by the SNBTS between 1975 and 1991 to the exclusion of donors at a higher risk of transmitting NANB hepatitis, including the exclusion of donors with a history of jaundice or hepatitis. **(I regret I do not recall specific occasions and would advise consultation, with Dr Jack Gillon (SNBTS). who made major contributions in the 1980/90s to the development of UK and SNBTS guidelines for donor selection programmes which were acknowledged throughout the UK and beyond.**

(17) The procedures in place within the SNBTS between 1975 and 1991 for the exclusion of donors at a higher risk of transmitting NANB hepatitis, including the exclusion of donors with a history of jaundice or hepatitis. **(See 16 above)**

(18) Whether there were national policies in that regard and/or whether each SNBTS region had its own practices and policies. **(As far as I can recall (see 15 above) one of the features in this aspect of blood transfusion practice throughout the 1980/90s was the development and maintenance of UK (later SNBTS) guidelines. As far as I'm aware these guidelines were adopted by each SNBTS RTC but I am reasonably certain that independent audit of compliance did not take place during the period I was with the SNBTS).**

(19) Whether, if all donors with a history of jaundice or hepatitis had been excluded from giving blood, (a) that is likely to have caused any difficulties in maintaining a sufficient supply of blood and (b) the extent to which post-transfusion hepatitis C in Scotland is likely to have been reduced. **(I regret I no longer have access to databases which would enable me to answer these questions. Nor am I familiar**

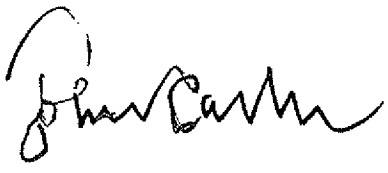
with the outcomes of the work we initiated with regard to the reduction of the clinical use of red cells. However, I would imagine satisfactory responses could be obtained if SNBTS was consulted.)

Footnote: In a document entitled: Preparations for Hearings, dated December 2010, three queries were raised. (1) And (2) have been incorporated in to the final draft of the text.

As regards (3) **(Selection of blood donors)** – In 1982/83 the selection of blood donors was the final responsibility of the doctor in the donor session team. In 1977, DHSS published a Memorandum on the Selection, Medical Examination and Care of Blood Donors which no doubt was intended to operate as a guideline for these doctors. The point I was making to Dr Brookes in 1983 was that as session doctors were finally responsible for making these selection decisions and as they were operating from guidelines, it was certain that there would be some differences in interpretation between different RTCs but also probably between doctors working in the same Centre. The question I posed, was there scope for more consistency? For an excellent account of this topic I would refer you to the SNBTS Briefing paper entitled: Donor Selection Policies and Procedures (September 2010), which I believe has already been lodged with the Inquiry Team.

Finally, the Inquiry Team is looking for **documentary evidence of blood shortages in the West of Scotland.** I can advise that there are several such documents in the papers you have already received from SNBTS. I'm afraid I do not have the resources to search for these but can refer you to a letter I wrote to Dr Mitchell on this topic dated 15 January 1990. Should you be unable to find this letter in your database I would be happy to provide a copy. I have no recollection of ever communicating on this topic with any other SNBTS Regional Transfusion Centre Director between 1974 -91.

Professor Ian Franklin In this final draft I have deleted Professor Franklin from the text as he has left the SNBTS and I understand has no authority for the issue of information to the Inquiry Team.

Signed: 

John Cash

Date: 25th January 2011