SNBTS DOCUMENT REQUEST No:

2010/00020

C2 Witness Statement (Surrogate Testing)

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Tuesday 31st August 2010 (by post and email to susana.murray@nhs.net)

Dear Madam,

Penrose Inquiry – Professor John D Cash – Request for witness statement

I understand that you act for Professor John D Cash in respect of your client's current or former employment by the NHS in Scotland. Please advise if this understanding is incorrect.

Lord Penrose would like your client to provide a written statement of evidence to the Inquiry in respect of the issue and matters set out in the schedule

below. It may assist your client when preparing the statement to have regard to the sections of the Preliminary Report referred to in the schedule.

While your client may derive some assistance from the Preliminary Report, the Report may not include all material relevant to the matters in respect of which a statement is sought, in which case your client should include in the statement any material your client considers relevant to these matters, whether contained in the Preliminary Report or not.

While it is a matter for your client as to how best to structure the statement, your client may find it helpful, in general, to set matters out in chronological order. If the statement is lengthy, it may also be helpful to consider inserting sub-headings. It would be helpful for your client to provide the statement in draft form in the first instance, as follow up queries may arise which may require amendment of the first draft.

I would hope that a first draft statement can be provided within four weeks from the date of publication of the Preliminary Report. If that timescale is likely to present a problem then please advise.

Lord Penrose hopes that your client's statement can be provided on a voluntary basis in the first instance. If there are any difficulties in obtaining a statement, however, then Lord Penrose will consider using his powers under

the Inquiries Act 2005 and the Inquiries (Scotland) Rules 2007 to issue a formal notice requiring a statement to be provided by a particular date.

Please acknowledge receipt of this letter.

Yours faithfully

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Yasmin Shepherd

cc Tracey Turnbull (by email)

Schedule (

Issue in respect of which a statement is sought

The non-introduction in Scotland of surrogate testing for Non-A Non-B Hepatitis.

Matters to be included in the statement

(1) The consideration given by the SNBTS in the 1980s to whether surrogate testing of blood donors for non-A non-B hepatitis (NANBH) should be introduced. **(There was much consideration in this period but I am unable to recall at this time any details. However I am aware that Dr Brian McClelland has researched this topic in some detail and would advise that he be contacted)**

(2) The research undertaken by the SNBTS in the 1980s into surrogate testing for NANBH. **(For a Service serving 5 million of a population this was substantial. Again I would advise that the Inquiry Team contact Dr McClelland for details.)**

(3) Why the multi-centre study into surrogate testing for NANBH (conducted at Edgware, Manchester and Bristol) did not include a Scottish

blood transfusion centre. **(I do not recall the details requested but am satisfied that they can be obtained from Dr McClelland (SNBTS.) who led the team intended to undertake the SNBTS contribution to this study.)**

(4) Why it took until October 1988 before the multi-centre study into surrogate testing for NANBH commenced (SNB.006.1988 and SNB.006.1975), when, for example, the need for research into surrogate testing had been identified by the SNBTS Directors at their meeting on 25 March 1986 (SNF.001.0135). **(I was not involved with the development, planning or assessment of this study and sadly its director, and the prime source of information (Dr Harold Gunson), is deceased. However, I have little doubt that Dr Brian McClelland (SNBTS) will be able to supply some or all of the information requested)**

(5) When the SNBTS sought funding from SHHD to introduce surrogate testing, including when it was proposed to introduce such testing [1]. **(I have no recollection of these dates but I assume that copies of PES documents, which I drafted, exist and which are already in the hands of the Penrose Team. If not, then they may be obtained from Professor Franklin (SNBTS.)**

[1] It appears that applications for funding to introduce surrogate testing were made by the SNBTS in 1986, for the introduction of testing in 1987 (PES 1986, SNB.011.2637); in 1987, for the introduction of testing in 1988 (PES 1987, awaiting Signature ref); and in 1988, for the introduction of testing in 1989 (PES 1988, awaiting Signature reference)

(6) Why the SNBTS first sought funding from the SHHD, in 1986, for the introduction of surrogate testing in 1987 (PES 1986 (SNB.011.2637)). **(As far as I can recall, during the preparation of the PES submission for 1986 I was requested (for the first time) to include a component which looked 5 years ahead. Against this background, and after consulting widely with European colleagues who were engage in the process which would lead to the issue of the seminal EU Directives in 1989/90, I concluded that we should alert SHHD that we envisaged increasing pressure from clinicians, patients' support groups and the EU/UK Regulatory Authorities to introduce surrogate (NANB) donation testing, as had already been done in some European countries and throughout north America.)**

(7) Why the Directors of the SNBTS agreed at their meeting on 3 March 1987 that surrogate testing of blood donors for NANBH should be introduced, with implementation from 1 April 1988 (SGH.001.6653). **(I do not recall but imagined we may have assumed SHHD would have wished us to move in advance of the EU Directive release - see 6 above.)**

(8) The steps taken by the SNBTS, and when, to prepare for the introduction of surrogate testing, including the evaluation of any surrogate tests and the preparation of guidance on testing and counselling donors. **(As**

far as I can recall no steps had been taken, primarily, I imagine, because we had reason to believe SHHD would not support/fund our proposals.)

(9) Estimates made at the time of the likely cost of introducing surrogate testing in Scotland. (I regret I have no information on this question but would be fairly certain it was developed by Mr John Francis (formerly SNBTS Finance Officer). More uncertain is whether the appropriate documents are still available and would suggest an approach is made to Professor Franklin (SNBTS)

(10) Why surrogate testing of blood donors for NANBH was not introduced in Scotland. (The introduction of any new donation testing programmes was controlled by SHHD which took its directions from DHSS. Control was delivered by SHHD through the CSA's Finance Director's functions. Throughout the 1980s the SNBTS Directors were cognisant of the attempt Dr John Wallace had made to act, with regard to introducing new donation testing donation testing techniques, without the agreement of SHHD, and how SHHD had reacted. Until the establishment of the ACVSB and ACTTD in 1989, SNBTS or indeed any UK transfusion centre director had no locus in the processes by which the Departments of Health acquired professional advice on donation testing for virus contamination. DHSS acquired its advice from a specific small group of PHLS and academics, some of whom had conflicts of interest.. The arrival of ACVSB and ACTTD in 1989 did not

totally solve all these problems, as was evident in the processes leading to the introduction of HCV donation testing in 1991.)

(11) 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. **(I regret that I no longer have access to this sort of information, but I imagine it exists and would therefore suggest you invite Professor Franklin (SNBTS) to comment.)**

(12) If surrogate testing for NANBH had been introduced in Scotland, the percentage of donations that are likely to have been rejected and the extent to which, if at all, that is likely to have caused difficulties in maintaining a sufficient supply of blood for the NHS in Scotland. **(I regret I no longer have access to the details requested but I would advise that contact with Professor Franklin (SNBTS) is likely to provide the information requested.**

(13) In his letter to Dr Gunson dated 27 April 1987 (Preliminary Report, paragraph 9.52, SGH.001.6627), what did Professor Cash mean when he stated, in respect of the minute of the meeting of the SNBTS Directors on 3 March 1987 recommending that surrogate testing for NANBH be introduced: (

"I don't think you should take the content of [the] minute ... with regard to the introduction of surrogate testing for NANB too seriously at this stage. I think it would be appropriate to say that it was a decision made with our PESC submission in mind

and, I suspect, a view that we have often expressed – that the results of the UK study are unlikely to have a material effect on our future operational practice"

(I believe that the answer to this question is covered above).

(14) The purpose of the Scottish Directors writing their letter "Testing blood donors for [NANBH]: irrational, perhaps, but inescapable", published in the Lancet on 4 July 1987, (LIT.001.0328). **(See response 6 above)**

(15) The extract of the minutes of the meeting of the SNBTS Directors on 12 April 1988 (SGH.002.8037) refers to reports of the commencement of ALT testing in at least one regional transfusion centre in England and Wales. Did any transfusion centre in England and Wales commence surrogate testing for NANBH and, if so, which centres and when? **(I regret that I can no longer recall what I suspect were rumours.**

(16) The extract of the meeting of the SNBTS Directors on 27 September 1988 (PR, paragraph 9.100, SGH.002.8027) states, "The NIBSC/UK BTS Working Group were recommending that ALT testing of blood donations should begin in England and Wales". Which working group is that a reference to and why did that working group recommend that ALT testing of blood donations should begin in England and Wales? **(I regret that I am unable to recall this event and would advise that you contact Professor Franklin (SNBTS) to illuminate.)**

Sections of Preliminary Report which may assist when preparing statement

- Chapter 6, "Hepatitis 1974 to 1981" (paragraphs 6.96, 6.118, 6.119, 6.121, 6.123 and 6.126).
- Chapter 7, "Hepatitis 1982 to 1985" (paragraphs 7.12, 7.16, 7.32, 7.33, 7.34, 7.48, 7.61, 7.63, 7.64, 7.66 to 7.69 and 7.70 to 7.75).
- Chapter 9, "Hepatitis 1986 to date".

Statement of Truth

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

Signed.....

Dated.....23/8/14.....