

## Penrose Inquiry

## C3 Statement of Alexander Murray

1. I have little or no recollection of these matters and my statement is based on a reading of the documents made available to me, including SHHD file NQL/5/1, "Clinical trials of therapeutic substances produced by SNBTS (compensation for adverse reactions)". Page numbers quoted in this statement refer to that file.
2. My involvement would appear to have begun in March 1985 when Dr McIntyre minuted John Davies (my senior officer) alerting him to the concerns of SNBTS and clinicians regarding the lack of a compensation scheme for clinical trials and the possible consequences of this, particularly for heat-treated Factor VIII (SGH.003.1969). Dr Cash had written on this subject to the CSA from whom we would be likely to hear. In a manuscript note on this document Mr Davies asked me to set in train investigations with SHHD Finance and the Central Legal Office (CLO – a division of the CSA) though as regards the latter this should await the action of Mr Mutch (Secretary, CSA) (SGH.003.1969). I have no recollection of events relating to this matter prior to March 1985.
3. On 22 March 1985 Dr Cash copied to Mr Davies (and Dr McIntyre) his letter of 11 March to Mr Mutch setting out his proposals for a compensation scheme for trials (pages 241-244). The proposals appear to concern a general compensation scheme in relation to clinical trials for BTS purposes.
4. On 22 March 1985 Dr Cash wrote to Dr McIntyre conveying Dr Ludlam's specific concerns and observing that if there were no speedy resolution then the whole of the SHS heat-treated Factor VIII programme would be very seriously affected (SGH.003.1958). On 28 March Dr McIntyre drew these concerns to the attention of Mr Davies (SGH.003.1957). In a manuscript note to me of the same date on Dr McIntyre's minute, Mr Davies said "I believe you are already looking into this – though as far as I can recall the CSA (Central Administration) have not yet written in. I find it a little strange, as surely there is also a risk of claims if non-heat treated Factor VIII is used which is known to be "riskier"?" (SGH.003.1957).

5. On 2 April 1985 Mr Wooller, General Administrator of the CSA, copied to me a memorandum he had sent to the CSA legal adviser on the issues raised in Dr Cash's letter of 11 March, and suggesting that in the meantime SHHD may wish to give preliminary consideration to these issues (pages 230-231) .
6. In April 1985 I wrote to DHSS explaining the present position and, as I understood CBLA had raised similar concerns with DHSS, I suggested a mutual exchange of deliberations would aid in reaching a common conclusion (page 229). On 10 April SHHD Finance advised me that Treasury approval would be required for any proposals for a compensation scheme (page 228).
7. On 2 April 1985 Mr Calder, Chief Pharmacist, minuted Dr McIntyre in reply to a request for comments on the issue of compensation. Mr Calder concluded that before SHHD went any further we should get legal advice (both from our own lawyers and CLO) on what can or cannot be done. He also raised a number of particular points (page 226). On 10 April Dr McIntyre copied Mr Calder's minute to Mr Davies saying "I understand from Mr Murray that the Secretary of the CSA is raising the matter with their legal advisers and perhaps we should defer further action until this legal advice is available. As the clinicians are much concerned about this matter I trust the legal advice will not be too long in coming." (page 225). On this document (on file) on 11 April Mr Davies replied "We are indeed expecting CLO to be consulted – this is part of an exercise to persuade the CSA to take themselves decisions properly theirs. While it would doubtless be possible to consult our Solicitor's Office in parallel, I am not persuaded it is necessary to do so. As to how long it will take, that depends on the lawyers." (page 225). The position of SHHD was that it was for the CSA to bring forward proposals concerning a compensation scheme.
8. On 29 April 1985 I wrote to Mr Wooller conveying the particular points raised by Mr Calder as regards clinicians (page 222). I followed up this request on 21 June (page 218). On 12 July he replied to me with the legal adviser's comments on these points (pages 215-216). On 6 August I copied this response to Dr McIntyre and Mr Calder, also informing them that the issues raised by Dr Cash were still being considered by CLO and that I had been advised that a further letter would be sent to us once that legal advice was available (page 214).

9. In a minute of 16 August 1985 to Mr John Davies, in connection with papers for a meeting of the BTS sub-committee on 21 August, I outlined the steps taken and the present position (pages 211-212). I also attached the file to help understand the issues involved.
10. In a minute to Mr Davies of 21 August 1985, Mr Hugh Morison explained that at a meeting that day of the BTS sub-committee he had said SHHD would pursue the compensation issue with DHSS as a matter of urgency; it would however be necessary for the CSA to clarify the boundaries of their proposals before SHHD took the matter forward. He had explained that the question would require to be considered in a GB context. Dr Cash had said that the English service had already approached DHSS (pages 205-206).
11. In an manuscript note of 10 September 1985 to Mr George Thomson (next in line after myself in the branch) I explained that I had confirmed with Mr Wooller that the CSA were pursuing Mr Morison's point about the boundaries of their proposal with SNBTS and CLO (page 204).
12. In November 1985 I wrote to DHSS outlining, among other matters, the present position in Scotland as regards compensation arrangements in relation to trials for BTS purposes, the desirability of consideration in a GB context, and enquired if DHSS had made any progress (page 203). I wrote again to DHSS on 11 February 1986, following up my letter of November 1985 and enquiring as to the likelihood of a response (page 202). From the documents made available to me, it does not appear that I received a response from DHSS on the issue of compensation
13. In February 1986 Professor R.H. Girdwood, Chairman of the Scottish National Blood Transfusion Association, raised a number of issues with the Minister, Mr John Mackay, including compensation for volunteers in SNBTS research projects. A draft reply for the Minister prepared by Mr George Paul (acting Head of Division) and which drew heavily on advice offered by medical colleagues explained, as regards compensation schemes, that there was at present no formal compensation scheme though each case would be considered on its merits (pages 199-201).

14. At a meeting on 20 August 1986, chaired by Hugh Morison, the BTS sub-committee noted that the National Medical Director had held a useful dialogue with the legal adviser concerning arrangements for the compensation of volunteers and agreed that the General Manager should now pursue the bringing forward of firm proposals (SGH.002.0455). I note however that the minutes do not state to whom the proposals are to be brought.
15. If one compares Hugh Morison's minute of 21 August 1985 concerning the BTS Sub-Committee meeting on that date (pages 205-206) and the minutes of the BTS Sub-Committee meeting on 20 August 1986, the matter of a compensation scheme for clinical trials had remained with the CSA, which was to 'clarify the boundaries of their proposals'/pursue the bringing forward of firm proposals'.
16. In a manuscript minute to me of 30 December 1986 Mr George Thomson explained that Dr McIntyre and Dr Forrester had informed Mr Macniven, who by then was Head of Division, that Dr Ludlam was seeking some form of compensation scheme before embarking on the testing of heat-treated Factor VIII. We could no longer wait for clarification from the CSA, and Dr McIntyre had suggested a compensation scheme on the lines of a previous Treasury approved scheme (page 198).
17. On the same date Dr Cash wrote to Dr McIntyre referring to a telephone conversation that day. Dr Cash requested a formal response on the question of a compensation scheme for heat-treated Factor VIII trials similar to one already in existence (page 197). Prior to that letter there is no reference in the documents made available to me, to Dr Cash or the CSA submitting to SHHD proposals for a compensation scheme, either general or specific to heat-treated Factor VIII. This would appear to be the position conveyed in a note that I sent to Mr Macniven and Mr Morison prior to the BTS sub-committee meeting on 25 February 1987, which states that a crises over clinical trials 'blew up' in the New Year. The note recalls that "sometime ago Dr Cash was asked to prepare a compensation scheme for all adverse reactions occurring within SNBTS procedure, in conjunction with CLO, for submitting to the Committee and then the Department. I understand that Dr Cash's proposals have been firmed up and were passed to central administration around Christmas." (pages 133-134).

18. It would appear that Dr Ludlam's letter of 11 December 1986 (SNB.005.8711) had prompted Dr Cash to contact Dr McIntyre concerning a compensation scheme for clinical trials of heat-treated Factor VIII. Prior to December 1986, compensation arrangements for clinical trials of heat-treated Factor VIII appear to have been subsumed within consideration of a general compensation scheme in relation to clinical trials for BTS purposes. It does not appear that anyone had previously proposed compensation arrangements specific to clinical trials of heat-treated Factor VIII.
19. On 7 January 1987 Dr Forrester minuted Mr Macniven regarding an assessment of risk to volunteers and attached a copy of a statement just received from Dr Cash (pages 190-195).
20. It would appear that between 7 and 12 January I spoke to both Treasury and DHSS to explore the possibility, in a GB context, of a compensation scheme for heat-treated Factor VIII trials based on previous Treasury approved compensation schemes.
21. On 12 January 1987 I minuted Mr Kernohan of SHHD Finance Division with a draft letter for him to send to Treasury. The minute explained why a compensation scheme was necessary; outlined previous compensation schemes approved by Treasury and on which the heat-treated Factor VIII scheme was based; that I had already alerted Treasury; that DHSS had informed me of the type of letter Treasury would be looking for and that such a draft letter to Treasury was attached. The draft included the required medical advice (pages 161-164).
22. On 12 January 1987, Mr Brunning of DHSS wrote to Treasury seeking agreement to compensation arrangements for the proposed clinical trial of Factor VIII, drawing similarities with arrangements for previous whooping cough trials (page 169). Miss Everest-Phillips of Treasury responded that day stating that, on reading the DHSS letter, she was not persuaded of the similarity between Factor VIII treatment and whooping cough vaccination on the question of compensation for volunteers. In this context she referred to a preliminary discussion with myself as to the circumstances leading to the request for

compensation arrangements for those treated with Factor VIII. Furthermore, she was not clear as to the difference between the proposed trials and those carried out with heat-treated Factor VIII in the past without compensation (page 168).

- 23. Mr Kernohan wrote to Treasury on 14 January 1987 seeking agreement to arrangements for compensation in the event of injury during clinical trials of Factor VIII (pages 159-160). Having seen on 4 February a draft DHSS response to Treasury (page 157), Mr Kernohan wrote again to Treasury that day addressing the concerns raised by Miss Everest-Phillips in her letter of 12 January to Mr Brunning (pages 151-152). Treasury approval to a compensation scheme for Factor VIII trials was given to both DHSS and SHHD on 5 February 1987 (page 149). On 6 February I wrote to Dr Cash confirming that SHHD agreed compensation arrangements for the clinical trials of heat-treated Factor VIII (SGH.003.1870).
- 24. I was on sick leave from later in February 1987 until early May. I note that during my absence a minute of 26 February by Dr Forrester records that he understood from Dr Perry that trials had already begun (page 131).
- 25. As regards the CSA considerations, Mr Wooller wrote to me on 23 July 1987 enclosing for SHHD approval suggested procedures for dealing with claims of compensation arising from clinical trials (pages 14-17). I set in train SHHD assessment of these before taking up a new post at the end of that month.

Statement of Truth

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

Signed ..... Alex. J. Murray .....  
Dated ..... 27/9/11 .....