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Penrose Inquiry

Witness Statement C4 – Screening of blood for hepatitis C

John Cash

A, Schedule of Questions

Introduction: In preparing statements, witnesses are asked to refer to pages 272 to 320 of the Preliminary Report. It should be noted that, due to the recovery and processing of further documents since the publication of the Report, there is additional material referred to in these questions. In addition, as referred to in paragraph 31 below, part of the narrative in Chapter 9 has been extended.

1. The Inquiry Team now has the correspondence referred to at paragraph 9.93. The letter of 5 July to Chiron is SNB.008.3584, SNB.008.3585 was a letter to Ortho asking if they were to market the test and SNB.008.3586 is the reply from Ortho dated 19 July.

2. The Inquiry team has minutes of the meetings of two groups which considered developments in the testing for hepatitis C over the period 1988 to 1991: the ACTTD and the ACVSB. **(a) Why was it necessary to have both the ACVSB and the ACTTD? (b) What lay behind the raising of the roles of the two groups at the meeting of 24 April 1990[1] – (c) had it come to seem that there was unhelpful overlap?**

   Answers: (a) I was advised in 1991 that the ACVSB had been conceived by DHSS officials partly in response to criticisms I had made of the way officials had managed the HIV/BTS interface (1). My concern in 1984/85 had been a lack of involvement of UK BTS professionals; a lack of urgency; an absence of transparency; and an uncertainty (in my mind) regarding accountability, with respect to SHHD and Scottish Ministers. The response of DHSS in 1989 – the creation of the ACVSB – was, I recall, welcomed but proved not to be entirely satisfactory. This committee was again short of donation screening virology expertise; there was no mechanism for the SNBTS management team to have an input on the construction of the ACVSB agendas, submit briefing papers or have access to Meeting Minutes. A strict code of secrecy, supported by SHHD, was imposed, so that on many occasions the SNBTS general manager, the medical and scientific director and the CSA's general manager had no knowledge of what was going on. There was a no evidence of any urgency with regard to the timely resolution of important operational issues. Finally, the role of Scottish Ministers in the process seemed unclear.

[1] Minutes SNB.001.9761

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(b) The ACTTD was the 'brain-child' of Dr Gunson. Dr Gunson believed it would assist him to take to the ACVSB the views of a wider group of UK BTS experts. He also wished to encourage the ACVSB academic virologists to dialogue with UK BTS virologists. This development enjoyed my full support, though in due course, it generated serious problems for Dr Gunson.

(c) On a number of occasions considerable tension arose between the two committees. The academic virologists were at times uncomfortable working with some other members of the ACTTD. Senior DHSS officials became alarmed that they had no control of ACTTD and at one time took extra-ordinary action to prevent attempts to establish formal links between the two committees. Dr Gunson was on occasions to find himself in a difficult position when he knew that the advice generated by the ACTTD would not be acceptable to DHSS. On one occasion this led Dr Gunson to offer his resignation as ACTTD Chairman. The deliberations of the ACTTD also provided the first ever opportunity for some members of wider UK BTS management teams to scrutinise closely the operational differences between the blood transfusion services in England and Wales and Scotland. At times, this was a cause of some distress and unhappiness.

3. **(a) How was the membership of each body determined, in particular the Scottish representation? (b) We have a copy of the letter inviting Dr Perry to serve on ACVSB[2] – was he in fact nominated by SHHD? (c) How did Dr Mitchell end up on both groups?**

Answers: (a) ACVSB members were selected by DHSS after, I presume, consultation with other Departments. ACTTD members were selected by Dr Gunson in consultation (for SNBTS members) with myself.

(b) Yes, I assume so.

(c) I proposed Dr Mitchell for membership of ACTTD on the grounds that he led the SNBTS team responsible for virology donation testing kit evaluations and that he might provide a valuable 'listening' link for us between ACVSB and ACTTD.

4. The first meeting of ACTTD was on 21 February 1989. Further papers are now available, at SNB.006.1920, 1921, 1922 and 1923. SNB.006.1923 is the draft terms of reference, which were agreed at the meeting as the terms of reference of the committee.

5. Each group met in May 1989: the ACTTD had its second meeting on 19 May and the ACVSB its second meeting on 22 May. The minutes of the former meeting are now available at MIS.001.0009. At that meeting, Professor Cash expressed a desire to proceed with testing the Ortho assay. The minutes of the latter meeting may reflect a different attitude. Reservations appear to have

[2] SNF.001.1263

been expressed about the benefits of the Ortho test, and the possibility of proceeding in due course without resort to the Ortho/Chiron test was mentioned. A figure of 50% was given as the sensitivity of the test –

(a) What was the source of that figure?

(b) What further data from Chiron additional to the information in the article in Science in April 1989 (LIT.001.0629) was being anticipated?

Answers: **(a) I was not a member of ACVSB and have no knowledge of how the figure of 50% arose or whether it enjoyed the support of the majority of members.**

(b) As 5a above

6. Professor Cash duly proceeded with his intention to arrange testing of the Ortho assay, as set out in paragraph 9.123. From the report of this study referred to in paragraph 9.148 (SNB.006.1596) it is evident that one objective was

"to determine the efficiency of the test in the examination of sera from patients with alleged post-transfusion non-A non-B hepatitis along with the implicated donations."

(a) **Was this the Scottish equivalent of the assessment discussed in paragraph 9.126?**

(b) **What was the particular function of these studies – were they seen at the time they were initiated as potentially sufficient to inform a decision as to whether or not to proceed to introduce the Ortho test or were they in some way preliminary to a further assessment?**

Answers:

(a) I believe so.

(b) To the best of my recollection we sought to avoid the difficulties we had in 1985, with the introduction of HIV donation screening. Whilst we anticipated that once again SHHD would insist on the primacy of DHSS, with respect to the timing of the introduction of HCV donation screening in the UK, we believed in 1989 that the SNBTS should generate significant independent data as soon as possible which could be used as a lever for timely central action. As I recall we also envisaged that by engagement with Ortho we might expedite outcomes from their confirmatory testing developments. We were later to discover that Dr Gunson shared these views and had arranged similar studies in England and Wales.

7. **What was the relationship between that assessment process and the exercise referred to at paragraph 9.124 (the assessment of samples of special interest using 1000 Ortho tests)?**

Answer: **To the best of my recollection this was made part of the original study, but Drs Mitchell and Dow should be better placed to confirm or deny this.**

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8. At the meeting of ACVSB on 3 July 1989, Dr Mortimer reported a view that the Ortho tests were reliable. The Chairman asked for all the data to be given to the committee at its next meeting. On the face of it, this does not appear to reveal a sense of urgency. (a) **Was there a sense of timescale within which testing might be introduced? (b) Why did ACVSB not consider it necessary to commission its own evaluation of the test?**

Answer: (a) It is my recollection that in August and October 1989 I advised SHHD that the SNBTS Directors believed HCV donation screening could be commenced between April-June 1990 (1a and 1b).

(b) I was not privy to the business of ACVSB. But I was advised that DHSS did not move to promote HCV kit assessment until January 1990 and that the anticipated deliberations on this topic by ACVSB were thereafter deferred until April 1990. Efforts to obtain the reasons for this deferral were not successful. That said, it is of interest that in August 1989 the need for introducing another donation screening test had not yet been considered by SHHD (1c). If this view was also shared by DHSS then the notion that action should have been taken by ACVSB to evaluate HCV kits in July 1989 might have been regarded in some quarters as wholly premature!

9 Paragraph 9.128 narrates a letter from Professor Cash of 28 July 1989, concerning the fact that the decision on testing was to be taken by SHHD not SNBTS. **Did Professor Cash ask for this letter to relieve pressure from Ortho representatives?**

Answer: No. This letter (from myself to Dr McIntyre SHHD) was primarily designed to confirm and put on record important conversations I had had with Dr McIntyre and to ensure that all SNBTS Directors were fully briefed on the policy position of SHHD with regard to HCV donation screening. (1d)

10. Dr McIntyre replied to Professor Cash on 2 August 1989. His reference to introduction of a further test was conditional, suggesting that the principle of introducing a further test designed to reduce the incidence of post-transfusion hepatitis had not yet been determined. (a) **Is this a correct impression**? He also mentioned his understanding that any new test would be introduced simultaneously throughout the UK. (b) **What was the source of his understanding?**

Answers: (a) Yes (see above)

(b) I seem to recall he advised me that his source of understanding was internal SHHD briefings and the Chairman of ACVSB (Dr McIntyre was the SHHD observer on this committee).

11. At this time there was also correspondence between Professor Cash and Dr Gunson regarding the timing of screening and the desirability of Scotland and England moving together on the matter. We now have the letter of 26

July from Dr Gunson (SNB.006.1574) to which the letter referred to in paragraph 9.129 is the reply. In his letter of 3 August 1989 to SNBTS Directors Professor Cash referred to its being only a matter of time before the new testing programme would be commenced. **At this point, was he envisaging a shorter time period than in fact eventuated?**

Answer: Yes, I anticipated the SNBTS/WBTS Ortho kit assessment would reveal that we had a kit which would allow us to make a start, on the basis that specificity would be acceptable and sensitivity would be better than no screening. It was clear that Dr Gunson had come to the same conclusion from the preliminary information he had from the first NLBTS studies.

12. Dr Mitchell and Dr Follett attended a meeting with Ortho representatives and also Drs Gunson, Contreras and Barbara in London on 23 August 1989. Dr Mitchell's report of the meeting is SNF.001.1449. It is clear from that report that the next meeting of ACVSB was scheduled for 17 October 1989, which would be after the Rome meeting on the virus, organised by Ortho. **Was there a view that the meeting of 17 October (subsequently postponed – see paragraph 15 below) was likely to take the decision to recommend the introduction of screening? What is the "turn-key" system referred to in paragraph 4? Were the figures presented by Dr Mitchell (paragraph 5) those from the ongoing studies referred to in paragraphs 9.123 and 9.148?**

Answer: I regret I am unable to provide useful information as I was not a member of ACVSB but would assume Dr Mitchell was referring to the initial WBTS data (1e)

13. A Civil Servant, G W Tucker, sent a memo to Michael Forsyth, (at the time a Minister rather than Secretary of State), on 23 August 1989 (as discussed in paragraphs 9.134-6). The memo was prompted by an article in the Guardian regarding the hepatitis C test. At the end of the memo, it is stated that "this (was) a UK issue" and that the Department of Health were "taking the lead". This appears slightly different from a position that the health departments were working together to appraise and, if appropriate, introduce the tests simultaneously. There is also the penultimate paragraph of page 3 of SNB.002.4627, which seems to suggest that the Scottish decision would be taken in its own right, on a recommendation from ACVSB. **What was the position – were the health departments for Scotland, England/Wales and Northern Ireland working jointly on the decision or was it an issue on which Scotland would follow whatever decision was taken in England? Was the formal position that the decision for Scotland would be taken in Scotland, independently from the decision for England?**

Answer: From the several conversations I had with Dr McIntyre I never had any doubt that although the decision for Scotland would finally be taken in Scotland, the SHHD operational policy on this issue was to defer totally to the primacy of DHSS, and that Scottish Ministers would fall in line with their

London based colleagues. I was further advised that this position had been conveyed to the CSA; an aspect of management which I assumed ensured that the release of funds permitting the purchase of kits for donation screening by SNBTS RTCs was actually in the hands of the CSA's Finance Director who was to await instructions from SHHD.

14. From the letter discussed in paragraph 9.140 (and from other statements made around this time) it appears that there was no question of introducing screening until a satisfactory confirmatory test became available. Our understanding of the thrust of this particular letter is that it was possible simply to repeat a positive test, using another kit the same as the first, or to carry out a further test using the same antigen but a different set of reagents and that the latter was preferable and should be facilitated by Ortho as soon as possible. **Is this correct?**

Answer: Yes, I recall that was my understanding

15. The Rome symposium in September 1989 was clearly an important meeting. We have reports of this meeting prepared by Dr Mitchell (SNB.001.8678) and Dr Gunson (SNB.006.1456), and the sequence of events from and after the meeting is set out in paragraphs 9.143 to 9.159. Dr Gunson's report of the Rome meeting was amended after the meeting of ACTTD on 9 October; his recommendation remained that introduction of testing be approved in principle by ACVSB. The meeting of ACVSB on 6 November did not accede to this recommendation. Evidence about this period and about the proceedings of the two committees at this time was given to Mr Justice Burton in A v NBA, and an extract from his judgement is provided. Unfortunately, it is not possible for this Inquiry to hear from Dr Gunson, he having died on 15 October 2005. **It would assist the Inquiry if those who were members of either group and who can recall this period could provide any further comments or recollections of events at that time, including the discussions at the meetings. Similarly, those who were not members of one of the two committees but who recall the atmosphere of the time may wish to provide their comments or recollections.**

Comments: My recollections are that this was the beginning of a period of much unhappiness and frustration. It began with the pressure I put on Dr Gunson to reveal why the ACVSB secretariat had deferred considering the existing HCV kit evaluation data (generated in 1989) until April 1990.

When the deferred ACVSB meeting finally took place on the 23 April 1990 I discovered (after a briefing from Dr Perry) that both he and Dr Gunson had argued in committee that there was already sufficient data for ACVSB to recommend to Ministers the introduction of a first generation HCV donation screening as soon as possible (2). (This was a view I shared). I was advised that Drs Gunson and Perry's views were rejected and instead the committee agreed to mount its own HCV kit evaluation exercise. I recall that Dr Gunson was distressed at this turn of events and repeatedly emphasised to me that the ACVSB was in the hands of DHSS officials and

the academic virologists and that his role as DHSS adviser was being openly challenged.

More unhappiness was to emerge for Dr Gunson and myself when the ACVSB came to examine the data generated from its evaluation of the first generation HCV kits when DHSS insisted that yet another evaluation should take place – of second generation kits – before routine testing would be authorised (see item 33, below).

16. Para 3 e ii of the minutes of the SNBTS Directors' meeting on 29 September 1989 says Scotland had not been invited to participate in UK evaluation but SHHD had asked that they should and so the West and SE regions had obtained kits for evaluation. This must have been a different exercise from the evaluation conducted by Dr Dow and his colleagues,[3] who looked at samples from Aberdeen, Dundee and Glasgow. We are able to follow the latter study but are unaware of how the participation of the West and South East regions in the former was organised. **Is it possible for any of those involved to recollect this information? It also appears from this set of minutes that Dr Mitchell was not particularly enthusiastic about the Ortho test ("not robust") – is this an accurate impression?**

Answer: I would defer to Dr Mitchell and Dr Dow

17. Ortho were pressing ahead with their confirmatory test – see Para 9.163. **Was this (RIBA) the one that was thought unsatisfactory at the autumn meetings? At that time, what were seen as the defining characteristics of a satisfactory confirmatory test?**

Answer: I would defer to Dr Follet and Dr Dow

18. We now have letters referred to in 9.162 and 9.163 (SNB.006.1560 and SNB.006.1561).

19. Dr Barbara's editorial in the December 1989 edition of Transfusion Today (LIT.001.3786) indicates that Ortho were developing confirmatory Western Blot assays. **Is it correct that they were simultaneously developing tests using both RIBA techniques and Western Blot? If so, was it considered that Western Blot would be superior?**

Answer: I would defer to Dr Follet and Dr Dow

20. In December 1989, the final report of the SNBTS evaluation of the Ortho kits was produced (paragraph 9.168). There was a concern, mentioned also in the

[3] As narrated in paragraphs 9.123 and 9.148 of the Preliminary Report

October report, about the reduced sensitivity compared with "the dev kit". **"Dev" may stand for development, but what was the "dev kit"?**

Answer: It was my recollection that the 'dev kit' was a development kit

21. Over this period, there are repeated references at meetings to the need for the Ortho test kit to be approved by the FDA for use in screening in the USA. Yet a number of evaluations of the kits were being carried out in the UK. Moreover, there does not appear to have been any legal requirement for licensing of the kits in the UK. **Why, therefore, was it necessary to tie introduction of the test in the UK to approval by the FDA?**

Answer: Rightly or wrongly I recall the FDA licensing process was regarded as important. There was a general view that the scientific processes of assessment of these diagnostic kits by the FDA were more rigorous and independent of political/commercial influences than in many countries, including the UK. That said, I recall that some were less certain that the issuing of FDA licences was entirely independent of political (US) pressures. No kit licensing arrangements existed in the UK.

22. Paragraph 9.187 of the Preliminary Report narrates the transmission in February 1990 of a Press Statement from the USA to Dr McIntyre and to the DOH. **Can any present or former civil servants shed light on the handwritten notes on the letter from Professor Cash, in particular the comment that the statement had "stirred up a hornet's nest"?**

Answer: I suggest it would be inappropriate for me to speculate!

23. The meeting of ACVSB on 24 April 1990 again stopped short of recommending the introduction of testing. According to a note Dr Perry sent to Professor Cash about this meeting on 2 May, (SNF.001.1710) he and Dr Gunson had both felt that there was sufficient data to justify testing now. **Can Dr Perry now recall his sentiments at the meeting? What did he consider to be the answers to the negative points made in paragraph 29 of the minutes of the meeting (SNB.001.9761 at 9764)?**

Answer: I will leave Dr Perry to respond.

24. The memo from Dr Young dated 23 May 1990 (paragraph 9.207) appears to suggest some concern about progress on the issue of hepatitis C screening. **Can Dr Young recall anything further about the CSA management committee meeting, and what in the discussion there prompted the memo? After Dr McIntyre attended each meeting of ACVSB, to whom within SHHD would he report its proceedings? It would also be helpful if all the "hieroglyphics" on this letter could be translated – who are all**

the individuals writing or referred to and what was the role of each in dealing with the memo?

Comment: No comment.

25. Dr McIntyre responded to this memo on 6 June (SGF.001.2034). Mr Panton then wrote on it on 7 June. **What is the background to his reference to the need to "dip" into the contingency fund? There is another (handwritten) memo from someone to Mr Hogg and Mr. Panton dated 6 June 1990 (SGH.002.7935) but this does not appear to add anything to the narrative of events – is this correct?**

Comment: No comment

26. The letter from Dr Metters to Dr Perry of 5 June 1990 (SNB.002.0245) suggested that the study to investigate the significance of a positive reaction to the antibody test might not now proceed; the subgroup comprising Drs Gunson, Mitchell, Mortimer and Tedder had taken the view on 23 May that an extended study of RIBA and PCR techniques might not be appropriate. **If the study had been considered important at the ACVSB meeting on 24 April, why was it no longer considered so? It appears that the grant of FDA approval of the test may be the explanation – was this so?**

Comment: I was not aware of this letter and have no comment to make, beyond to note that in June 1990 the Deputy (DHSS) CMO advised Dr Perry that 'events are moving fast' and that the time had come for ACVSB to consider not when to start HCV donation screening but rather whether it need be done at all! (C5-9a). This statement gives some credence to the position described in August 1989 by Dr McIntyre (see answer to 8b above and reference 1c).

27. In his letter of 21 June 1990 to Dr Gillon (SNB.005.5023) Dr Cash said "now that we know we will have access to confirmation testing". At the ACVSB meeting of 24 April Professor Zuckerman remarked that the RIBA test was not good enough to use routinely as a confirmatory test (explained in A v NBA as meaning not good enough because it also tested for the antibody). Dr Tedder commented that the PCR test was not yet suitable for the mass screening needs of RTC laboratories. **Can Professor Cash recall what testing he was thinking of in his reference to access to confirmatory testing being available?**

Answer: As I recall this was both RIBA and PCR. The important difference between England and Wales and ourselves on this issue was not the science but rather management arrangements for access.

28. Paragraph 9.215 refers to a bid for funds to introduce testing. It appears to the Inquiry team that, given the information in SNB.013.4871, had screening

been introduced before the financial year 1991 – 92, it could only have been paid for from the reserve (the contingency referred to in SGH.002.7930). **Is this correct?**

Answer: I believe so

29. The ACVSB meeting of 2 July did recommend that screening be introduced, but not before the results of a comparative study of the Ortho and Abbott tests, (the latter only having become available at the beginning of July**). (a) Why was it considered necessary to have a UK wide comparison of the two tests, and selection of one of them?** The alternative would have been to allow each centre to decide individually which test to use – as was ultimately the outcome (see paragraph 9.241). **(b) Does the fact that this was ultimately the route followed (see for example letters SNB.005.2555 and SNB.004.7202) mean that the time taken for this study was, in retrospect, wasted?**

Answer: (a) This question would be best answered by Dr Metters and/or members of ACVSB.
(b) I believe so

30. We have not found any memo by Dr McIntyre reporting the decision of 2 July 1990 to others in SHHD. **Was there such a report or note of the meeting**? The minutes record that a submission would be put to Ministers and the minutes of the next meeting (21 November) record that "a note had gone to ministers" after the July meeting. We have located some documentation from the Department of Health but have not found any memorandum or submission to the Scottish Health Minister and would be grateful if any such document could be identified to us.

Comment: I have no comment to make (see below)

31. As is recorded in the Preliminary Report (paragraph 9.241), the meeting of ACVSB on 21 November 1990 decided that hepatitis C screening should be introduced as soon as practicable. At that meeting, Dr Gunson thought that a six month period to set up testing would be excessive (paragraph 21 of minutes). In his note of the meeting, Dr McIntyre records that the chairman had suggested 1 April 1991 as a realistic start date. We have not found it easy to determine why, given those views, testing was not introduced until 1 September 1991. We have amplified this section of the Preliminary Report with additional material now available to us, and enclose a copy of this enhanced narrative for reference. The following questions address this period.

32. It appears from Dr McIntyre's note of the meeting of ACVSB on 21 November 1990 (SGH.002.8501) that any submission to the Scottish Health Minister was to await sight of the draft ofm the English submission. The memo from Mr Tucker to Mr Panton dated 21 January 1991 (SGH.002.7890) asks for preparation of a submission; a later memo apparently dated 19

March 1991 (SGH.002.7880) indicates that the Scottish submission was based on the English one but shorter. It appears that the submission did not go to the Scottish Minister until 24 July 1991 – SGH.002.7828. **Is it possible for those involved within SHHD to explain why the submission was not sent more quickly?**

Comment: No comment other than to refer the Inquiry team to Items 33 and 35 below.

33. The correspondence at the end of January 1991 now referred to in paragraphs 9.251 and 252 suggests that both in Scotland and England there was difficulty in moving the issue forward in the early part of 1991 – is this correct?

Comment: To the best of my recollection it was at the ACVSB meeting of the 25 February 1991 that the decision, made in November 1990 to start routine donation screening in July 1991, was reversed – though I am not aware of any documents which confirm this and I recall I was later advised by Dr Gunson that he did not attend this meeting. But there is a document dated 21 February (4 days before the ACVSB meeting) which seems to indicate that DHSS had already determined, without consultation with ACVSB, that there would be yet another kit evaluation – the second generation study (3). I was later advised (23 March 1991) that SHHD had previously been consulted and had agreed to this second DHSS inspired and unnecessary delay. Dr Gunson advised NBTS Directors and others of this position on 3 April 1991 (4).

34. Why was SNBTS not to be told that there was an unofficial start date of 1 July 1991 (SGH.002.7886)? Why would this be confidential to the extent of not informing the transfusion service?

Comment: No comment, save to note that the answers to these questions from former SHHD colleagues may shed much light on the nature and quality of the governance of the SNBTS throughout the 1980s.

35. As is recorded in the Preliminary Report, Newcastle unilaterally commenced testing in April 1991. It is evident that Professor Cash and other transfusion Directors were opposed to this action, although it is also evident that Dr McClelland became increasingly uneasy at the delay (SNB.002.7902). **Is it the case that there was no consideration of Scotland similarly going ahead more quickly? If ministerial approval had been granted in Scotland around the same time as such approval was granted for England and Wales (January 1991), could this have happened, albeit with a second generation kit which was still being evaluated?**

Comments: (1). Some very distressing conversations with Dr Gunson over the week end before the ACTTD meeting of the 25 March 1991 left me in no doubt that, despite his letter of the 22 January to NBTS Directors signalling the commencement of forward planning for a full HCV donation screening start day (4), this had been reversed by DHSS in

early February 1991 against Dr Gunson's wishes and without consultation with him or other members of ACVSB. Dr Gunson also insisted that SHHD had been party to this decision and that both Departments of Health were extremely anxious that there would be no difficulties at the 25 March ACTTD meeting. There was no reason at all why we could not have introduced screening using the first generation kits

(2.) Until sight of this witness statement request, I was not aware that Scottish Ministers had not been briefed about the start date until 24 July 1991. I suggest this is a matter of great significance and believe may give some support to Dr Gunson's claim that SHHD officials had been party to the contrived further delay, which had been conceived and implemented by DHSS officials.

(3). I recall that Dr Mitchell advised me that the ACVSB was aware of the existence of second generation tests at its November 1990 meeting, but had agreed that an evaluation of these kits could be fitted in after the commencement of full screening using the first generation test (5). It follows that for some reason there was a significant change in policy and that the ACVSB was not consulted. Certainly the notion that the second generation kits could have readily been evaluated soon after the introduction of routine HCV donation screening enjoyed the support of the SNBTS. Thus earlier Ministerial approval would also have enjoyed our support.

(4). The position adopted by the Director of the Newcastle RTC in April/May 1991 proved to be very revealing. Among other things I recall it had much to do with the proposition made to the SNBTS Board in June 1991 that the SNBTS should emulate Newcastle, disregard the positions of SHHD and CSA and establish full HCV donation screening ASAP. As I recall it was a hotly contested debate, but the proposal was defeated. Some of us who opposed it viewed it as one, which if approved, could have triggered a descent into chaos and hence my reference to a potential 'disaster' (see below). In my view, the disaster would have been the operational fragmentation of the UK BTS, but closer to home the SNBTS. The impact of a fragmented UK BTS to the quality of care of UK patients would have been considerable.

36. **What was the "near disaster" referred to in Professor Cash's letter of 17 June 1991 (SNB.011.8178)?**

Answer: **See above**

37. **SNB.005.4822 appears to be recognition that there had been failings in the process leading to the introduction of screening. Do those now providing statements agree with Mr McIntosh's views?**

Answer: Yes indeed, but a good deal more than failings!

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B. Additional Question/SNBTS Microbiology Laboratory

Questions: It is evident that such a laboratory was indeed established at Ruchill. It also appears that part of the reason for the perceived need was the anticipation of donor screening for hepatitis C. (a) **Is this correct? (b) Is there further information regarding the establishment of this laboratory which the Inquiry might find helpful?**

Responses:

(a) No. It had to do with the quality of our HIV confirmatory services.

(b) Yes. As I recall it was in late 1987 that I first became aware that we had some difficulties with our HIV reference laboratories. The two problems were slow response times and different laboratory techniques and standards, both of which had particular implications for our donor counselling programmes.

In February 1988 the Directors agreed to the proposal that Dr Mitchell would liaise closely with Drs Follet (Ruchill Hospital) and Peutherer (Edinburgh University) and bring forward proposals which addressed these difficulties (6). In due course Dr Mitchell reported, and his advice, that we should establish a single national reference laboratory at Ruchill under the direction of Dr Follet, had the support of all the SNBTS Directors. In advance of this decision SHHD were appropriately briefed (7, 8) and it had become evident that there were a number of problems (9).

The proposal that there should be established an SNBTS Microbiology Reference Laboratory was put into the PES programme and thereafter enjoyed the support of Jim Donald (CSA General Manager) (10, 11 and 12)

In anticipation of some reticence of SHHD support for this proposal, in January 1989 I provided Jim Donald with some information on the outcomes of Dr Mitchell's study (13). Thereafter, in February 1989, I sought the support of the Dr Calman (CMO, Scotland) (14) and in May 1989 conveyed my concern to SHHD that no decision had yet been made (15). The CSA General Manager also conveyed his concern to SHHD in July 1989.(16).

The Inquiry Team are already aware of the three subsequent communications which led up to the release of funding to establish the SNBTS Microbiology Laboratory in October 1989 (SNB.011.5781, SNB.011.5780 and SNB.011.5779).

Mention might also be made of the establishment of an SNBTS PCR reference facility in July 1991 (17 and 18)

References to Answers/Comments

1. Letter from Dr Gunson to JDC dated 20 May 1991 (C5-27)
1a Letter from JDC to Dr McIntyre (SHHD) dated 4 August 1989 (C5-10)

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1b Briefing note (prepared by JDC and dated 2 October 1989) for CSA's BTS Subcommittee. (C5-10c)
1c Letter from Dr McIntyre to JDC dated 2 August 1989. (C5-10d)
1d Letter from JDC to Dr McIntyre (SHHD) dated 28 July 1989. (C5-10 ci)
1e WBTS Report entitled: 'SNBTS evaluation of Ortho HCV Antibody ELISA Test System, December 1989. (C5-9)
2. Letter from Dr Perry to JDC dated 2 May 1990 (C5-10k)
3. Letter from Mark Fuller (DHSS) to Dr Contreras dated 21 February 1991 (C5-16)
4. Letter from Dr Gunson to all RTDs (England and Wales) and others dated 3 April 1991 (C5-15e)
5. Letter from Dr Mitchell to JDC dated 23 November 1990 (C5-15)
6. Letter from JDC to Dr Follet dated 19 February 1988 (C2-20)
7. Letter from JDC to Duncan McNiven (SHHD) dated 19 May 1988 (C2-21)
8. Letter from Duncan McNiven to JDC dated 22 June 1988 (C2-22)
9. Letter from Dr Follet to JDC dated 29 July 1988 (C2-23)
10. Memo from Jim Donald to JDC dated 23 December 1988 (C2-24)
11. Letter from Jim Donald to Mr McNiven (SHHD) dated 23 December 1988 (C2-25)
12. Letter from Jim Donald (CSA) to Mr McNiven (SHHD) dated 1 December 1988 (C2-26)
13 Letter from JDC to Jim Donald (CSA) dated 16 January 1989 (C2-27)
14 Letter from JDC to Dr Calman (SSHD) dated 6 February 1989 (C2-28)
15. Letter from JDC to Dr Skinner (SHHD) dated 22 May 1989 (C2-29)
16 Letter from Jim Donald to Mr Tucker (SHHD) dated 11 July 1989 (C2-30)
17. Letter from Mr Derek Waddell (Edinburgh University) to JDC dated 11 July 1991 (C2-31)
18 Letter from JDC to David MacIntosh dated 12 July 1991 (C2-32)

Signed:

Date: