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WITNESS STATEMENT FROM DR R J PERRY

Issue in respect of which a statement is sought

Topic C4
HCV Screening

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. **Why was it necessary to have both the ACVSB and the ACTTD?**

Response:

I have no direct knowledge of discussions within the UK Blood Transfusion Services or Government Health departments which led to the separate evolution of these two committees. I was a member of the ACVSB from its inception but only very occasionally participated in discussions at the ACTTD (primarily on matters relating to plasma products).

However my understanding is that the ACTTD was established by the UK Transfusion Services, in the absence of any other suitable mechanism at the time, to coordinate its professional view on the need for additional measures concerning the virological safety of blood and any operational research considered necessary to support proposals for new or revised safety interventions. The original intention, as described in the Preliminary Report was that it would provide advice to Departments of Health either on request or at its own instigation.

The formation of the ACTTD coincided with the formation of the ACVSB, the latter having been established by UK Ministers to provide expert advice to Health Departments and to ensure a uniform approach to blood safety throughout the UK. The ACVSB membership and attendees included expert virologists, Public Health experts, Regulators from the Medicines Control Agency, UK Fractionators and representatives of all UK Health Departments as well as experts from the UK Transfusion Services. On the face of it, its role and purpose was similar to that of ACTTD although,

perhaps importantly, its discussions and activities were determined by senior government officials and concerned, according to its chairman, matters of policy rather than operational detail.
In its first meeting it was strongly emphasised by the chairman that its proceedings were to be regarded as confidential by all participants and members and that it was considered to be the authoritative source of advice for Health Departments and Ministers.
Despite the creation of ACVSB, but also because of its strictly confidential nature, UK Transfusion Service Directors held the view that a professional group of technical, medical and scientific experts in transfusion transmissible diseases remained an essential source of information and advice for ACVSB and also acted as a vital mechanism for the implementation of policy agreed by ACVSB.
It is difficult to imagine how major new safety measures such as HCV testing and continuous epidemiological monitoring of donor populations could be effectively managed without detailed operational consideration by a group such as ACTTD.

What lay behind the raising of the roles of the two groups at the meeting of 24 April 1990[1] – had it come to seem that there was unhelpful overlap?

Response:
I attended this meeting. In making his statement concerning the respective roles of the two committees I do not recollect the chairman providing an explanation of the need for it and I do not recollect taking the time or trouble to find out.
However my impression at the time was that the statement was intended to be an assertion of the authority of ACVSB to make policy recommendations (at that time concerning the introduction of HCV testing) and that ACTTD was subordinate to this authority. There was obviously overlap between the committees (both membership and agendas) although I do not recall this being perceived as unhelpful. More likely DOH officials (including ACVSB Chairman, Dr Metters) were concerned that discussions at ACTTD might pre-empt any future decision in principle by ACVSB to introduce (or not) HCV testing.

3. How was the membership of each body determined, in particular the Scottish representation? We have a copy of the letter inviting Dr Perry to serve on ACVSB[2] – was he in fact nominated by SHHD?

Response:
My understanding is that the membership of ACTTD would have been determined by Dr Gunson and Professor Cash, perhaps with input from other Transfusion Directors with particular expertise in Transfusion Transmitted Diseases.

[1] Minutes SNB.001.9761
[2] SNF.001.1263

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I am not aware of how membership of ACVSB was determined but most likely DOH officials (including MCA senior professionals) would have identified well known UK experts from relevant fields perhaps in consultation with Dr Gunson.
I do not believe I was nominated by SHHD (although I cannot be certain of this) More likely I was nominated by Dr Frances Rotblatt from the MCA in light of my experience on the Committee on Safety of Medicines.

How did Dr Mitchell end up on both groups?

Response:
There was overlap in the membership of ACTTD and ACVSB.
It is not surprising that Dr Mitchell was a member of both committees. He and his colleagues in the West of Scotland Blood Transfusion Service had experience and expertise in the large scale evaluation of test kits for viral markers. Professor Cash (supported by other SNBTS colleagues) would have nominated him to represent SNBTS on the ACTTD. I would conjecture that his membership of ACVSB would have been proposed by Dr Gunson to provide a vital operational perspective to the committee.

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."

Was this the Scottish equivalent of the assessment discussed in paragraph 9.126?

Response:
My understanding and interpretation of the Scottish study is that it sought to 'establish the prevalence of HCV in the Scottish donor population and any geographical variations'. This also appeared to be the objective for the study carried out at North London, Bristol and Manchester Centres (ie a prevalence study), but the Scottish study had a series of other objectives in respect of specific donor and patient groups. These are described in the report of the study (SNB.006.1596).

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?
Response:
I was not involved in the design, execution or analysis of these studies which represented the first opportunity SNBTS (or other blood services) had to evaluate a test reported to be sensitive to and specific for HCV. However, my understanding from general discussions between SNBTS Directors was that this first wide ranging study was not expected to inform a decision to use this test system without further in house operational evaluation, validation and assessment of wider UK and international experience of its suitability.

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)?

Response:
Subject to the above caveat my understanding was that the 'special interest' samples were to be included in the above assessment to provide a preliminary understanding and assessment of the test's performance in routine use.

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. **Was there a sense of timescale within which testing might be introduced?**

Response:
I was present at this meeting. I do not recall there being any discussion of timescales for introduction of testing. My general sense of the meeting was that there were some exciting international developments in relation to a specific HCV test but that it was far from clear when or if a test suitable for routine use (including confirmation) would emerge.

Why did ACVSB not consider it necessary to commission its own evaluation of the test?

Response:
I cannot answer this on behalf of ACVSB or its new (from July 1989) Chairman (Dr Metters).
My personal view is that ACVSB (and the DOH) at that time were content with the prevailing expert view (from both virologists and transfusion experts) that there was insufficient scientific data or international experience to inform the design of a UK study. Moreover such a study would be led by or involve ACVSB members who already were involved in planning such preliminary studies within the UK Blood Services.

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. **Is this a correct impression**?

Response:
I believe this impression is correct.
It was certainly periodically emphasised by Dr Metters at ACVSB meetings that the primary purpose of the committee was to establish the policy and principle for introduction of new screening tests. At this time such a policy had neither been stated or agreed – notwithstanding the fact that many believed it to be only a matter of time.

He also mentioned his understanding that any new test would be introduced simultaneously throughout the UK. **What was the source of his understanding?**

Response:
Dr McIntyre was a regular SHHD 'observer' at these meetings and either from these or other internal Government contact he would have been aware of a view held by DOH and other UK Health Departments that any new test would be introduced simultaneously.
This view was presumably not recorded in minutes because the decision in principle to introduce HCV testing had not at this stage been taken.
Clearly Dr McIntyre is better placed to offer an authoritative answer.

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?**

Response:
As a recipient of this letter I took it to be an informed guess of a likely timescale for introduction – primarily intended to ensure that SNBTS Centres could be ready if his estimate was correct. From my very limited experience and knowledge of discussion at ACVSB this was not an unrealistic prospect.

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?**

Response:
I did not attend this meeting but I believe Drs Gunson and Mitchell would have been careful to avoid giving such an impression to the Ortho representatives. From my understanding of ACVSB or other discussions around that time I do not believe there was necessarily a view that a positive decision in principle in October to implement testing was likely. At that time ACVSB had only briefly discussed HCV testing and at the meeting in July called for information to be submitted to the committee.

What is the "turn-key" system referred to in paragraph 4?

Response:

My understanding is that this describes a complete system for testing including equipment, reagents, precise operating instructions and result analysis.

Were the figures presented by Dr Mitchell (paragraph 5) those from the ongoing studies referred to in paragraphs 9.123 and 9.148?

Response:
This seems likely – I am not aware of any other studies at that time in Scotland to which this could be referring. I am sure Dr Mitchell will be able to confirm this.

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?**

Response:
This subtle distinction is probably best clarified by SHHD officials. I have no knowledge of the government protocols and procedures between health departments for the enactment of 'UK wide' decisions and policies.
However, my impression was that for all practical purposes the decision and timing of the introduction of HCV testing was led by the DOH and in particular by the DCMO (Dr Metters). Participation or involvement of Scotland, N Ireland and Welsh departments of health appeared to be limited to the presence of officials from these departments as observers at ACVSB meetings.
There was a clear understanding and assertion of the principle that any decision to introduce HCV testing would be taken on a UK wide basis and with a common start date across all four countries. (e.g. paras 9.130, 9.242).

Was the formal position that the decision for Scotland would be taken in Scotland, independently from the decision for England?

Response:
I have no knowledge of the formal position in Scotland or the technical procedures for translating a 'UK decision', through ministers, into Scottish policy. I was not aware of any suggestion that the decision in Scotland would be considered or taken independently from England – rather it was understood that a decision by DOH (and presumably English ministers) would be replicated in Scotland.

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?**

Response:

I believe this is a correct interpretation of the letter. However I think there is also an implication that repeating the ELISA test using a similar or identical test kit would not constitute satisfactory confirmation.

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 GRO-C 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.**

Response:

The Preliminary Report, minutes of the meetings and the judgement from Mr Justice Burton provide a fairly comprehensive account of the discussions and events at that time. My recollections are primarily informed by these documents. My only additional comment is that in presenting his recommendation to ACVSB, Dr Gunson was attempting to present the view of Transfusion Directors that, notwithstanding the outstanding and unresolved issues of test specificity, confirmatory testing and donor counselling etc, the implementation of HCV testing was 'inevitable' and that an early formal recognition of this (by ACVSB) would facilitate the necessary operational and financial planning by UK Transfusion Services for its eventual introduction. I recall that others members of ACVSB (particularly expert virologists and the Chairman), whilst recognising the practical reasons for this approach, considered it premature and an insufficient basis on which to formally agree in principle to the routine introduction of testing.

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

Response:

My understanding is that "dev kit" refers to early 'development' versions of Ortho test kits supplied for evaluation by Transfusion Services. SNBTS in its evaluation of the Ortho test had used both the 'development' and latter 'standard manufactured' versions of the kits and found significant differences in test sensitivity.

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?**

Response:

Unlike the US where diagnostic test kits were subject to formal FDA licensing and evaluation procedures, no such requirement existed in the UK. The early adoption of FDA licensing as a prerequisite to the introduction of the test system in the UK was, I believe, intended to provide further evidence to the UK of the satisfactory test kit performance in the absence of a formal UK evaluation and also to avoid the possibility and risks of early introduction by the UK and subsequent refusal by the FDA to authorise its routine use in the US.

Moreover, whilst the test system had received a US export licence prior to its licensure in the US it is unlikely that this would have been maintained if FDA evaluation had subsequently identified significant problems with the test system.

FDA licensure was therefore seen as an important element of the UK's evaluation of the efficacy and quality of the test system for routine use.

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)?**

Response:

In responding to this question it is important to understand that I am not a virologist and was not involved in the detailed evaluations of the emerging HCV test kits.

My comments at the meeting and recorded in my briefing note to Professor Cash simply reflected my concern that (1) there was now available a test system capable of preventing approximately 60% of cases of post transfusion NANBH, (2) that FDA licensure of the Ortho test was imminent, (3) that confirmatory testing systems were at an advanced stage of development and (4) other countries had already introduced testing and were apparently managing the outstanding issues with the test.

My feeling (shared by Dr Gunson at the meeting) was that there was at least a sound basis to recommend <u>in principle</u> that HCV testing should be introduced in the UK and that further delays in making this recommendation (for what seemed to me to be an increasingly inevitable outcome) could in the future be seen as excessively cautious.

I was aware of the arguments presented by others in favour of deferring a decision but I personally held and expressed the view that a positive decision at this time would allow operational managers to get on with the task of preparing for and therefore shortening the timescale for the eventual introduction of testing.

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?**

Response:

I believe so.

My understanding was that the licensing of the Ortho ELISA test by FDA, the availability of a confirmatory assay (RIBA) and the introduction of HCV antibody testing in the US had removed any residual obstacles to the introduction of testing.

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**). Why was it considered necessary to have a UK wide comparison of the two tests, and selection of one of them?**

Response:

As previously indicated I was not directly involved in the SNBTS or wider UK evaluation of candidate test kits.

However my recollection is that there was a desire to better understand the reasons why the two tests identified different (though overlapping) populations of screen positive donations and whether either kit offered an advantage for the UK population. Also it would have been considered useful (if not essential) to identify any problems or advantages associated with the large scale routine operational use of both tests (eg false positivity rate, ease of use, robustness etc).

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). **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?**

Response:

Not necessarily.

I would not describe the time taken for this particular evaluation as 'wasted'. Operational 'validation' of a new test system would have been considered essential 'best practice', notwithstanding the fact that no clear preference or advantage from either test emerged from the evaluation.

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.

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.

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?**

Response:
I have no recollection of SNBTS Directors or SHHD officials proposing independent action in Scotland which would lead to earlier introduction of routine HCV testing ahead of other parts of the UK. It was widely understood that DOH and UK Ministers had, from the outset of discussions, established the principle of a common start date for testing and this position was periodically reiterated at ACVSB (eg 8th meeting, November 1990). However, I was aware that during the first half of 1991 SNBTS Directors were concerned that the timing of introduction of routine testing in Scotland was increasingly being determined by the readiness of the English service. Also, the actions of Newcastle Transfusion Centre (supported by its Health Authority), whilst widely deprecated, were seen to potentially undermine the rigidity of a common UK starting date, or indeed the enforceability/validity of a 'DOH policy'. Similarly, the involvement of the Glasgow Centre in the so called 'extended study' from May 1991 (which in practice meant that approximately 50% of donations collected in Scotland after May 1991 were tested for HCV antibody) was seen as particularly difficult to reconcile with a common UK (or Scottish) start date.
Notwithstanding these concerns, my recollection is that SNBTS Directors remained supportive of a common UK start date, perhaps partly in the belief that SHHD would be unwilling or unable to countenance independent Scottish action.
I recall that these issues were considered and debated at some length at the SNBTS Board Meeting on 11th/12th June, although it was finally agreed to remain firm on the agreed date of 1st September 1991 for introduction of testing throughout Scotland – as is very briefly recorded in the minute of that meeting.

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?

Response:
Although I was not directly involved in the operational planning for introduction of HCV testing my understanding at the time was that SNBTS was capable of introducing testing in practical terms (including funding provisions) well before the agreed date of September 1st 1991 and certainly by the original date of April 1991 (eg SGH.002.7887). However it is difficult to imagine how this would have been achieved without SHHD (or CSA) authority which bodies presumably continued to be bound by UK Health Departments' agreement for a common starting date. Also SNBTS had (through Professor Cash) consistently expressed its commitment to a common UK start date (9.251).

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

Response:
Professor Cash may be referring to the SNBTS Board discussion on 11th/12th June in which the possibility of independent action by SNBTS was considered (and rejected).

37. SNB.005.4822 appears to be a 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?

Response:
Yes, I broadly agree with Mr McIntosh's views which I believe also reflected the views at the time of his senior management and professional colleagues who ultimately would be seen as accountable for their actions and inactions. My personal view is that the early decision to introduce new blood safety measures on a UK wide basis and on a common start date was correct. However I believe there were a number of shortcomings in the overall UK management process ultimately leading to a late delivery of that outcome. These included:

- ***Unnecessary secrecy and confidentiality associated with the considerations of ACVSB and other 'behind the scenes' discussions.***
- ***Absent or confused processes for communication of ACVSB decisions to operational managers.***
- ***A late recommendation in principle (in my view) by ACVSB and DOH for the introduction of HCV testing. This appeared to be driven primarily by scientific rigour rather than urgent public health considerations.***
- ***The apparent absence of a clear plan, timescale, strategy or policy guidance (from either DOH or SHHD) for the introduction of testing following the decision in principle by ACVSB in July 1990 to introduce testing.***

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- ***The progressive (and largely unexplained) deferral of the UK start date from April to July to September 1991 believed to have been caused at least in part by administrative and funding issues between the English services and DOH rather than operational readiness.***
- ***With hindsight, and given its readiness (both operational and financial) to introduce testing in early 1991, the failure of SNBTS to robustly argue a case for earlier introduction of testing in Scotland with SHHD/Scottish Ministers including the public health consequences of delays. Equally an SHHD apparent reluctance to consider such an option preferring instead to be guided exclusively by timescales determined by DOH.***

Statement of Truth

I believe the facts stated in this witness statement are true

Signed

Dated