

## **PATIENT INTEREST CORE PARTICIPANTS - SUBMISSIONS FOR THE C4 TOPIC**

### **Ambit of the topic**

C4) The interval between the availability of tests for the Hepatitis C virus in 1989 and the introduction of screening of donated blood for the virus in the United Kingdom in September 1991

### **Division of responsibility in connection with decision making about anti-HCV testing**

- 1. The responsibility of (a) the Scottish National Blood Transfusion Service and (b) the government in Scotland for the introduction of routine anti-HCV testing in Scotland and, in particular, for any delay**

The division of the responsibilities regarding decision making on blood transfusion matters in Scotland is dealt with in our C2 submission. It is our understanding that the basic structure remained the same in the period covered by this section, when (as has been addressed in the C2 submission) both surrogate and anti-HCV testing were options under consideration by these bodies. As far as the internal workings of the SHHD are concerned, it is our understanding that the internal structure remained the same though different personnel had become involved in the important roles by 1988 than had been the case in the preceding years. The structure and the identity of the individuals involved within the SNBTS remained the same, other than the creation, for the first time, of the position of general manager, a post held from 1990 by Mr David McIntosh. His involvement in the decision making process is discussed in more detail below.

The virus which caused NANB hepatitis was isolated in the spring of 1988. The Chiron press release (dated May 1988) announcing the discovery of the hepatitis C virus made not only that announcement but also pointed out that a prototype assay which may lead to a screening test for the virus had already been developed.<sup>1</sup> Details of the ELISA which had been developed to detect

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<sup>1</sup> SGH.002.8036

HCV antibodies were published in April 1989.<sup>2</sup> As was the case with the introduction of anti-HTLV III testing following the isolation of HIV, the test which was proposed detected antibody to the virus. Following the isolation of the hepatitis C virus, huge international commercial efforts were made by pharmaceutical companies to develop an anti-HCV test which could be scaled up for mass production and sale on the international market. The FDA granted a licence to Ortho to export its anti-HCV ELISA in November 1989. It granted a domestic licence to Ortho for use of its anti-HCV ELISA in the USA in May 1990 and routine anti-HCV testing started there at that time.<sup>3</sup> By that time, a confirmatory RIBA had also been developed to confirm the Ortho ELISA positives. In Scotland routine anti-HCV testing of blood donations was not introduced until September 1991. By the time Scotland introduced routine anti-HCV testing, many other countries in the world had instituted such a routine testing programme.

As far as the responsibility for that delay is concerned, the decision making processes relating to this topic are analysed in more detail below. Professor Cash appears to have wanted to make it very clear from the outset that the decision making on anti-HCV testing was the responsibility of the SHHD and not the SNBTS.

## **2. The role of advisory committees in the decision making process surrounding the introduction of anti-HCV testing in Scotland**

The Inquiry has heard evidence about the role of two particular advisory committees in the implementation of routine anti-HCV testing in the UK, including Scotland. These two committees were (a) the Advisory Committee on the Virological Safety of Blood ("ACVSB") and (b) The Blood Transfusion Service's Advisory Committee on Transfusion Transmitted Diseases ("ACTTD"). The remit of these committees was to advise the government on *inter alia* the introduction of routine testing for anti-HCV. The ACVSB was set up in April 1989, its first meeting having been on 4 April of that year. The Blood Transfusion Service's Advisory committee, the ACTTD first met on 24 February 1989. Further, other committees also existed to provide advice to the Departments of Health on issues which included testing blood donations to prevent the transmission of hepatitis C including (a) a BTS/NIBSC group whose remit it was to formulate guidelines for the standardisation of the safety of blood and blood products and (b) an Advisory Group on Hepatitis.

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<sup>2</sup> LIT.001.0629 @ 0632

<sup>3</sup> PR, para 9.204

In our submission, the existence of committees with overlapping remits was hardly conducive to the government receiving clear and consistent advice on the issue of routine anti-HCV testing. Dr Perry accepted that over this crucial period, the boundaries between the ACVSB and the ACTTD became blurred.<sup>4</sup> Dr McClelland gave evidence to the effect that it was essential that such clear, consistent advice was forthcoming for the government to take action on matters such as routine testing of blood.<sup>5</sup> Whereas we would submit that a multi-disciplinary approach to the solution of matters such as the prevention of the transmission of infectious diseases was appropriate in general terms, we would emphasise the need for there to be an avoidance of multiple committees with different priorities and agendas. The Inquiry heard evidence about the reality of the operation of these committees from Mr David McIntosh, who pointed out (a) that the ACTTD had been formed to enable the BTS to get some input from a practical standpoint into the matters with which the AVCSB had been charged<sup>6</sup> and (b) that there was tension and conflict at this time.<sup>7</sup> This could have been avoided by the creation of a single multi-disciplinary committee with a clear focus on the ultimate beneficiaries of testing, the recipients of blood.

The make-up of the membership of the ACVSB committee also caused significant problems. This committee had the main policy formation role in this area. Dr Perry, who was a member, described that committee as having the main policy role and the ACTTD as being more concerned in the implementation of that policy.<sup>8</sup> The predominantly microbiological experience of the ACVSB, perhaps as far removed from clinical concerns as one can imagine, seemed to focus throughout its meetings on the biological minutiae of developing understanding of the virus and not enough on the fact that there was no testing in place in the United Kingdom until September 1991 and therefore relatively little protection from the virus for the recipients of blood. This was confirmed by Dr Perry in his evidence who said that there was an emphasis in the committee on understanding the science rather than on saying that they must get a test introduced as soon as possible.<sup>9</sup> It was noted at the SNBTS directors' meeting on 13 February 1990 that at the fifth meeting of the ACVSB (held on 17 January 1990), a decision to not to recommend the introduction of routine anti-HCV testing had been based on the advice of the microbiologists within the ACVSB.<sup>10</sup> Dr Perry noted that the discussion on testing at the next ACVSB had been dominated by the academic virologists.<sup>11</sup> He also

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<sup>4</sup> Transcript for 23/11/11 (day 68); 115 (22 to 23) (Dr Perry)

<sup>5</sup> Transcript for 15/11/11 (day 63); 133 (9 to 10) (Dr McClelland)

<sup>6</sup> Transcript for 29/11/11 (day 70); 13 (9) to 14 (3) (Mr David McIntosh)

<sup>7</sup> Transcript for 29/11/11 (day 70); 14 (21) (Mr David McIntosh)

<sup>8</sup> Transcript for 23/11/11 (day 68); 8 (3 to 8) (Dr Perry)

<sup>9</sup> Transcript for 23/11/11 (day 68); 33 (1 to 7) (Dr Perry)

<sup>10</sup> SNB.002.4627 @ 4629

<sup>11</sup> SNF.001.1710 @ 1711 (30 April 1990)

noted that the decision to recommend further deferral was based, in part, on the perceived need to gain a "further understanding of the science".<sup>12</sup> It is further worthy of note that the Inquiry heard evidence from Professor Lever who made it clear that **clinical** virology was only emerging as a discipline in the 1980s.<sup>13</sup> This would appear to correlate with the suggestion from Dr Perry about the "academic" backgrounds of those who appear to have been wielding much influence on this extremely powerful committee at this crucial time. Dr Perry recognised that it might have been better to have an advisory committee with a greater public health perspective.<sup>14</sup> Dr McClelland contrasted this committee with the Expert Advisory Group on AIDS ("EAGA") of which he was a member. He described that group as being one whose recommendations were well accepted in the professional community and identified the fact that it was well chaired, well disciplined and was multi-disciplinary in nature (enabling it to look at things from a number of different angles) as reasons for that. He contrasted that with the relatively narrow membership and approach of the ACVSB.<sup>15</sup>

Further, the ACVSB contained only two Scottish members (Dr Perry and Dr Mitchell) and was thus unrepresentative of the interests of Scottish patients. The minutes disclose little input from either of them. Dr Perry confirmed that the main difference of opinion on the ACVSB was on the timing of the introduction of routine anti-HCV testing.<sup>16</sup> He seemed to be trying, in his evidence, to refute the suggestion that there were widespread disagreements within the committee. Be that as it may, in our submission, the question of timing was the key issue and the apparent disagreement on that is, in itself, of critical importance to a determination about the ability of that committee to function properly in the interests of patient safety.<sup>17</sup>

Further, the proceedings of the ACVSB seemed to operate on a confidential basis. This was not fully respected, as contemporaneous notes from Dr Perry to Professor Cash show.<sup>18</sup> Indeed, Dr Perry described the requirement that things be kept on a confidential basis as being based on fears about public perception. He found that very frustrating and was not sure if important information got to people who needed it, such as within SNBTS.<sup>19</sup> This demonstrates that the business of this committee (including its essential role in the issue of anti-HCV testing) was being handled according

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<sup>12</sup> SNF.001.1710 @ 1712 (30 April 1990)

<sup>13</sup> Transcript for 18/05/11 (day 27); 19 (1 to 7) (Professor Lever)

<sup>14</sup> Transcript for 23/11/11 (day 68); 137 (24) (Dr Perry)

<sup>15</sup> Transcript for 24/11/11 (day 69); 11 (12) to 12 (8) (Dr McClelland)

<sup>16</sup> Transcript for 23/11/11 (day 67); 66 (20) (Dr Perry)

<sup>17</sup> Transcript for 23/11/11 (day 67); 66 (9 to 11) (Dr Perry)

<sup>18</sup> SNF.001.1710 (30 April 1990)

<sup>19</sup> Transcript for 23/11/11 (day 68); 141 (22) to 143 (15) (Dr Perry)

to an essentially political agenda and not with the best interests of patients at heart. It is also interesting to note that EAGA did not function on a confidential basis and Dr McClelland through that its recommendations were well thought through and well accepted (see above).<sup>20</sup>

The Inquiry heard evidence from David McIntosh that these committees had no locus in Scotland as far as he was concerned on the basis that they were advisory committees of the Westminster Department of Health.<sup>21</sup> In our submission, there was a significant lack of clarity as regards the extent of the responsibility of these committees, in particular in Scotland. Mr McIntosh pointed out that the fact that anti-HCV testing was started in Newcastle without the approval or authorisation of these committees demonstrated that the SNBTS certainly had the power to control matters relating to blood transfusion in Scotland.<sup>22</sup> In the sections below, we discuss the desire on the part of the SNBTS (and Professor Cash, in particular) to make it clear that the introduction of anti-HCV testing was not their decision to take. In doing this, it appears that the SNBTS ceded control of the anti-HCV testing issue to the Westminster committees, in particular the ACVSB. Mr McIntosh made it clear that Scotland did indeed have the power to make decisions for itself and introduce anti-HCV testing if it thought that it was the best thing to do in the interests of the Scottish people.<sup>23</sup> It was because of this that the then minister for health required to give his agreement to the very formation of the ACVSB.<sup>24</sup>

In his evidence, Dr Mitchell suggested that it was an advantage that the ACVSB had "people who were from the finance side of the departments and they had money to think about too".<sup>25</sup> The title of this committee might have made one think that it was there to advise on the virological safety of blood and measures which might be adopted to increase it. Dr Mitchell's position creates the impression that its recommendations were tightly controlled by financial considerations.

In our submission, the role of these committees (in particular the ACVSB) and flaws in their decision making processes were clearly the cause of unnecessary delay (as indicated by Dr McClelland in his evidence<sup>26</sup>).

### **Knowledge about hepatitis C**

<sup>20</sup> Transcript for 24/11/11 (day 69); 13 (7 to 9) (Dr McClelland)

<sup>21</sup> Transcript for 29/11/11 (day 70); 14 (16) to 15 (2) (Mr David McIntosh)

<sup>22</sup> Transcript for 29/11/11 (day 70); 16 (7) to 17 (7) (Mr David McIntosh)

<sup>23</sup> Transcript for 29/11/11 (day 70); 20 (16) to 21 (12) (Mr David McIntosh)

<sup>24</sup> SGH.003.1242

<sup>25</sup> Transcript for 24/11/11 (day 69); 164 (9 to 15) (Dr Mitchell)

<sup>26</sup> Transcript for 24/11/11 (day 69); 62 (21) to 63 (8) (Dr McClelland)

### **3. Awareness of the prevalence and potential severity of hepatitis C from the isolation of the virus to the point at which routine anti-HCV testing was introduced in Scotland in 1991**

We have addressed, in both our C3A and C2 submissions, the emergence of information about the prevalence, post-transfusion incidence and severity of NANB hepatitis. Given that, in our submission, clear evidence was available by 1982 and at the latest 1985 that this was a potentially lethal disease which was known to progress to a chronic state in a significant proportion of those infected, the argument that efforts were merited towards the institution of testing designed to minimise the incidence of PT NANBH applies *a fortiori* to the period with which this topic is concerned. Indeed, by 1988, similar rates of progression amongst haemophiliac patients to the chronic phase of the disease as those found in the 1985 Sheffield study had been reported in a paper by Miller & Ors. This paper agreed that progressive liver disease was now a problem in haemophilia patients<sup>27</sup> We would also refer to the materials discussed on our C3A submission about the known risk of transmission of HCV to blood transfusion patients. Further, we would refer to the evidence of Dr McClelland regarding the state of knowledge about the severity and prevalence of PT NANBH in the C2 section, where he accepted the terms of the description of the standard textbook on blood transfusion by Professor Mollison (published January 1983, seventh edition)<sup>28</sup>, including the passage which stated that NANB hepatitis was deemed to be prevalent following transfusion.<sup>29</sup>

#### **The introduction of routine anti-HCV testing in Scotland**

### **4. The reasons why anti-HCV testing started in certain parts of Scotland before others**

In Glasgow, testing commenced before it did elsewhere in Scotland. The reasons for this appear to be set out, to a certain extent, in a letter from Professor Cash to Dr Gunson dated 8 May 1991.<sup>30</sup> The purpose of the letter appears to be to set out a plan which Professor Cash had devised to deal with the "disaster" of testing having been commenced unilaterally in Newcastle. In paragraph 5, one sees that Professor Cash was suggesting that a trial could be started with Newcastle (which was already using the Abbott kit) used as a test centre for that kit along with Glasgow which was the only Scottish centre which, at that time proposed to use that kit. Other centres could be found to test the

<sup>27</sup> LIT.001.3840 @ 3843 (1988)

<sup>28</sup> Transcript for 15/11/11 (day 63); 30 (8 to 14) (Dr McClelland)

<sup>29</sup> Transcript for 15/11/11 (day 63); 27 (6 to 7) (Dr McClelland)

<sup>30</sup> SNB.005.1723

Ortho kits.<sup>31</sup> Thus, Glasgow, like Newcastle appears to have been able to start testing before the other centres in Scotland as it became part of this trial. It is noteworthy that in this letter Professor Cash recognised and rejected the possibility of other Scottish centres (Dundee and Inverness) being involved in the trial. In our submission, by this point he should have been fighting to get testing started in Scotland by any means, including by proposing that other Scottish centres could be used in the trial. This may have provided a mechanism whereby he could have withdrawn from the ill-advised commitment to simultaneous introduction of testing, to which he had agreed with Dr Gunson (addressed in more detail below).

Further, it appears that routine testing may also have started in the south east region in July or August on the basis that, by this stage, Dr McClelland wanted to get things started as quickly as they could.<sup>32</sup> This suggests that the simultaneous start date, so important in the planning phase, had, in reality disappeared by this point. At long last, decisions were being taken which were focussed on patient safety.

The impetus to have testing started in Glasgow was not a concern for patient safety or principally a desire for further research feedback but, in the words of Dr Perry "to accommodate the activities of Newcastle".<sup>33</sup> This demonstrates, in our submission, the extent to which the simultaneous start date had become an all consuming political goal, despite the fact that by 1991 (as Dr Perry also indicated) that there were colleagues in Scotland who did not think that this was sustainable any longer.<sup>34</sup> He also pointed that he that he thought that the national start date of 1 April 1991 had been removed from the ACVSB minutes of the meeting on 21 November 1990.<sup>35</sup> He also pointed out that the proceedings of the government's advisory committee, the ACVSB, were controlled by the circulation of papers in advance by the DoH<sup>36</sup>, the preparation of summaries of important material was by DoH employees in advance<sup>37</sup> and the apparently very heavy influence of the DoH members of the group over decision making.<sup>38</sup> It is hard to see how, in these circumstances, the advice being received by the department was truly independent at all. These factors indicate, in our submission, that the entire system which was responsible for the introduction of routine anti-HCV testing in the UK had

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<sup>31</sup> SNB.005.1723 @ 1724

<sup>32</sup> Transcript for 24/11/11 (day 69); 63 (16 to 23) (Dr McClelland)

<sup>33</sup> Transcript for 23/11/11 (day 68); 129 (10 to 16) (Dr Perry)

<sup>34</sup> Transcript for 23/11/11 (day 68); 129 (17 to 23) (Dr Perry)

<sup>35</sup> SGH.002.8501 @ 8502 and Transcript for 23/11/11 (day 68); 124 (18 to 25) (Dr Perry)

<sup>36</sup> Transcript for 23/11/11 (day 68); 21 (3 to 11) (Dr Perry)

<sup>37</sup> Transcript for 23/11/11 (day 68); 94 (16 to 19) (Dr Perry)

<sup>38</sup> Transcript for 23/11/11 (day 68); 50 (10 to 14) (Dr Perry)

become essentially a political exercise. In our submission, these overriding political considerations resulted in a loss of focus on the safety benefits for patients which would have resulted from the swift and efficient introduction of routine anti-HCV testing.

As is discussed in greater detail below, one of the arguments advanced for the requirement that testing be introduced across the UK at the same time was that any other approach would result in a "postcode lottery" whereby the standard of care would be dependent on the place where one lived. This concern seems hard to accept on an Anglo-Scottish level from decision makers in Scotland against a background of testing being introduced at different times within Scotland. Testing had, by April 1991, also been introduced in Newcastle, albeit by unilateral action on the part of the transfusion director there. As Dr David McIntosh pointed out in his evidence to the Inquiry, by this point there was no uniformity as certain places were already doing routine screening. He saw no reason why this plan could not simply have been followed everywhere in Scotland, with the result that all Scottish centres would have introduced testing at that time.<sup>39</sup>

## **5. When anti-HCV testing could practically have been introduced throughout Scotland**

Dr McClelland expressed the clear view that routine testing could have started in accordance with the start dates of other countries, even relatively small countries with poorer resources like Finland and the Netherlands.<sup>40</sup> He gave evidence to the effect that SNBTS were, by the second half of the 1980s, experienced in rolling out testing programmes.<sup>41</sup>

At the very latest, we would refer to the evidence of Mr McIntosh who had pointed out that everything was in place for anti-HCV testing to start in Scotland in April 1991.<sup>42</sup> It was also suggested by Mr Tucker that funding could have been found whenever there was deemed to be a need for testing to be started. This is addressed in more detail below.<sup>43</sup> In our submission, the lengthy lead in period between the isolation of the virus and the availability of tests and the early consideration within SNBTS of how testing would work, combined with their experience of rolling out testing, would have meant that, had a case for earlier introduction been pushed more than it was, routine testing could have been introduced any time and, indeed, in the summer of 1990 in accordance with the timing achieved by many other countries worldwide.

<sup>39</sup> Transcript for 29/11/11 (day 70); 44 (6 to 9) (Mr David McIntosh)

<sup>40</sup> Transcript for 24/11/11 (day 69); 6 (16 to 21) (Dr McClelland)

<sup>41</sup> Transcript for 15/11/11 (day 63); 141 (2 to 12) (Dr McClelland)

<sup>42</sup> Transcript for 29/11/11 (day 70); 35 (11 to 13) (Mr David McIntosh)

<sup>43</sup> PEN.017.2060 @ 2065 (statement of SHHD assistant secretary Mr George Tucker)

## 6. The effectiveness of the management structure and the decision making processes within SNBTS and the SHHD relating to the introduction of anti-HCV testing

As far as the structures within SNBTS were concerned, the Inquiry heard evidence that Professor Cash was able to impose his will that testing should be introduced in Scotland at the same time as in England (in accordance with assurances he had given to Dr Gunson).<sup>44</sup> He wrote to Dr Gunson offering him the SNBTS directors' fullest support for the changes of the roll out date to 1 September 1991<sup>45</sup> which, according to Mr McIntosh, it did not, in reality, have.<sup>46</sup> The letter was not copied to the other directors. This was, in our submission, not an environment which was conducive to clearly reasoned decision making and proper advice being offered to government on matters of blood transfusion.

Mr McIntosh described his efforts, at this time, to change the managerial structure in order to introduce what he considered as a necessary clarity to the dissemination of advice to ministers by those responsible for blood transfusion.<sup>47</sup> In his view (as he had set out in correspondence at the time<sup>48</sup>) the decision making processes were "shadowy" and required to be changed.<sup>49</sup> He seemed to suggest that the involvement of advisory committees such as the ACVSB, which did not have any direct managerial responsibility, was not an efficient way of getting decisions made.<sup>50</sup> He accepted in his evidence that it was the responsibility of the SNBTS to give advice to the government, to be clear about it and to be clear about the consequences of not accepting it which was not done in connection with the issue of anti-HCV testing.<sup>51</sup> As is described in more detail below, this advisory responsibility seems to have been abdicated by the SNBTS by this time.

As far as the SHHD was concerned, the position throughout this period appears to have been that the introduction of anti-HCV testing would happen in Scotland at the same time as in England. This is addressed in more detail elsewhere in this submission.

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<sup>44</sup> Transcript for 29/11/11 (day 70); 63 (9) to 64 (6) (Mr David McIntosh)

<sup>45</sup> SNB.006.3958 (5 April 1991)

<sup>46</sup> Transcript for 29/11/11 (day 70); 55 (12 to 24) (Mr David McIntosh)

<sup>47</sup> Transcript for 29/11/11 (day 70); 67 (4 to 14) (Mr David McIntosh)

<sup>48</sup> SNB.005.4822 (30 August 1991)

<sup>49</sup> Transcript for 29/11/11 (day 70); 81 (20) to 82 (5) (Mr David McIntosh)

<sup>50</sup> Transcript for 29/11/11 (day 70); 83 (16) to 84 (1) (Mr David McIntosh)

<sup>51</sup> Transcript for 29/11/11 (day 70); 85 (3) to 86 (6) (Mr David McIntosh)

## 7. The account taken of the fact of and opinions about the introduction of routine anti-HCV testing in other countries

Unlike the position as regards surrogate testing, there appeared to be relatively little debate as to whether the more specific anti-HCV testing should be introduced in Scotland (or indeed UK wide at all). Whereas the local applicability of data collected abroad as to prevalence of NANB hepatitis, the incidence of PT NANBH and the likely usefulness of testing for surrogate markers as a means of preventing PT NANBH were (to a point) legitimate concerns in connection with surrogate testing, relatively few such concerns could be deemed to have justified any delay in the introduction of anti-HCV testing.

The USA introduced routine anti-HCV screening on 2 May 1990. It was noted that testing was coming or had arrived in Italy, France, Belgium and Luxembourg at the sixth meeting of the ACVSB on 24 April 1990.<sup>52</sup> It is interesting to note that this fact, though recorded, seems to play little part in the argument about introducing testing. The observation appears to be trumped in the reasoning by scientific concerns mentioned in the very next paragraph.<sup>53</sup> Routine anti-HCV testing was introduced in many other countries before it was in the UK (including Scotland) as recorded in the opinion of Burton J in the case of *A v National Blood Authority*.<sup>54</sup> The views of those who were responsible for blood transfusion matters around the world were clearly available to those in the United Kingdom who were charged with decision making about routine anti-HCV testing. In a note of the Council of Europe Committee of Experts on Blood Transfusion in May 1990 (circulated by Professor Cash) it was the view of the meeting that the introduction of routine anti-HCV testing would increase the safety of blood, though it was realised that not all positive donors would be infective.<sup>55</sup> Professor Leikola gave details of the system which was being adopted in Finland, which involved the deferral of patients who had tested positive with "two bands" in the Ortho RIBA test on the basis that a study which had been undertaken on cardiac patients (published in the *Lancet* on 21 April 1990<sup>56</sup>) and which indicated that such a result correlated well with infectivity. This meant that 0.1% of donors were being deferred whereas 0.6% and 0.5% were testing positive on the ELISA test.<sup>57</sup> This approach seems to balance the desire not to lose too many false positive donors but also the need to do

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<sup>52</sup> SNB.001.9761 @ 9763 (24 April 1990)

<sup>53</sup> SNB.001.9761 @ 9763 (24 April 1990)

<sup>54</sup> PEN.017.0302 @ 0387/0388

<sup>55</sup> SNB.005.5026 (26 June 1990) and SNB.005.5027 @ 5030 (notes from May 1990)

<sup>56</sup> LIT.001.0270

<sup>57</sup> SNB.005.5027

something in a system which had no surrogate testing (like in Scotland) to prevent PT NANBH by testing.

In a letter to Dr Gunson dated 28 July 1989, Professor Cash had indicated that it would be a "wonderful idea" if the introduction of anti-HCV testing could be co-ordinated with other countries in Europe.<sup>58</sup> As the tone of this letter suggests, that comment appears to have been made more in hope than in expectation. In our submission, relatively little account appears to have been taken of the fact that anti-HCV testing was being introduced throughout the world ahead of its introduction in the UK. As noted above, the committees advising the government on these matters (in particular the ACVSB) appear to have prioritised technical matters and scientific detail over the general safety of the recipients of blood. In our submission, the failure to take account of the fact of and the reasons for the introduction of routine anti-HCV screening around the world was a mistake.

**8. The reasons for, effect and appropriateness of the emphasis placed by SNBTS and SHHD on synchronisation with introduction in England in delaying the introduction of routine anti-HCV testing in Scotland until September 1991**

Scotland enjoyed administrative devolution over the period with which this topic is concerned. It had a separate health service and a separate blood transfusion system. Health matters in Scotland at a governmental level were dealt with by a department within the Scottish Office. In the B4 section, Professor Cash gave evidence to the effect that, in early 1985, he was very keen that Scotland institute its own testing system on US anti-HIV kits with a view to Scotland "going it alone" in introducing an HIV testing programme independent of England. He had been prevented from doing so by Dr McIntyre within the SHHD.<sup>59</sup> In his evidence in the C2 section, Dr McClelland indicated that he had no compunction about recommending surrogate testing even if the English transfusion directors had no plans to do the same.<sup>60</sup> The directors had recommended surrogate testing be implemented in Scotland at their meeting on 3 March 1987 with no apparent regard for the English failure to take any real steps in that direction.

When it came to the introduction of anti-HCV testing, it appears clear that a commitment was made at an early stage to the introduction being synchronised with the rest of the UK. At the government level, the Department of Health "took the lead" on this issue which, in our submission, meant that

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<sup>58</sup> SNB.008.2606

<sup>59</sup> Transcript for 27/09/11 (day 48); 83 (7) to 85 (10) (Professor Cash)

<sup>60</sup> Transcript for 15/11/11 (day 63); 132 (6 to 11) (Dr McClelland)

they made the decisions and the SHHD followed. On the ACVSB, Dr Perry indicated that he had considered it to be "a given" that testing would be introduced throughout the UK at the same time.<sup>61</sup> He had the impression that the decision making on this issue all took place within the DoH and was not aware of any involvement on the part of the SHHD in the debate.<sup>62</sup> Its involvement appeared to be as an observer.<sup>63</sup>

Even within SNBTS, it appears clear that Professor Cash had agreed with Dr Gunson at an early stage that Scotland would not introduce routine anti-HCV testing before England. The evidence available to the Inquiry suggests that, by this point in time, Professor Cash was very keen to emphasise that he considered it to be the responsibility of SHHD (and not SNBTS) to make a decision about the introduction of routine anti-HCV testing in Scotland.<sup>64</sup> Further, he made it clear in a letter to Dr Gunson on 28 July 1989 that Scotland would not introduce anti-HCV testing unilaterally unless he was instructed to do so by the SHHD and that he had informed Ortho that contracts for the supply of kits to Scotland could not be discussed until he had authorisation from the SHHD to do so.<sup>65</sup> It was hardly likely, given the fact that the SHHD would not be keen to introduce testing unless and until it had been sanctioned by the Department of Health for England and Wales (which Professor Cash knew well), that such an instruction would be forthcoming. Dr Macdonald gave evidence in the C2 section to the effect that the DHSS would have taken the lead on major matters and SHHD would have been required to fit its policy around the DHSS view.<sup>66</sup> In our submission, this left Scottish patients without an independent voice to support the case for an urgent introduction of testing to protect their safety. It left Scottish patients exposed to any problems which might arise which were peculiarly English in nature and which should not have affected the introduction of testing north of the border. Whereas Professor Cash and the SNBTS had tried in the past to argue the case for moving quickly on safety measures like testing for anti-HTLV III and surrogate testing, by this point they appear to have given up any such efforts. The position of the government in Scotland that the introduction of routine anti-HCV testing in Scotland would be simultaneous with the introduction in England and Wales was confirmed by Dr McIntyre in his reply to Professor Cash's request for confirmation of the position.<sup>67</sup> It remained the position that the intention was for a synchronised introduction of routine testing on 22 January 1991 when Dr Gunson wrote to the regional

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<sup>61</sup> Transcript for 23/11/11 (day 68); 36 (17 to 23) (Dr Perry)

<sup>62</sup> Transcript for 23/11/11 (day 68); 38 (11 to 25) (Dr Perry)

<sup>63</sup> Transcript for 23/11/11 (day 68); 39 (2 to 8) (Dr Perry)

<sup>64</sup> See letter from Professor Cash to Dr McIntyre dated 28 July 1989 (SNB.008.2603)

<sup>65</sup> SNB.008.2606

<sup>66</sup> Transcript for 21/11/11 (day 66); 80 (22 to 25) (Dr Macdonald)

<sup>67</sup> SGH.002.8026 (2 August 1989)

transfusion directors seeking feedback as to when they would be able to start routine testing.<sup>68</sup> On 15 February 1991, it was declared that 1 July 1991 would be the date for the introduction of routine anti-HCV testing.<sup>69</sup>

Whilst this desire for a joint approach and simultaneous introduction may have been considered to have certain advantages, in our submission, the commitment appeared to be total and it should not have been. It appears clear that on certain important issues progress was made by the Scottish directors which was hampered by a relative lack of progress in England. At the SNBTS directors' meeting on 13 February 1990, the Scottish directors had agreed that counselling would be offered to all positive donors throughout Scotland with the possibility of referral to specialist care. At the same time, the English directors were reported to be split 50/50 on the issue. By this time, Professor Cash had clearly written to the SHHD about the issue of counselling. It was, however, pointed out by Mr Watt that he did not think it appropriate for a response to be expected until the ACVSB had given advice to the DoH on the issue.<sup>70</sup>

In a letter written by Professor Cash at the time about the seventh meeting of the ACTTD on 25 May 1991, he pointed out that the delay in England was caused predominantly by financial issues.<sup>71</sup> A decision had been taken at that meeting that the start date would be delayed until 1 September 1991 due to the desire to evaluate the now available second generation kits.<sup>72</sup> It had been predictable for some time that these financial issues may arise, on the basis that it had been pointed out at an early stage by the Chairman of the ACVSB that funding for the introduction of anti-HCV testing would required to be found from existing NHS budgets.<sup>73</sup> Professor Cash made it quite clear in his evidence that the delay between April 1991 and September 1991, allegedly for the evaluation of second generation kits, was actually (to his knowledge at the time) actually due to problems with funding routine testing in England.<sup>74</sup> He proposed that this was also known about by the SHHD.<sup>75</sup> In our submission, this had the result of the introduction of routine testing in Scotland being delayed as a result of funding issues specific to England. We do not consider this to be position to have been in the interests of Scottish patients. That Professor Cash was persuaded against his will to go along with

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<sup>68</sup> SGF.001.2029

<sup>69</sup> SNB.001.8919 @ 8923

<sup>70</sup> SNB.002.4627 @ 4629

<sup>71</sup> SGF.001.2026 (letter from Professor Cash to Mr McIntosh dated 27 March 1991)

<sup>72</sup> SNB.001.8793 @ 8794

<sup>73</sup> SNB.001.9657 @ 9660 (fifth meeting of the ACVSB on 17 January 1990)

<sup>74</sup> Transcript for 01/12/11 (day 72); 136 (21) to 137 (6) (Professor Cash)

<sup>75</sup> Transcript for 01/12/11 (day 72); 169 (23) to 170 () (Professor Cash)

the decision to defer testing to September 1991<sup>76</sup> against this background was, in our submission, a failure in his responsibility to Scottish patients. There is no suggestion in the contemporaneous documentation that, in the end, he did this anything other than willingly and in full knowledge of the real reasons for the delay.

There developed in Scotland an apparently obsessive desire to ensure synchronisation with England, no matter what the reason for any ongoing delay. This is demonstrated, in our submission, by Professor Cash's overreaction to the decision of Dr Lloyd in Newcastle to introduce anti-HCV testing there unilaterally before the official start date in April 1991. Further, this episode contradicts any suggestion that Professor Cash even considered making a recommendation to the SHHD that Scotland could do something similar at that time. This is also contradicted by the contemporaneous correspondence which makes it clear that Professor Cash understood this to be a decision for SHHD to take alone (referred to above). In our submission, this obsession with synchrony overtook what should have been the overriding concern of the SNBTS and the SHHD - maximising the safety of blood for Scottish patients. That Professor Cash was able to force this policy onto the other directors, as was suggested in his evidence by David McIntosh<sup>77</sup>, was not, in our submission, in the interests of those patients. As he stated, there may have been advantages of a co-ordinated approach but this did not mean that it required to be simultaneous.<sup>78</sup>

**9. The reasons for and appropriateness of concerns about (a) confirmatory testing and (b) the accuracy and usability of test kits and the effect of decisions taken regarding these matters in delaying the introduction of routine anti-HCV testing in Scotland until September 1991**

Evaluation of the test kits

It is clear from the evidence available to the inquiry that one of the major reasons for the delay in the introduction of routine anti-HCV testing of blood in the UK was concern about the sensitivity and specificity of the available ELISA tests. This led to extensive evaluation of test kits. It appears that this process started early after the isolation of the virus and the release of details of the Chiron prototype ELISA. It is noted in the preliminary report that SNBTS had written to Chiron about the

<sup>76</sup> Transcript for 01/12/11 (day 72); 175 (14 to 18) (Professor Cash)

<sup>77</sup> Transcript for 29/11/11 (day 70); 61 (9 to 17) (Mr David McIntosh)

<sup>78</sup> Transcript for 29/11/11 (day 70); 89 (22 to 23) (Mr David McIntosh)

timescale for the availability of tests had received a reply by July 1988 that a marketable test might be available by the end of 1989.<sup>79</sup> The Ortho test (being developed in association with Chiron) was discussed at the SNBTS directors meeting on 27 September 1988.<sup>80</sup>

By the time of the first meeting of the ACTTD in February 1989, Dr Gunson had been approached by Ortho about the possibility of trials of the Ortho anti-HCV ELISA in the UK.<sup>81</sup> Dr McClelland made certain comment about the observation that the Ortho ELISA only had a 50% sensitivity rate made at the meeting of the ACVSB on 22 May 1989. He pointed out that he recalled that the actual position at that time was that it was nearer 70 - 80%.<sup>82</sup> By July 1989, Professor Cash had arranged access to Ortho ELISA test kits for evaluation, an initial evaluation having been completed by staff in the west of Scotland by July 1989.<sup>83</sup> A report on the Ortho ELISA by the west of Scotland group was available by 5 October 1989.<sup>84</sup> In this limited study, it was concluded that the Ortho ELISA had an acceptable specificity.<sup>85</sup> Thus, it was confirmed by Professor Cash in his evidence that the study showed that the Ortho ELISA was "fantastic and it didn't get much better than that over the years". He described the lengthy evaluation process as "this chase for the holy grail of the perfect test kit - it's an illusion".<sup>86</sup> In our submission, this makes quite clear that concerns about the kits leading to endless further evaluation were unfounded from this point on as far as Scotland and the interests of Scottish patients were concerned. Dr Perry gave evidence to the effect that local evaluation was necessary as there required to be consideration of the possibility of there being a difference in local epidemiology.<sup>87</sup> However, he accepted that that would be deemed to be overkill now and, in our submission, that does not justify an unlimited delay, especially against a background that there was no testing to prevent transmission of a lethal disease. Further, in Scotland it appears that such local evaluation had been undertaken to the satisfaction of the directors at this early stage.

Professor Cash had advised the SNBTS directors on 3 August 1989 that he thought that it was only a matter of time before testing would be introduced and that it would be likely to happen sometime

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<sup>79</sup> PR, para 9.93

<sup>80</sup> SGH.002.8027

<sup>81</sup> SNB.006.1975 @ 1978 (24 February 1989)

<sup>82</sup> Transcript for 24/11/11 (day 69); 6 (16 to 21) (Dr McClelland)

<sup>83</sup> PR, para 9.123

<sup>84</sup> SNB.001.9611

<sup>85</sup> SNB.001.9611 @ 9617

<sup>86</sup> Transcript for 01/12/11 (day 72); 136 (21) to 137 (9) (Professor Cash)

<sup>87</sup> Transcript for 23/11/11 (day 68); 119 (7 to 14) (Dr Perry)

after April 1990.<sup>88</sup> There is no suggestion in this statement that such a timescale would cause any problem and the letter seems to suggest that various mechanisms were being put in place to prepare for introduction. He once again reiterated the fact that, as far as he was concerned, this was a UK decision to be made by the UK health departments. By 24 August 1989, Dr McClelland had felt the need to write to his staff alerting them to the possibility of the introduction of anti-HCV testing and emphasising its importance.<sup>89</sup>

By the time of the Rome meeting in September 1989 (as reported to the fourth meeting of the ACVSB on 30 October 1989) it appears to have been realised internationally of the then available Chiron test (a) that the tests which had been done showed consistent results and (b) that the presence of antibody did mean that the person being tested was positive for NANBH (the test was detecting a marker of NANBH infection).<sup>90</sup> Dr Perry characterised the recommendations in that report as being the basis upon which Dr Gunson was effectively proposing that it should be recommended that the test should be introduced and approved in principle.<sup>91</sup> Despite Dr Gunson's influential view, it was noted that a more cautious approach was adopted at the meeting than had been expressed by Dr Gunson in his paper to the point that it was not even willing at this stage to recommend anti-HCV testing be adopted in principle.<sup>92</sup>

By the time of the fifth meeting of the ACVSB in January 1990, material was available from English evaluations of the test kits which were available which had been carried out at 3 centres (NE Thames, Trent and West Midlands) at each of which 5,000 of the tests had been evaluated in December 1989.<sup>93</sup> In our submission, this data demonstrates that the tests were deemed to be easy to perform and that there were no other significant reports from these studies at that time. By the time of the fifth meeting of the ACVSB, Dr Perry recorded that the overriding concern continued to be with false positivity.<sup>94</sup>

In our submission, what requires to be borne in mind is that throughout the period of test evaluation, there was no testing regime in place at all in Scotland to protect the recipients of blood from infection with hepatitis C. It is true to say that in other countries evaluation of the test kits went on as well. In some of them (such as the USA, Germany, France and Italy) such evaluation took

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<sup>88</sup> SNB.006.1580

<sup>89</sup> SGF.001.2055 and SGF.001.2056

<sup>90</sup> SNF.001.1393 @1402

<sup>91</sup> Transcript for 23/11/11 (day 68); 47 (21) to 48 (9) (Dr Perry)

<sup>92</sup> Transcript for 23/11/11 (day 68); 49 (15) to 51 (9) (Dr Perry)

<sup>93</sup> SNF.001.1491 @ 1505 - 1506

<sup>94</sup> SNF.001.1491 @ 1500

place against the background of there being a system of routine surrogate testing which afforded some protection against transmission of PT NANBH. In any event, even with this protection in the background, these countries made the decision to introduce routine anti-HCV testing considerably before it was achieved in Scotland. No doubt these countries faced similar concerns as those faced in the UK about the accuracy of the tests and the possible unnecessary loss of blood to their transfusion systems through false positivity. By the time Dr Mitchell attended the meeting in Rome in September 1989 to discuss the Ortho ELISA, it was being reported that 10% of persons transfused developed NANB hepatitis and that 90% of hepatitis cases were NANB hepatitis. 50% of those infected were thought to progress to chronic phase of the disease.<sup>95</sup> Those countries, however, appear to have realised the severity of the disease and the need to afford some form of protection against it by way of a specific test.

By 21 February 1990, Dr Boulton was expressing the clear view to Professor Cash that they should be getting on with routine introduction due to the known chance of infection from blood transfusion and the possibility of severe consequences such as hepatocellular carcinoma.<sup>96</sup> In March 1990 an article by van der Poel & Ors made a strong recommendation that anti-HCV testing be introduced.<sup>97</sup>

By the time of the ACVSB meeting in April 1990 Dr Perry noted that both he and Dr Gunson were of the view that the material available from the US which suggested that the introduction of routine anti-HCV testing would result in a 50% reduction in the incidence of PT NANBH.<sup>98</sup> Dr Perry indicated in his evidence that by the time of the April 1990 meeting he was of the view that the epidemiological data (relating to the number of infections which would be likely to be prevented by the introduction of routine anti-HCV testing) and the test kit performance data indicated that the time had come for there to be a recommendation that routine testing should be introduced.<sup>99</sup> He confirmed that this has led to him to "slightly" breach the confidentiality rules of the ACVSB<sup>100</sup> and communicate his position to Professor Cash, given that the data he had seen by this point suggested that the current testing had the capability to reduce PT NANBH by almost 60%.<sup>101</sup> Therefore, he and Harold Gunson had advocated a more positive approach.<sup>102</sup>

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<sup>95</sup> SNB.001.8678 @ 8680

<sup>96</sup> SNB.014.1644

<sup>97</sup> SNB.001.9850 (10 March 1990)

<sup>98</sup> Dr Gunson appeared to express his view on the US data at the meeting - SNB.001.9761 @ 9764 (24 April 1990)

<sup>99</sup> Transcript for 23/11/11 (day 68); 93 (25) to 94 (7) (Dr Perry)

<sup>100</sup> Transcript for 23/11/11 (day 68); 100 (25) to 101 (1) (Dr Perry)

<sup>101</sup> Transcript for 23/11/11 (day 68); 101 (9 to 11) (Dr Perry)

<sup>102</sup> Transcript for 23/11/11 (day 68); 102 (4 to 7) (Dr Perry)

In the meeting notes of the April 1990 meeting themselves, Professor Zuckermann had referred to the US TTV study which had concluded that 77% of those who tested positive for anti-HCV were indeed infected.<sup>103</sup> The meeting (and it would appear the decision making) was dominated by the academic virologists on the committee.<sup>104</sup> Dr Gunson had been impressed with the Ortho ELISA from the time of the Ortho conference in Rome in September 1989 and had reported back favourably and reported back favourably to the ACVSB and the ACTTD at that time.<sup>105</sup> It is interesting to note that Dr Perry describes the majority of the committee, who were in favour of deferral of the introduction of testing, as having adopted a "more cautious approach".<sup>106</sup> As far as patient safety was concerned, we would argue that they were, in fact, adopting a significantly less cautious approach than those, like Dr Perry, who favoured introduction of routine testing based on the available US data at that time. This is reminiscent, in our view, of the view taken by Dr McClelland in connection with surrogate testing, which had reached the view that the US data was sufficiently persuasive in the absence of any testing regime to protect against transmission of NANBH to recommend that type of testing regime be introduced in March 1987. Once again, patient safety appears to be sacrificed to the need for more conclusive evidence of the likely impact of testing in disease prevention before a positive move will be made. This, in our submission, is not a cautious approach. Further, it is also very interesting to note that Dr Gunson was in favour of introduction at this stage, given that it was he who later persuaded Professor Cash to accept delaying routine testing to a date 17 months after this point in time. In our submission, the position adopted at this point by Dr Perry and Dr Gunson was the correct one.

In his evidence, Mr David McIntosh drew attention to the delays caused by the lack of the proper public health questions being asked at a policy level, by which we took him to mean within SHHD. He was of the view that leaving the decision making to "microbiologists talking about whether the test is perfect" was not an answer to the "issue of a public service... to do something that will improve patient care in Scotland".<sup>107</sup> He was of the view that the desire expressed on committees such as the ACVSB about the need to gather data about the tests could have been satisfied by data being gathered after full implementation of testing.<sup>108</sup> The lack of urgency to introduce some form of

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<sup>103</sup> SNB.001.9761 @ 9763 (24 April 1990)

<sup>104</sup> SNF.001.1710 @ 1712 (30 April 1990)

<sup>105</sup> PEN.017.0302 @ 0311 @ para 11 (judgement of Burton J in A v National Blood Authority)

<sup>106</sup> SNF.001.1710 @ 1712 (30 April 1990)

<sup>107</sup> Transcript for 29/11/11 (day 70); 31 (14 to 23) (Mr David McIntosh)

<sup>108</sup> Transcript for 29/11/11 (day 70); 47 (4 to 17) (Mr David McIntosh)

protection by way of testing to prevent infection was not acceptable and certainly not in the best interests of patients.

### FDA approval

The Inquiry heard evidence that the advisory committees (in particular the influential ACVSB) were keen to await FDA approval of US test kits before recommending the routine introduction of testing in the UK. Although the approval of the FDA does not seem objectionable in itself as a pre-requisite to the recommendation of testing in the UK (such approval having come domestically in the US in May 1990), one requires to bear in mind that there were also UK based evaluations of the kits going on (including the very early and successful Scottish evaluation). In the US routine testing was able to start as soon as the FDA approval was granted. Further, the expert licence was granted by the FDA in November 1989, 6 months before the domestic licence was granted.<sup>109</sup> In our submission, the UK should have been in a position to move quickly following the granting of FDA approval with the result that routine anti-HCV testing could be brought in line with such a move being taken in the US. As Professor Zuckermann pointed out in a letter to Dr Rejman of the DHSS in around December 1889, the introduction of testing "could not be delayed much beyond FDA approval".<sup>110</sup>

### Comparative evaluation of the Ortho and Abbott kits

Further, it was decided by the ACVSB that they would recommend the introduction of routine anti-HCV testing in the UK subject to the ongoing evaluation of the Ortho and Abbot first generation kits which was about to be undertaken in 3 nominated centres.<sup>111</sup> This decision was taken at the seventh meeting of the group on 2 July 1990. Testing eventually showed that there was not much to choose between the two tests and that it should be left to individual centres to determine which of the tests they would use for routine testing in their regions.<sup>112</sup> In our submission, there was no need for this comparative evaluation. It had been a matter for regional centres to choose which of the available test kits they would use in their regions when anti-HIV testing was introduced in the UK in 1985. There was an urgent need for anti-HCV testing to get underway by the middle of 1990 and, that urgent need should have overridden the need for a comparative evaluation to be carried out. This decision delayed matters sufficiently to push things back to the point where it became necessary to

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<sup>109</sup> Transcript for 23/11/11 (day 68); 52 (10 to 11) (Dr Perry)

<sup>110</sup> SNF.001.1491 @ 1512

<sup>111</sup> SNF.001.1705 1708

<sup>112</sup> This was discussed at the eighth meeting of the AVCSB on 21 November 1990 - SGH.002.8501

make a decision as to whether to start routine testing with first generation tests at all, as second generation tests were on the horizon. The results of the comparative study were discussed at the eighth meeting of the ACVSB in November 1990, by which time clinical trials of the second generation ELISA were already underway.<sup>113</sup>

The requirement for there to be an available confirmatory test before the routine introduction of anti-HCV testing

The evidence available to the Inquiry would also appear to suggest that a further concern which caused a delay in the introduction of routine anti-HCV testing was the absence of a satisfactory confirmatory test.

By the middle of 1990, there had been an evaluation within the UK of both the available ELISA test and the RIBA confirmatory test.<sup>114</sup> At a meeting on 4 January 1990, the absence of a confirmatory test did not, according to Dr Gunson, seem likely to be the cause of any delay in the routine introduction of testing.<sup>115</sup> Dr Follett received the RIBA for evaluation in February 1990.<sup>116</sup> A positive report on the first generation confirmatory test from Ortho the "RIBA 1" (by Dr Skidmore in Birmingham) was issued on 2 June 1990.<sup>117</sup> As was pointed out in a memo written by Dr McIntyre on 6 June 1990, there was a considerable concern about the number of positive donors who would be detected if routine testing were introduced, which would cause an increase in the workload of consultant to whom those patients would require to be referred.<sup>118</sup> The concept of turning donors into patients is one which is addressed in more detail in our C2 submission. However, in our submission, Dr Gunson appeared to be of the view in April 1990 that the absence of a confirmatory test should not necessarily be a bar to the introduction of routine anti-HCV testing. In other countries, they realised the need to press ahead despite these concerns. In our submission, a similar attitude should have been adopted in the interests of recipient safety in Scotland.

In any event, the Ortho RIBA appears to have been launched in May 1990.<sup>119</sup> Dr Perry indicated in his evidence that, although the non-availability of a confirmatory test had had a major part to play in the thinking of the ACVSB on the issue of routine anti-HCV testing that "one could [at this point] tick

<sup>113</sup> PR, para 9.235 (29 October 1990)

<sup>114</sup> PR, para 9.227

<sup>115</sup> PEN.017.0302 @ 0401 (para 165 of the judgement of Burton J in A v National Blood Authority)

<sup>116</sup> PR, para 9.186

<sup>117</sup> PR, para 9.208

<sup>118</sup> SGF.001.2034

<sup>119</sup> SNB.004.5013

that particular box" as a confirmatory test was now available which had "the broad support of the scientific community".<sup>120</sup>

#### **10. The reasons for and appropriateness of the decision to instigate testing on second generation kits and the effect of that decision in delaying the introduction of routine anti-HCV testing in Scotland until September 1991**

In our submission, the decision to delay the introduction of routine anti-HCV testing in order to allow testing to be done on second generation test kits was a mistake. The extent to which the need for such an evaluation was the real reason for further delay at this time (as opposed to funding difficulties in England) is considered above. The Inquiry heard clear evidence that routine testing could have been instituted using the first generation kits in April 1991 (at the latest) with the evaluation of the second generation kits being run alongside such a programme. Dr McClelland gave evidence to the effect that, even before this time, the SNBTS were experienced in the roll out of testing systems.<sup>121</sup> Dr Perry described the delay to wait for the evaluation of the second generation kits being a case of the best being the enemy of the good.<sup>122</sup> Professor Leikola made it clear that starting routine testing with one test would not preclude switching to a better one once it became available.<sup>123</sup>

In our submission, the misguided approach of this time is summed up in the evidence in this section of Dr Mitchell, a member of both the ACVSB and the ACTTD. He explained the decision to delay the introduction of testing until an evaluation of the second generation of kits had been performed on the basis that (a) the first generation kits were useless<sup>124</sup> (b) there was an overriding concern for falsely positive donors<sup>125</sup> and (c) getting the top of the range kit was what patients would have wanted.<sup>126</sup> Meanwhile, the patients had no testing at all to protect them from infection. He then went on to state that all harm diminished him<sup>127</sup>, that the guiding principle was "primum non nocere"<sup>128</sup> and that blood was a dangerous drug.<sup>129</sup> In our submission, these laudable guiding principles could hardly be less consistent with the reasoning given only moments before in his

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<sup>120</sup> Transcript for 23/11/11 (day 68); 109 (23) to 110 (94) (Dr Perry)

<sup>121</sup> Transcript for 15/11/11 (day 63); 141 (2 to 12) (Dr McClelland)

<sup>122</sup> Transcript for 23/11/11 (day 68); 136 (1 to 4) (Dr Perry)

<sup>123</sup> PEN.017.1957 @ 1959

<sup>124</sup> Transcript for 24/11/11 (day 69); 188 (24 to 25) (Dr Mitchell)

<sup>125</sup> Transcript for 24/11/11 (day 69); 189 (7 to 13) (Dr Mitchell)

<sup>126</sup> Transcript for 24/11/11 (day 69); 190 (8 to 13) (Dr Mitchell)

<sup>127</sup> Transcript for 24/11/11 (day 69); 191 (4 to 5) (Dr Mitchell)

<sup>128</sup> Transcript for 24/11/11 (day 69); 191 (22) (Dr Mitchell)

<sup>129</sup> Transcript for 24/11/11 (day 69); 191 (24) (Dr Mitchell)

evidence, which is based on (a) an erroneous view that the first generation kits afforded no protection at all (b) concern for the interests of donors rather than those of recipients and (c) a failure to appreciate that what patients would have wanted would be some protection, rather than none. We would also note that this apparent commitment to the value of evaluating the second generation test kits conflicts with Professor Cash's evidence to the effect that the decision to undertake this evaluation was, in fact, a government controlled device (put in place through the ACVSB) to deal with the fact that there were funding problems with the introduction of routine testing in England.<sup>130</sup>

### **11. The balancing of the rights of donors and the rights of recipients of blood and blood products in connection with the introduction of anti-HCV testing in Scotland**

The requirement for the counselling and treatment<sup>131</sup> of donors who test positive for anti-HCV was a matter which was considered in connection with the question of routine anti-HCV testing, as it had been in connection with surrogate testing (see our C2 submission). Dr Mitchell sat on both the AVCSB and the ACTTD committees. His attitude on this matter in evidence is alluded to above. In our submission, at the time he consistently demonstrated a serious pre-occupation with the position of donors who have tested positive (we refer to the comments he made in his evidence in the C2 section about the need to avoid turning donors into patients and our submission on that, which apply equally here). At the fifth meeting of the ACVSB he raised the issue of causing alarm to donors.<sup>132</sup> He reiterated this concern at the sixth meeting on 24 April 1990 where he warned that there may be problems counselling donors on the basis that the true meaning of a positive anti-HCV test was not fully understood.<sup>133</sup> He also expressed concerns about unnecessary deferral of donors as result of the introduction of anti-HCV screening.<sup>134</sup>

Concern for donors appears to be largely the reason why there was concern about having a "proper" confirmatory test.<sup>135</sup> However, by the time of the fifth meeting of the ACVSB on 17 January 1990, Professor Zuckermann was pointed out in a letter to the DoH that it would be possible to defer donors who tested positive on the ELISA test and to wait for a confirmatory test for up to 12

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<sup>130</sup> Transcript for 01/12/11 (day 72); 167 (11) to 168 (8) (Professor Cash)

<sup>131</sup> SGF.001.2034

<sup>132</sup> SNB.001.9657 @ 9660

<sup>133</sup> SNB.001.9761 @ 9762 (24 April 1990)

<sup>134</sup> SNB.001.9761 @ 9764 (24 April 1990)

<sup>135</sup> Transcript for 22/11/11 (day 67); 142 (18 to 21) (Dr Dow)

months.<sup>136</sup> This would seem to suggest that, in the interests of getting initial testing up and running (whilst still recognising the need to have a confirmatory test for the sake of donors at some point) it would be possible to start routine testing without a confirmatory test system in place. This came from an individual whom Dr Perry described as "a great proponent of the need for a scientifically robust confirmatory assay".<sup>137</sup> Work was clearly being done on producing such an assay at that time.

The requirement for there to be a balance between the rights and interests of blood donors and the recipients of their blood and blood products made from it was a necessary part of the decision making process relating to the introduction of anti-HCV testing. We have made submissions on some of the general considerations concerning the appropriate striking of this balance in the C2 section and we adopt those submissions as equally applicable to this topic. In our submission, the position of Professor Zuckermann in January 1990 makes it clear that it was an option to introduce routine testing some time before confirmatory testing. We submit that this was an option which should have been taken.

In any event, at the tenth meeting of the ACVSB on 21 May 1991 it was determined that nothing would be said to donors who tested positive until the AVCSB met to discuss the matter again, though this was the last scheduled meeting before the introduction of routine testing in September 1991.<sup>138</sup> Given this decision to process without counselling, in our submission it can be deduced that the significance attached to counselling was excessive throughout the debate on anti-HCV testing.

## **12. The impact of funding considerations on the decision making process as to when to introduce routine anti-HCV screening in Scotland**

The evidence available to the Inquiry suggests that funding for anti-HCV testing would not have been a problem, had the need of its introduction been deemed to be pressing.<sup>139</sup> Mr McIntosh agreed that the arrangements would have been likely to have been sufficiently flexible to accommodate the introduction of testing, had the case for it been pushed.<sup>140</sup>

There was an early commitment (both at governmental level and within the SNBTS) to go along with the timing of the introduction of anti-HCV testing in England. Evidence was heard that the

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<sup>136</sup> SNF.001.1491 @ 1512

<sup>137</sup> Transcript for 23/11/11 (day 67); 61 (7 to 8) (Dr Perry)

<sup>138</sup> SNB.001.9054 @ 9057 (para 16)

<sup>139</sup> PEN.017.2060 @ 2065 (statement of SHHD assistant secretary Mr George Tucker)

<sup>140</sup> Transcript for 29/11/11 (day 70); 29 (23) to 30 (9) (Mr David McIntosh)

introduction of anti-HCV testing there was delayed by funding problems which was the predominant reason for delay particularly in 1991.<sup>141</sup> It does not seem that this was a problem which should have come as a surprise. At the fifth meeting of the ACVSB, Dr Gunson had pointed out that the funding for routine anti-HCV testing in England and Wales would require to be found from existing health allocation there.<sup>142</sup> Mr David McIntosh took the view that recommendation for more testing in 1991 was a means of dealing with funding problems in England.<sup>143</sup> The result of the apparent priority to wait for the introduction of anti-HCV testing in England and Wales was, that Scottish patients were subjected to English funding delays. This was totally unnecessary.<sup>144</sup>

However, in Scotland, the SNBTS did not make a specific application for funding to cover anti-HCV until July 1990<sup>145</sup>, which application was to cover the financial year 1991/92. As was explored in our submission in the C2 topic, an application for funding had been made for that type of testing in 1986 (for the financial year 1987/88) without there being any indication on the part of SHHD that they were going to introduce surrogate testing. Consistent with the apparently changed attitude of Professor Cash and the directors by the time anti-HCV testing was being considered (see above), no such pressure was applied by way of a funding application. In our submission, the SNBTS directors should have applied for funding in the year before 1990 to cover anti-HCV testing from April of that year, at the very least (as they had done for surrogate testing) to force the SHHD to consider it and put some pressure on them to introduce testing in the interests of patients at same time as was the case in other countries in 1990.

Further, there appears to be no evidence of any attention having been accorded to in potential savings in care costs resulting from prevention of infection in the decision making process surrounding this issue. It was clearly alluded to in the July 1987 Lancet letter from the SNBTS directors regarding surrogate testing (see our C2 submission). This aspect of things should have been considered as part of the public health responsibilities of SHHD and the SNBTS.

### **13. The involvement of and the advice given to the appropriate minister within SHHD in the decision making process in connection with the introduction of anti-HCV testing in Scotland**

<sup>141</sup> SGF.001.2026 (27 March 1991)

<sup>142</sup> SNB.001.9657 @ 9660

<sup>143</sup> Transcript for 29/11/11 (day 70); 46 (23) to 47 (3) and 47 (11 to 17) (Mr David McIntosh)

<sup>144</sup> Transcript for 29/11/11 (day 70); 51 (11 to 23) (Mr David McIntosh)

<sup>145</sup> SNB.002.7426 @ 7340 and PR, para 9.21

As is outlined in our submission in the C2 section, the ultimate decision regarding matters relating to public health such as the introduction of routine anti-HCV testing in Scotland lay with the appropriate minister within the SHHD. He relied upon recommendations and advice on such important and technical matters from medical and non-medical civil service staff. It seems that formal authorisation from the minister was given on 26 July 1991 in response to a request from Mr Tucker on 24 July.<sup>146</sup> Before this, a memo had been sent from Mr Tucker, assistant secretary with responsibility for blood transfusion matters within SHHD, to the then health minister within SHHD, Mr Michael Forsyth on 23 August 1989.<sup>147</sup> This concerned press interest in the matter at around that time. Mr McIntosh confirmed that the minister must have given his approval to anti-HCV testing in Scotland some time before the beginning of the financial year from April 1991 on the basis that it was part of the approved funding application which he had submitted for that year.<sup>148</sup>

The long unnecessary delay in the routine introduction of anti-HCV testing in Scotland appears to have been caused by an attitude which was rooted in scientific discipline and not sufficiently focussed on patient care. This resulted in there being a number of small delays leading to a long overall delay.

Who was supervising the committees and keeping control of the bigger picture? The minister for health within the Scottish Office had ultimate responsibility for this public health issue. The fact that it was brought to his attention only where the press became involved and for ultimate authorisation seems to have deprived him of the opportunity to take that overall control which this process was so clearly lacking. It seems likely that this state of affairs resulted from responsibility for this entire issue being abdicated by the SHHD to the DoH and its advisory committee. Mr Tucker confirmed that the decision making power on this issue had been abdicated to the ACVSB.<sup>149</sup> He placed considerable importance on the consistency between ministers in England and Scotland and appeared to consider the potential embarrassment of ministers, litigation and matters of presentation before the safety of Scottish patients.<sup>150</sup> In our submission, these considerations should at all times have been subsidiary to the interests of Scottish patients, whom they served.

#### **14. The significance of the obligations owed by SNBTS to consumers of its products under the Consumer Protection Act 1987 from its introduction 1 March 1988 and the extent to**

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<sup>146</sup> SGH.002.7817

<sup>147</sup> SGH.002.8012

<sup>148</sup> Transcript for 29/11/11 (day 70); 73 (22) to 74 (4) (Mr David McIntosh)

<sup>149</sup> Transcript for 24/11/11 (day 69); 106 (8 to 16) (Mr George Tucker)

<sup>150</sup> Transcript for 24/11/11 (day 69); 106 (20) to 107 (4) (Mr George Tucker)

**which proper cognisance was taken by the government/the NHS in Scotland of information and guidance on the nature and extent of those obligations in reaching decisions about the introduction of anti-HCV testing**

The introduction of consumer protection legislation in Scotland was addressed as a significant part of the backdrop to the debate about the introduction of surrogate testing in our C2 submission. The strict liability provisions of the Consumer Protection Act 1987 came into force on 1 March 1988 and so their introduction closely preceded the discovery of the hepatitis C virus and the debate about anti-HCV testing. In our submission, the same considerations apply to the importance of this legislation in connection with anti-HCV testing as was the case with surrogate testing. Burton J took the view in *A v National Blood Authority* that the failure to introduce anti-HCV testing in England and Wales was a breach of the defendants' legal obligations under the Act.

As was covered in our C2 submission, Professor Cash had been making the argument on numerous occasions that, in his view, the SNBTS would be liable if the provisions of the Act applied to the production of blood and blood products in Scotland. It is clear that the issue of legal liability was not lost on the members of advisory committees. At the very first meeting of the ACVSB, it was suggested that the failure to introduce testing designed to prevent the transmission of NANB hepatitis by blood and blood products (which had been introduced in the USA) may have product liability implications. By the time of the fifth meeting of the ACVSB on 17 January 1990, Professor Zuckermann was pointing out that the non-introduction of testing would be likely to result in "indefensible litigation".<sup>151</sup> We submit that the introduction of the legislation and its more consumer-orientated approach is another factor which should have resulted in routine testing being introduced sooner than it was.

**Consequences of the timing of the introduction of routine anti-HCV testing in Scotland**

**15. The number of infections with Hepatitis C in Scotland which are likely to have been avoided, had anti-HCV testing been introduced in Scotland earlier, in particular in accordance with timing achieved in other countries**

Material relating to the total number of infections with HCV from blood transfusions is available to the Inquiry. The apparent position in this regard is addressed in our C2 submission and we adopt

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<sup>151</sup> SNF.001.1491 @ 1512

those submissions here. As far as the number of infections with HCV which could have been prevented, had routine anti-HCV screening been introduced earlier in Scotland, we submit that a significant number so infections could have been prevented. In our submission, the rates of infection avoidance which could have been achieved can be ascertained on consideration of the Aach & Ors paper of 7 November 1991.<sup>152</sup> This concludes that although the second generation tests (93% detection) were more accurate the first generation tests but that a significant percentage of donors would also have been identified by the first generation tests (81% detection) and indeed by surrogate testing (73% detection).<sup>153</sup>

## **Conclusions**

### **16. When routine anti-HCV testing in Scotland should have been introduced**

In our submission, routine anti-HCV testing should have been introduced in Scotland by the time that it was introduced in the USA in May 1990. In this regard, it necessary to observe that by this time, it was well known that infections were being transmitted, that hepatitis C could be a very serious disease and that the testing kits available from Ortho could prevent a material number of infections. Satisfactory evaluations had been done in Scotland on the Ortho kits considerably earlier than this. In our submission, it should have been realised that something needed to be done to prevent the transmission of this virus, a point which had been made at various advisory committee meetings before this point. It should have been realised that improvements to the testing systems could have been considered and incorporated once the testing programme was up and running. Literature from after the introduction of routine testing indicated that the second generation kits did perform better than the first generation kits. However, the performance of the first generation kits eliminated a substantial proportion of infective donations.<sup>154</sup> In any event, doing nothing was not acceptable.

After a thorough assessment of the materials available on this issue by the Inquiry, Professor Leikola could not see a justification for the failure (a) to take a decision to recommend surrogate testing by June/July 1990<sup>155</sup> (it was not actually recommended until November 1990) or (b) to get testing up

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<sup>152</sup> LIT.001.0851

<sup>153</sup> LIT.001.0851 @ 0854 - 0855

<sup>154</sup> LIT.001.0851 @ 0854 - 0855

<sup>155</sup> PEN.017.1957 @ 1959

and running by October/November 1990.<sup>156</sup> As noted above, countries with small resources like his achieved routine introduction well before these dates.

In our submission, over the period from 1989 to 1991, one can identify a number of small delays which were unnecessary, as we have done above. These all led to a significant unnecessary general delay in the introduction of routine anti-HCV testing. The small delays were all caused, in our submission, by the absence of a real sense of urgency about getting routine testing underway, a lack of understanding about the fact that some protection was needed and about the fact that testing, once started, could operate in a fairly flexible fashion (especially given the experience of SNBTS in rolling out such testing programmes) in the best interests of the recipients of blood and blood products. By the time of the fifth meeting of the AVCSB, it was thought that the overall incidence of PT NANB in the UK could be as high as 10,000 cases per annum.<sup>157</sup> It was not acceptable, in our submission, for nothing to be done in light of this situation.

**17. Whether the fact that it took until September 1991 for routine anti-HCV testing to be introduced in Scotland was in the best interests of the recipients of blood and blood products**

In our submission, the fact that routine anti-HCV testing was not introduced in Scotland until September 1991 represents a serious disservice to the recipients of blood and blood products (in particular blood transfusion recipients) in Scotland. The SNBTS and the Scottish NHS in general have frequently described their position in connection with matters falling within the Inquiry's remit in comparative terms. The Inquiry has heard evidence that the arrival of a heat treated concentrate free from HIV was done before other countries in the world. The Inquiry has heard evidence that less patients were infected with HIV through their use of blood products in Scotland than was the case elsewhere. It was even claimed that Scotland was the first country in the world to be self sufficient in HCV safe blood products. Such a comparative approach in relation to the introduction of anti-HCV testing, however, shows that Scotland lagged behind the rest of the world. Dr McClelland thought that the reason for the delay was due to the fact that it was perceived that there was no need for urgency on the basis that NANB hepatitis was perceived as an American problem. This was why he thought that there had been a lack of decisions.<sup>158</sup> Such an attitude, if it existed, took insufficient account of the safety of patients and the very real threat which this disease posed to them. The

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<sup>156</sup> PEN.017.1957 @ 1960

<sup>157</sup> SNB.001.9657 @ 9661

<sup>158</sup> Transcript for 24/11/11 (day 69); 67 (21 to 22) (Dr McClelland)

responsibility for this lies with those in government and those advising the government over this period. As Dr McClelland said in his evidence nobody appeared to consider the question "what about the patients?".<sup>159</sup>

### **Recommendations for the future**

#### **18. What lessons can be learned from and what recommendations for the future arise out of the Inquiry's consideration of the evidence in the C4 section?**

In our submission, the following lessons can be learned from the Inquiry's consideration of the evidence in this section:

- Membership of government advisory committees relating to blood transfusion policy should include strong representation from clinicians involved in patient care as well as representatives of patient groups in addition with a more laboratory based expertise
- Such committees should be truly independent of the government
- The roles and remits of government committees should be carefully defined within a management structure to ensure that government ministers receive clear and decisive advice on matters of public health, such as the introduction of anti-HCV testing and so that other bodies with a role to play in the running of the transfusion service know what their roles are in that process
- Representation on government committees must also be capable of making strong and meaningful submissions on behalf of the distinct interests of Scottish patients
- The independence of SNBTS from the English BTS must be clearly defined and constitutionally enshrined, otherwise there would appear to be little point in having a separate Scottish transfusion service to represent what, in some situations, may be the very different position and interests of Scottish donors and patients
- There requires to be a clear definition of the responsibilities of the transfusion service and the government towards both donors and the recipients of blood and blood products
- There require to be better systems to allow account to be taken of information and opinions from and actions being taken in other countries for the safety of the recipients of blood and blood products

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<sup>159</sup> Transcript for 24/11/11 (day 69); 74 (1 to 10) (Dr McClelland)

**JTD**