

## The Penrose Inquiry

### Submissions on behalf of the Scottish Government

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#### ***Introduction***

1. These are closing submissions on behalf of the Scottish Government. They do not attempt to address every issue raised by the Inquiry team or by one of the other core participants. They do, however, attempt to deal with all issues that affect the position of the Scottish Government as a core participant in the Inquiry.
2. The present Inquiry was announced by the Cabinet Secretary for Health and Wellbeing on 23<sup>rd</sup> April 2008. In her statement to the Scottish Parliament on that day, the Cabinet Secretary emphasised that those who have suffered, and the families of those who have died, deserve answers to the complex questions surrounding their or their loved one's infection with Hepatitis C or HIV as a result of NHS treatment with blood and blood products. The Inquiry has heard at times harrowing evidence of the physical, psychological, and social hardships endured by those affected by these pernicious conditions. The Scottish Government hopes that the Inquiry will provide the answers and the explanations which those who have been infected and their families have awaited for so long.
3. In addition the Inquiry has investigated the deaths of a number of individuals, as set out in paragraph 6 of the Terms of Reference. The Scottish Government is glad that this has now been done but it does not wish to make any submissions about the conclusions the Inquiry should reach in relation to those deaths.

#### ***Background***

4. Section 19 of the National Health Service (Scotland) Act 1972 provided for the establishment of the Common Services Agency (now NHS National Services Scotland), of which the Scottish National Blood Transfusion Service (SNBTS) is a division. The National Health Service (Functions of the Common Services Agency) (Scotland) Order 1974 delegated to the CSA (among other functions)

the provision of supplies of human blood for the purposes of carrying out blood transfusion and related services, including the production of blood fractions.

5. The National Health Service (Scotland) Act 1978 Act replaced the 1972 Act. Section 10 of the 1978 Act again provided for delegation to the CSA, and the 1974 Order was preserved.
6. Sections 1(1) of the 1972 and 1978 Act imposed a general duty upon the Secretary of State (now upon the Scottish Ministers) to promote the effective provision of an integrated health service in Scotland. Thus the principal duty to provide effective health care in Scotland lay upon the Secretary of State for Scotland, and the Scottish Office retained strategic control in matters of health care policy. The day to day running of the service was delegated to territorial health boards or to Special Health Boards, such as the Common Services Agency, of which SNBTS forms part.
7. During the period with which this Inquiry is principally concerned, government of the UK was unitary, and the National Health Service was a truly national organization. While the Scottish Office existed to represent Scottish interests within government, its freedom to act independently was limited by the extent to which the doctrine of collective responsibility of the UK cabinet would permit it to do so. There were issues on which it was considered desirable that the UK should act as a whole. Blood policy was one such issue. Differences in the provision of treatment from one part of the UK to another were thought to be difficult to explain from a policy point of view and were in general to be avoided.<sup>1</sup> This was particularly so where the source and content of the expert advice which informed the formation of policy was the same in Scotland and England, as would very often be the case. Nonetheless, as the Inquiry has heard, it was open to those responsible for taking decisions in Scotland to take a line different from that taken in England.<sup>2</sup> Dr Macdonald recognized that this had in fact never been

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<sup>1</sup> Statement of Dr Keel, PEN.018.0396 § 2 iv.

<sup>2</sup> See e.g. on topic B4, Scott, Day 49 pp. 130-131; on topic C4, Tucker statement PEN.017.2060 (§13); more generally, Dr Macdonald, Day 66 p. 157.

tested in practice, and that if divergent views had become entrenched on either side of the border they might ultimately have had to be resolved at cabinet level.<sup>3</sup>

### ***Obtaining advice and formulating policy***

8. Advice on matters of health policy was primarily provided to Ministers by administrative officers within SHHD.<sup>4</sup> Such officials were, in turn, advised by medical colleagues, whose function it was to liaise with key medical personnel in the health service and to convey to administrative colleagues sufficient knowledge about the technical aspects of a topic to allow appropriate policy to be formulated. Within the department the administrative and medical officials worked closely together, exchanging information daily without necessarily holding formal meetings.<sup>5</sup> Medical officers also produced a monthly report, in addition to attending weekly meetings.<sup>6</sup> Government medical advisers were not themselves necessarily expert in any particular field. For the most part, the medical officers would have a wide portfolio of responsibilities, and while some clearly gained considerable experience in particular fields, such as blood transfusion, and others might take the lead in relation to a particular issue, such as needle sharing arrangements for IV drug users, all would have had a number of other areas to cover.<sup>7</sup> For example, Dr McIntyre, who became a Principal Medical Officer in 1977, was required to cover communicable diseases and environmental health. This wide brief thus included issues such as outbreaks of food poisoning, water quality and sewage disposal, radiation hazards and the aftermath of the Chernobyl disaster, as well as issues related to the blood transfusion service. Medical advisers contributed to the formation of policy by reporting back on the outcome of meetings they had attended for example with Regional Transfusion Directors, by maintaining a network of contacts with informed clinicians, providing a filter for external expert advice and by providing general advice on medical matters.<sup>8</sup>

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<sup>3</sup> Day 66 pp. 82-3.

<sup>4</sup> On the staffing and structure of SHHD, see Murray, Day 61 pp. 89-94.

<sup>5</sup> See e.g. Scott, Day 49 p. 111; Macniven, statement PEN.017.2053 and Day 65 pp. 135-6, 144.

<sup>6</sup> Macdonald, Day 66 pp. 106, 110.

<sup>7</sup> Statement of Dr Macdonald PEN.017.1702 § 6.

<sup>8</sup> Statements of Dr McIntyre, PEN.013.1431, PEN.017.0019; Hamill, PEN.017.0007.

9. The small cadre of medical staff in SHHD was not and could not be expected to be expert in HIV or hepatitis.<sup>9</sup> They did have access to medical publications and sought to keep abreast of developments.<sup>10</sup> But where specialist knowledge was required they necessarily turned to the experts.
10. One means by which specialist medical or scientific advice was obtained – for example in relation to the appropriate methods of testing for hepatitis or HIV – was through the government practice of establishing advisory committees, composed of acknowledged experts in the particular field. SHHD was reliant on such expert advice in the formulation of medical policy.<sup>11</sup> For reasons of economy and efficiency, and because the medical issues generally bore upon the NHS throughout the UK, such advisory committees tended to be administered by the DHSS in London; Scottish interests were represented on such committees by the presence of experts from north of the border, and Scottish civil servants including medical advisers attended as observers and reported back to SHHD. In such cases, it might be said that DHSS were ‘taking the lead’ on a particular topic. This simply meant, however, that the larger administrative Department was providing the primary support for the particular topic concerned.<sup>12</sup>
11. Another means of keeping abreast of medical and scientific developments and obtaining the advice necessary to respond to them was the participation by SHHD medical officers in the regular meetings of SNBTS. Dr Bell attended the SNBTS directors’ meetings ‘religiously’;<sup>13</sup> subsequently Dr Forrester carried out a similar role. After these meetings the medical officer would generally write up a note of the key issues and circulate it to administrative and other colleagues as appropriate.<sup>14</sup> Dr McClelland explained that as one of the regional directors his communications with SHHD were either relayed through the national director, Dr Cash, or else took place in the course of discussions around the directors’ meeting and coordinating group, in both of which SHHD was involved.<sup>15</sup> SHHD

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<sup>9</sup> McClelland, Day 64 p. 47, Day 69 p. 4.

<sup>10</sup> Macdonald, Day 66 pp. 95-9; Scott, Day 49 pp. 111, 144;

<sup>11</sup> Statement of Dr Scott, PEN.017.1854 § 4.

<sup>12</sup> Statement of Dr Macdonald, PEN.017.0559; statement of Dr McIntyre, PEN.017.2073 § 3.

<sup>13</sup> Professor Cash, Day 43 p. 77.

<sup>14</sup> McIntyre statement PEN.017.2073 §24; cf. Macniven, Day 65 pp. 142-4.

<sup>15</sup> Day 64 p. 105.

views were in this way informed by the information and advice given to them by SNBTS directors.<sup>16</sup>

12. In addition, SHHD made routine use of the advice of its consultant adviser, Dr - later Professor - Cash. So, for example, departmental memoranda show that on the anxious questions whether and when to introduce screening for HTLV-III in Scotland SHHD was eager to involve Dr Cash in the discussion.<sup>17</sup> He duly wrote to the chief medical officer with his assessment of the benefits and risks.<sup>18</sup> The documents also show that Dr Cash's advice was accorded significant weight.<sup>19</sup> Professor Cash recognized in evidence that the department was dependent on good briefing from people on the ground.<sup>20</sup>
13. This information and advice was employed in order to formulate government policy. So, for instance, in relation to the questions arising in topic B4, whether and when to introduce a screening test for HTLV-III, the policy to introduce tests on 14 October 1985 was formulated after taking account of expert views about the reliability of initial screening tests and confirmatory tests, the various practical arrangements for counselling and alternative testing that needed first to be put in place, and an assessment of the desirability of adhering to a uniform starting date throughout the UK. Likewise, the formulation of policy on topic C2, whether or not to introduce surrogate testing for NANBH, was based on a judgment among other things as to the reliability of those tests, the seriousness of the risk posed by NANBH, the desirability of policy in Scotland being coordinated with that in England, and a conclusion as to whether the public expenditure involved could in these circumstances be justified.

### **Guidance**

14. Apart from formulating policy which was then implemented in the health service in Scotland, from time to time it was appropriate for guidance to be issued to

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<sup>16</sup> Cf. Keel, Day 86 pp. 115, 124-5, 128.

<sup>17</sup> SGH.002.7293, 11 February 1985, and SGH.002.7292, 12 February 1985 'just the sort of situation when we need to call on him in his role as Consultant Adviser'. Cf. also Scott, Day 49 pp. 145-6.

<sup>18</sup> SNB.013.2233, 12 February 1985.

<sup>19</sup> See e.g. SGH.002.7294, 8 February 1985, noting that 'If Dr Cash were to advise unequivocally against the introduction of the test, that might be another matter.'

<sup>20</sup> Day 48 p. 65.

medical practitioners. For example, a series of circulars in relation to such things as testing facilities for HTLV-III was issued by or on behalf of the chief medical officer.<sup>21</sup> It is easy to understand why central guidance of this kind was appropriate: it involved issues of public health policy but it did not trespass into questions of clinical judgment. It is less easy to understand why it would have been appropriate for the CMO to issue guidance about how particular patients should be treated (for example, whether previously untransfused patients should be given cryoprecipitate or some other product). Professor Ludlam thought this would have been helpful.<sup>22</sup> Dr Macdonald, a former CMO, explained that he would expect CMO guidance to cover such things as provision of information on infectious diseases; vaccination and immunization; and the acceptability of blood donations from various groups of donor. He was of the view that it would be neither helpful nor acceptable to issue guidance about clinical treatment and, if asked, he would have declined to do that.<sup>23</sup>

### ***Common Services Agency***

#### *(i) Financial issues*

15. SNBTS made an annual bid for funding. The process formed part of what was referred to as the public expenditure survey ('PES'). It was submitted in the first instance to the Common Services Agency, which would consider it and amalgamate it with the bids being advanced by other divisions for which it was responsible. The CSA bid would then be forwarded to the SHHD where it would be considered by the administrative sections within SHHD responsible for the services in question, along with the funding of all other bids, whether from the health boards or generated internally. Advice would also be sought from medical colleagues in the department, and also from the finance division about the limits of what was available. Generally the bids would be based on the allocation for the previous year, with a percentage uplift, and they might also seek new money for new projects. Once comments on the bid had been received from various departmental colleagues, it would be reframed as appropriate, approved by senior officials on the administrative side of the department, and submitted to the

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<sup>21</sup> Scott, statement PEN.017.0513 at 0516 (§31).

<sup>22</sup> Day 55 pp. 124-8.

<sup>23</sup> PEN.018.0620.

SHHD finance division. The role of the department prior to submission to finance division would be to construct as good a case as they could to justify any extra expenditure that was sought.<sup>24</sup>

(ii) *General*

16. The formal lines of communication from SNBTS to SHHD ran through CSA, in particular its management committee. CSA had numerous other responsibilities (the Scottish Ambulance Service and Central Legal Office, to name but two). The members of the management committee were, so far as blood transfusion matters were concerned, mostly lay members, although some of them served on the Blood Transfusion Service subcommittee<sup>25</sup> and no doubt gained some special understanding of transfusion matters in that way. This did not, however, appear to cause problems in practice, since the committee was not concerned with matters of medical judgment.<sup>26</sup> While the utility of CSA in the management structure was at some stages questioned, it is important to emphasize that its role was part of the general arrangements under which both special and territorial health boards exercised the principal responsibility for the day to day running of the health service in Scotland. Those arrangements devolved responsibility from SHHD as the central department and distanced the NHS from political interference.<sup>27</sup>
17. The formal lines of communication were followed so far as submission of funding bids was concerned. It does not appear from the evidence, however, that there was strict adherence to the formalities in relation to issues of medical or scientific policy; nor indeed was there rigidity about the level at which communications took place between SHHD and CSA.<sup>28</sup> Both Mr Murray and Mr Tucker explained that the reporting system ought to have led from SNBTS to the managing committee of CSA<sup>29</sup>, and the formal position was that SNBTS directors were responsible to the Blood Transfusion Service subcommittee of the CSA management

<sup>24</sup> Murray, statement PEN.017.1755 §§9-19; Macniven, Day 65 pp. 148-59.

<sup>25</sup> Perry, Day 45 pp. 4-5, 66.

<sup>26</sup> Morison statement PEN.018.1519.

<sup>27</sup> See Murray, Day 61 pp. 146-7; Macniven, Day 61 pp. 163-4, 165-7; Morison statement PEN.018.1519.

<sup>28</sup> Morison statement PEN.018.1519; Murray statement PEN.018.1515.

<sup>29</sup> Day 61 p. 114-15, Day 69 p. 133.

committee.<sup>30</sup> But in practice this route was evidently not always taken: Dr Perry mentioned the role of the CSA management committee in relation to funding, employment of staff and disciplinary matters, but he did not recall it having provided policy guidance to SNBTS. His view was that it deferred to SNBTS managers and to SHHD, which did have medics and scientists who understood what SNBTS was doing.<sup>31</sup> Mr McIntosh was of the same view: so far as he, as general manager of SNBTS was concerned, he reported directly to Mr Donald, the general manager of CSA, but the reality was in effect that SNBTS reported direct to SHHD, who would then advise Ministers.<sup>32</sup> The Inquiry has also seen many instances where Professor Cash communicated directly with SHHD rather than relaying his communications through CSA.<sup>33</sup> Thus, while there were clearly established lines of communication, these were not slavishly adhered to, ensuring that where appropriate matters could be raised and resolved with reasonable speed and at the appropriate level.

18. The question of legal advice about compensation for those involved in clinical trials may be a helpful illustration. The documents to which Mr Murray of SHHD was taken in evidence show that at least initially communications went from SNBTS to CSA and CSA to SHHD.<sup>34</sup> At a later stage SHHD became directly involved: Mr Macniven explained that it was appropriate for it to become involved once matters had reached the stage where there was need for liaison with other government departments, including Treasury approval for expenditure. While he accepted that in hindsight it might have been better for SHHD to step in earlier than it actually had done, he pointed out the limits on what was practicable for a department faced with many other challenges in the health service at the time.<sup>35</sup>

### *Conclusions*

19. These administrative structures enabled SHHD

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<sup>30</sup> PEN.012.1742, discussed with Cash, Day 43 pp. 85-9.

<sup>31</sup> Day 45 pp. 7-9.

<sup>32</sup> Statement PEN.017.2126 §7.18 and Day 70 pp. 96-8.

<sup>33</sup> In addition Mr Murray refers to him having regular meetings with the under-secretary for health: Murray statement PEN.018.1515.

<sup>34</sup> Murray, Day 51 pp. 116 ff.

<sup>35</sup> Day 61 pp. 161-5.

- to obtain expert advice on matters relating to blood, blood products and transfusion;
- to maintain regular contacts with SNBTS so as to be aware of any issues that were of particular concern to SNBTS;
- thereby to formulate policy on the basis of the advice of experts and those involved in transfusion practice;
- thereby to provide appropriate advice to Ministers to enable policy decisions to be made and communicated through SHHD to the profession and to the public at large; and
- where considerations of general health policy (as opposed to clinical practice) made this appropriate, to issue guidance through the Chief Medical Officer to medical practitioners.

### ***The evidence available to the Inquiry***

20. The Inquiry has available to it an enormous volume of documentation. Even this amount of material is inevitably incomplete: some files appear to have been mislaid and some to have been destroyed. But what remains does appear to enable the Inquiry to arrive at reasonably clear conclusions on most issues.
21. The Inquiry has also had the benefit of hearing evidence from a large number of witnesses who were involved even at an early stage in its reference period. Indeed, it is perhaps surprising how many of those involved at that time remained able to give evidence in 2011/12. Here too there are of course unfortunate gaps. It is most regrettable that the Inquiry did not have the benefit of hearing the evidence of the late Dr Bell, a key figure in SHHD in relation to SNBTS matters especially in the 1980s. The Inquiry was able to hear from a number of other SHHD witnesses, not least on the medical side, but it is notable that most of the medical officers retired a long time ago (in the late 1980s or early 1990s) and have since then not had any continuing involvement in the issues with which the Inquiry is concerned. It is therefore unsurprising that on some points they had very limited recollections. One might perhaps contrast the position of many of the SNBTS witnesses, who appear to have remained in post until relatively recently. Apart from the continuing involvement that that has given them in transfusion

issues, SNBTS witnesses have also to some extent been involved in recent years in providing evidence to other inquiries into blood products, both in Scotland and elsewhere.

22. The question arises to what extent, if any, it is appropriate to place weight on the evidence recorded, and the assessment of the evidence made, by Mr Justice Burton in *A v National Blood Authority*.<sup>36</sup> This does represent a potential additional source of evidence for the Inquiry. Nonetheless, the Scottish Government submits that this material should be employed with some circumspection. It is no substitute for the evidence of witnesses the Inquiry heard for itself, who were examined fully by Inquiry counsel and cross-examined as necessary on behalf of the various core participants. To take a specific example: Mr Justice Burton concluded that surrogate tests ought to have been introduced in England by 1 March 1988.<sup>37</sup> The Scottish Government submits that it would clearly be inappropriate to have regard to that conclusion, other than by way of the most general background. The scientific and other evidence for and against the introduction of such tests has been placed in detail before the Inquiry, which is as a result as well (or better) placed to make its own assessment. Nor were the conclusions reached by Mr Justice Burton put to any of the witnesses at the Inquiry. Equally, the concerns of the Inquiry are rather different from those of Mr Justice Burton: in particular *A* was an action for damages under the Consumer Protection Act 1987, whereas the terms of reference of the Inquiry do not extend to liability under that Act or on any other basis. For the same reason the issue for Mr Justice Burton was purely what the producer of the product should have done by way of adopting tests or precautions. This Inquiry has a wider focus, which goes beyond the product and the producer. That is connected with the question of the appropriate standard of scrutiny, which is the next question to consider.

### ***The standard of scrutiny***

23. The question arises by what standard the decisions taken in the period considered by the Inquiry are to be judged.

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<sup>36</sup> [2001] 3 All ER 289.

<sup>37</sup> §141; cf. §106.

24. The terms of reference of the Inquiry require it to examine and investigate various matters, including the steps taken by certain people, and to make recommendations. The Inquiry is not concerned to decide questions of legal liability. That being so, it does not appear to be appropriate, for instance, to examine the decisions taken by clinicians by reference to the standard that would apply in an action based on clinical negligence.
25. So far as administrative decision-making is concerned, the test that would ordinarily apply in public-law litigation, whether a particular decision fell within the range of responses reasonably open to a decision-maker is not automatically applicable. That is because the Inquiry is not being asked to determine whether in public-law terms certain decisions were illegal or irrational.
26. Nonetheless the Scottish Government's view is that the public-law test is helpful in showing the approach that is most appropriate. Suppose, for example, that the Inquiry report were to express views to the effect that, if the chairman had been taking a particular decision at a particular time, he would have placed greater weight on one factor rather than another or would have taken a different decision altogether. Those views, supported by reasons, would of course be entitled to respect. But the difficult issues with which the Inquiry is concerned are difficult precisely because the decisions that had to be made involved weighing up complex matters of science, medicine, logistics, and public policy. In those circumstances it would hardly be surprising that a different decision-maker might have reached a different view, now or at an earlier stage.
27. It is for this reason that the Scottish Government's view is that, in considering the decisions that were taken, the appropriate approach for the Inquiry is to recognize that views may reasonably differ about the weight to be attached to a particular factor relevant to making a decision and that there may therefore be a range of reasonable decisions open to the decision-maker. In making such judgments the Inquiry is inevitably faced with the difficulty that the precise circumstances that faced the decision-maker at the time cannot be recreated, given the lapse of time and the lack of complete evidence on certain points. But this too, it is submitted, points towards the appropriate approach to scrutiny of

decision-making being to consider whether the decisions taken were reasonably open to the decision-maker in the circumstances; whether, in other words, they were within the range of reasonable responses.

## **TOPIC B1**

### **Key points**

- SNBTS moved swiftly to discourage unsuitable donors.
- Their task raised unprecedented practical difficulties and sensitive issues of donor privacy.
- In spite of the political sensitivity of the issues involved they encountered no official obstacles in Scotland.

### **Efforts to discourage high risk donors**

28. The Inquiry heard detailed evidence from Dr McClelland<sup>38</sup> about the production of leaflets designed to discourage blood donations from “high risk” groups. The first draft of this leaflet was produced by 24<sup>th</sup> May 1983<sup>39</sup> - commendably swiftly following the publication by the CDC on 4<sup>th</sup> March 1983 of recommendations for preventing the spread of AIDS<sup>40</sup>. These leaflets sought to bring the AIDS crisis to the attention of donors, and particularly to the attention of gay men, at that time thought to be perhaps the main risk group. Thereafter the leaflets developed over a period of time, and went through a number of iterations as more information emerged about the disease and thinking evolved as to the best means of communicating the necessary message to donors.

### **The scale of the task**

29. The situation which developed in the UK because of the advent of AIDS in 1983 was unprecedented. It is therefore perhaps unsurprising that initial efforts to agree on the appropriate approach to donor selection and public information proved problematic<sup>41</sup>. It is true that different blood transfusion regions took different approaches to the content and distribution of these leaflets, but those approaches reflected genuine and understandable differences of opinion and

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<sup>38</sup> Day 12

<sup>39</sup> SNB.003.7153

<sup>40</sup> In the Morbidity and Mortality Weekly Report for 4<sup>th</sup> March 1983 [LIT.001.0568]

<sup>41</sup> See e.g. Dr Bell’s excellent summary of the position at that time, SGH.002.6755

uncertainty as to how to proceed. This was the first time that the blood transfusion services and the government had required to deal with such a sensitive issue - namely the sexual behaviour of blood donors. Discussion of homosexuality was at that time much more difficult and limited than it is now; asking donors in effect whether they were practising homosexuals was perceived to be a very difficult and sensitive task<sup>42</sup>.

### ***SHHD's position***

30. Similarly, health issues arising from the misuse of drugs were politically sensitive, and aroused strong views. There was a real fear that distribution of these leaflets might deter low risk donors from giving blood. There was uncertainty as to the best method of distributing leaflets – should they be physically handed to individual donors, or should it be left to donors to pick them up? There were concerns that donors should be left with discreet “escape” routes from blood transfusion centres if they discovered that they were in one of the “at risk” groups. There was uncertainty about the extent to which donors would actually read and “internalise” the information provided to them<sup>43</sup>. Nevertheless, for all the political sensitivities and practical uncertainties, Dr McClelland’s efforts, and those of the other Scottish regional blood transfusion services, met with no official obstruction in Scotland - indeed SHHD officials encouraged their efforts<sup>44</sup>. By contrast, the Minister of State for England and Wales was apparently very keen to keep distribution of leaflets “very low key”, and wished to retain control over the way in which efforts to discourage suitable donors were made<sup>45</sup>. That appears to have slowed progress with the process of donor selection in England and Wales. SNBTS was left to proceed as it thought fit, and matters progressed more quickly as a result<sup>46</sup>.

## ***TOPIC B2***

### ***Key points***

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<sup>42</sup> Evidence of Dr McClelland, day 12, pp.42, 43

<sup>43</sup> Evidence of Dr McClelland, Day 12, p.90

<sup>44</sup> See e.g. PEN.002.0001

<sup>45</sup> DHF.001.9914

<sup>46</sup> Evidence of Dr McClelland, Day 12, pp.45, 46, 107,108

- By 1983 Scotland had largely achieved self-sufficiency in the manufacture of blood products. There remained only rare occasions on which it ought to have been necessary to prescribe imported products.
- It was neither possible nor appropriate for the Scottish CMO to issue guidance banning or restricting the use of commercial blood products.
- The government relied heavily on expert advice in making statements about the safety of blood and blood products. Expert advice during 1983 about the cause of AIDS was equivocal.
- Haemophilia clinicians were in a better position than government officials to decide whether it was appropriate to prescribe imported blood products for patients. They were free to decide not to do so.

### ***Self-sufficiency***

31. SHHD were committed to the principle of self-sufficiency in the supply of blood and blood products. SHHD medical officers repeatedly emphasised that commitment, and indicated that if possible, clinicians should use NHS blood products in preference to imported products. At a meeting of the SNBTS and Haemophilia Directors on 21<sup>st</sup> January 1983<sup>47</sup>, Dr Bell stressed that:-

“...SNBTS had been set up to have the capability to cope with all Scottish requirements...and that in terms of national policy the purchase of commercial products should be avoided so far as possible.”

32. At a further meeting of the Joint Directors on 2<sup>nd</sup> February 1984<sup>48</sup> Dr Bell again emphasised that:-

“...the aim of SNBTS and of national policy was for Scotland to be self-sufficient, and although the Department would not wish to intervene in what clinicians prescribed, it was not sensible to purchase imported material when suitable NHS product was available.”

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<sup>47</sup> SNB.001.5160 at 5162

<sup>48</sup> SNB.001.5252 at 5254

33. Suggestions that SNBTS or haemophilia directors did not receive “any particular steer” from SHHD on self-sufficiency or the use of commercial products are therefore unfounded<sup>49</sup>.
34. Developments in haemophilia treatment, notably the advent of home therapy, and prophylactic therapy, meant that the amount of product required for self-sufficiency was constantly rising<sup>50</sup>. Projection of demand was difficult and PFC understandably faced a constant battle to maintain supplies in the period leading up to 1983<sup>51</sup>.
35. However, by 1983 self-sufficiency in the production of blood products had largely been achieved in Scotland<sup>52</sup>. Indeed, by early 1984, production may have been exceeding demand<sup>53</sup>. SNBTS obtained sufficient blood, and PFC produced sufficient product to ensure that, under most normal circumstances, domestic product was available for use by clinicians to treat patients, including haemophilia patients. At meetings of the Joint Directors in November 1981 and January 1983, haemophilia clinicians congratulated PFC on the quality of their products which were said to be “very satisfactory” in their quantity and quality<sup>54</sup>. At the Joint Directors’ meeting of 2<sup>nd</sup> February 1984, Dr McDonald indicated that clinicians at the West of Scotland’s adult haemophilia centre were “totally satisfied” with the NHS product and that there was no longer any need to purchase commercial product<sup>55</sup>.
36. Nevertheless, it appears that some clinicians continued to prefer to use commercial products, which they regarded as more reliable in quality and

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<sup>49</sup> Compare e.g. Professor Forbes, Day 17, p.82, and 141; Professor Cash, B2 witness statement, PEN.015.0362

<sup>50</sup> See e.g. PEN.012.0205

<sup>51</sup> Dr McClelland, B2 witness statement - PEN.015.0307 at 0319; letter from Dr Boulton to Dr Ludlam 10<sup>th</sup> May 1982 - SNB.001.5199. It is worthy of note that a register of Scottish haemophiliacs, designed to assist Haemophilia and Transfusion Directors in treating patients and predicting demand, was proposed or at least promoted by Dr McIntyre of SHHD in the late 1970s and early 1980s – see SNB.001.5006, SNB.001.5033, SNB.001.5055, SNB.001.5064, SNB.001.5069

<sup>52</sup> SNB.007.3998

<sup>53</sup> SNB.001.5282

<sup>54</sup> SNB.001.5069 at 5070; SNB.001.5160 at 5161

<sup>55</sup> SNB.001.5252 at 5254

potency than NHS product<sup>56</sup>. SHHD officials monitored purchases of commercial products during 1983, and appear to have expressed concern about “substantial purchases” in the West of Scotland region at a meeting of the SNBTS Directors in December 1983<sup>57</sup>.

37. Professor Ludlam expressed a view that he wished to continue to keep stocks of high-purity commercial product for particular patients, and continued to do so until at least February 1984<sup>58</sup>. Moreover, emergency situations arose in which a particular patient might need more product than was available from PFC at the particular time.

### ***Guidance and clinical freedom***

38. Although SHHD’s clearly expressed preference was that NHS product should be used where possible, the choice of product to be prescribed for a particular patient or patients was (and remains) a matter for the treating clinician. The principle of clinical freedom was (and remains) an important one. Provided that a product had been licensed for use in the UK – and in some circumstances, even where a licence had not yet been granted – clinicians were free to use what in their view was the most efficacious product. At the Joint Directors’ meeting of 2<sup>nd</sup> February 1984, Dr Bell clearly wished to emphasise that in his view, purchase and use of commercial products was neither sensible nor desirable. Nevertheless, as the extract from the minutes of that meeting show, he also plainly felt that he required to acknowledge the principle of clinical freedom. During 1983 and at least part of 1984, many haemophilia clinicians took the view that the benefits of continuing with treatment with factor concentrate outweighed the risks<sup>59</sup>.

39. The Committee for the Safety of Medicines, made up of “highly experienced professionals”<sup>60</sup> itself took the view in July 1983 that the balance between the

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<sup>56</sup> Evidence of Professor Forbes, Day 17, p.29; Professor Ludlam’s B2 witness statement PEN.015.0445 at 0459 - 0461

<sup>57</sup> SNF.001.0178 at 0180

<sup>58</sup> SNB.001.5252 at 5254

<sup>59</sup> SNB.001.7535 at 7538 – some clinicians went so far as to say that patients “should be encouraged not to refuse imported factor VIII”.

<sup>60</sup> Evidence of Dr Perry, Day 25, p.46

risks and benefits of treatment with factor concentrate was so fine that a decision to continue treatment with imported concentrates was a matter of clinical judgment<sup>61</sup>. The Committee's view was that there was no justification for banning commercial products, and that it was a matter for individual clinicians to assess.

40. Professor Hann suggested that clinicians required more guidance from government at that time<sup>62</sup>. However, government in Scotland had indicated to haemophilia clinicians even before the AIDS crisis emerged that commercial products should be avoided if possible. In 1983 and 1984, it is difficult to know what further guidance could properly have been given. As already noted, government relied heavily on advice from experts, and there appeared to be little agreement among experts at that time as to the gravity of the risk posed by blood products, particularly imported blood products, and as to the appropriate treatment for haemophiliacs. Dr Winter took the view that the only tenable explanation of the available data in December 1982 was that blood products had been responsible for at least some transmissions of HIV<sup>63</sup>. On the other hand, Professor Lever suggested that the period April to July 1984 was really the turning point in achieving general acceptance that imported blood products were responsible for AIDS in European haemophilia patients<sup>64</sup>. The evidence clearly showed that during 1983 and well into 1984 at least some eminent haematologists had great difficulty in believing what Dr Winter said they "had to believe" – namely that AIDS was present in factor concentrates - and preferred the view that "AIDS" in haemophilia patients was really due to the overloading of patients' immune systems by foreign proteins from the concentrates used in their treatment<sup>65</sup>.
41. Professor Cash claimed to have sought a direction from the Scottish CMO on the use of concentrates in the early summer of 1983<sup>66</sup>. There is no documentary evidence to support that claim. In the absence of such evidence, the Inquiry

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<sup>61</sup> DHF.001.4587 at 4589

<sup>62</sup> Day 21, pp.54-55

<sup>63</sup> Day 16, p.8.

<sup>64</sup> PEN.015.0517 at 0524

<sup>65</sup> The "antigen overload" theory. See e.g. Professor Ludlam, Day 18, p.115, 118; LIT.001.0416; LIT.001.0215

<sup>66</sup> PEN.015.0273

should be slow to make a finding on the matter. A great deal of other documentation is available in relation to Professor Cash's activities and opinions. It is accordingly odd that no correspondence survives in relation to this chapter. However, even if it is accepted that Professor Cash made such a suggestion, it is unsurprising that it was not taken forward by the Scottish CMO. First, the CMO would naturally, and appropriately, be cautious about dictating to clinicians, expert in their field, what products they should or should not prescribe, for the reasons outlined above. Second, questions regarding safety, licensing, restriction, or banning of particular products were UK matters, dealt with by the biologicals sub-committee of the Committee on the Safety of Medicines. It was not open to Scottish officials unilaterally to ban or restrict particular products. The CMO for Scotland would have been subject to criticism if he had taken upon himself any attempt to restrict the use of particular products in Scotland, both from within government, and from those commercial companies for whose products licences had already been granted for use in the UK. It is at least possible that legal action might have been taken by the latter. Any statement to the effect that particular imported products were thought to be dangerous, or that competing NHS product was thought to be safer, would have been commercially, politically and legally extremely sensitive. Questions would legitimately have been asked why statements of the sort proposed were being made in Scotland, but not in England. It is likely that it would have caused very significant public anxiety, and might have resulted in a flood of patients from south of the border seeking treatment in Scotland.

### ***Dr Galbraith's suggestion***

42. On 9<sup>th</sup> May 1983, Dr Spence Galbraith of CDSC for England & Wales sent a paper to a Dr Ian Field at the DHSS in which he stated that having reviewed the available literature he had concluded that "all blood products from blood donated in the USA after 1978 should be withdrawn from use"<sup>67</sup>. Dr Field indicated that in his view the suggestion was "premature in relation to the evidence and unbalanced in that it does not take into account the risk to haemophiliacs of

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<sup>67</sup> MIS.001.0001

withdrawing a major source of their FVIII supplies”<sup>68</sup>. In taking that view he appears to have relied largely on a statement drafted for the minutes of a special meeting of the Haemophilia Reference Centre Directors on 13<sup>th</sup> May 1983<sup>69</sup>. Following that meeting, the Haemophilia Society, presumably on advice from the haemophilia clinicians concerned, wrote to the DHSS indicating a desire to speak to the Minister with a view to securing “no ban on the importation of American concentrates meantime”<sup>70</sup>.

43. Dr Galbraith’s suggestion was debated at the meeting of the biologicals sub-committee of the CSM on 13<sup>th</sup> July 1983<sup>71</sup>. PFC had a representative on that sub-committee, but the outcome of the meeting does not appear to have been communicated to others at PFC, to SNBTS or to SHHD. The sub-committee’s view was that there was insufficient evidence as at June 1983 to justify a ban on imported commercial products. There is no indication that Mr Watt dissented from that view; nor is there any indication that he took steps to indicate to officials at SHHD that the policy agreed at the sub-committee meeting was misguided, or should be departed from in Scotland. There is no evidence that Dr Galbraith’s suggestion was seen by anyone at SHHD, including the CMO.

### ***Statements by government***

44. Ensuring the safety of the blood supply was and is clearly a very high priority for the government and the health service. However, shortages in or interruptions to the blood supply also carry very significant risks. The possibility that donors might be deterred in large numbers from giving blood was and remains a highly undesirable prospect, which would clearly pose substantial risks to the continued provision of essential medical services. Ministers were bound to consider the effect upon the blood supply generally of taking particular measures or providing particular information, as well as any risks to the virological safety of that supply.
45. Similarly, it is an important and legitimate consideration for government to balance the provision of information to members of the public about the safety of

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<sup>68</sup> DHF.001.4387

<sup>69</sup> DHF.001.4384

<sup>70</sup> DHF.001.4413

<sup>71</sup> MIS.001.0291

the blood supply, with appropriate reassurance as to the magnitude of any risk. The possibility that members of the public might decline essential medical treatment, or become unnecessarily or unduly worried about the safety of such treatment is also an undesirable outcome and one which government was bound to consider in making public statements about the safety of the blood supply.

46. The government in the UK as a whole was heavily dependent on expert advice in relation to the issue of imported concentrates, and in other areas of medical or pharmaceutical safety. The advice issued by SHHD in September 1983<sup>72</sup> was entirely in line with advice received by the government – viz. that there was insufficient evidence to justify a ban on imported products, and that the link between blood products and AIDS had not been proved<sup>73</sup>. It is true that there was by that stage some evidence to support such a link, but that evidence was thought to be equivocal<sup>74</sup>. As we have seen above, the government had been actively lobbied by the Haemophilia Society *not* to ban imported products.
47. Officials and clinicians were clearly struggling to reconcile the conflicting views on this issue. While the link between concentrates and blood products had “not yet been conclusively proved”, English RTDs and the DHSS had by October 1983 produced a leaflet for blood donors designed to reduce the risks of transmission of AIDS by blood and blood products<sup>75</sup>, and the SHHD press release of September 1983 sought to emphasise that nearly all the Factor VIII used to treat haemophilia in Scotland was produced from Scottish plasma, which at the time was genuinely believed to be a low risk plasma source. But at the same time, the Haemophilia Society, again presumably on the advice of haemophilia clinicians was emphasising that the risk from imported concentrates was “greatly reduced” and that the “advantages of treatment [with such concentrate] far outweigh any risks”<sup>76</sup>. Such reassurance was perhaps less appropriate in the English context

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<sup>72</sup> That there was no conclusive proof that factor concentrates were implicated in the AIDS outbreak - SNF.001.0416

<sup>73</sup> See in particular Professor Bloom’s statement at the UKHCDO meeting of 17<sup>th</sup> October 1983 that “there was no need for patients to stop using the commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS” - SNB.001.7517 at 7526

<sup>74</sup> Compare US guidance issued in September 1983 - DHF.001.4724

<sup>75</sup> SGH.001.8446 at 8449

<sup>76</sup> DHF.001.4767

than in the Scots, given their greater reliance on imported products. But it should be borne in mind that a great deal about AIDS was still unknown at that time, and there was a view among some haemophilia clinicians – a view which persisted until at least 1984 - that the syndrome observed in haemophilia patients might have a different cause from GRIDS<sup>77</sup>. Moreover, England and Wales were at that time very far from being self-sufficient in blood products, and there was little practical alternative, at least in the short term, to continuing to rely on imported product. As the Inquiry has heard, the risks to haemophilia patients from uncontrolled or untreated bleeding were as great as ever. Production in both England and Scotland had moved very significantly away from cryoprecipitate to the manufacture of factor concentrates. A refusal to accept treatment with concentrates or transfusions carried significant and obvious risks for the patient. All that was left, in those circumstances, was reassurance. As Professor Lever put it<sup>78</sup>:-

“...the balance of opinion or the balance of evidence was in favour of an infectious agent at that stage. However...the amount of distress and concern and worry, sometimes unnecessarily, that you can induce in people by raising the fear of an infectious agent in something like a blood product would be undesirable unless it was absolutely certainly the case, or as near certain as you could be that that was the case. I think people would not necessarily have been very understanding had this turned out to be a false alarm and individuals had either bled or died by withdrawal of the clotting factors and then it having been found that there was not the threat which had been assumed.”

### **Conclusions**

48. In any event, clinicians in 1983 and 1984 were in a better position than government officials to decide what products they should and should not prescribe for patients. Even in the absence of a “ban” on imports by the UK

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<sup>77</sup> “Gay related immune deficiency syndrome”. Dr Boulton’s account of the UKHCDO meeting of 17<sup>th</sup> October 1983 - SNB.001.7535 - gives an impression of the rather confusing information then available to clinicians; and compare evidence of Professor Lever, Day 26, pp.91-97. The presence of Kaposi’s Sarcoma in the “gay” cases, but not in the “blood products” cases appears to have been a particular confounding factor, and one not explained until the 1990s. See also the references at footnote 64 above.

<sup>78</sup> Day 26, p.92

government, clinical freedom meant that clinicians were perfectly entitled to decline to use particular products. In Scotland at least they were generally able to use NHS product, and were encouraged to do so by SHHD officials. That some clinicians appear to have continued to prefer commercial rather than NHS product, even in situations where NHS product was available was, in hindsight, unfortunate. But the balance of risks perceived by clinicians at that time was a matter of judgment, and the judgment made by such clinicians to continue with imported material was one which was endorsed by a number of leading physicians at the time, including the Chair of the UKHCDO, Professor Bloom.

### **TOPIC B3**

#### **Key points**

- The introduction of heat treatment to inactivate LAV/HTLV-III faced numerous technical challenges.
- The introduction of heat treatment in early 1984 was not warranted given the state of scientific knowledge at that time.
- Once the key scientific knowledge became available in November 1984, SNBTS achieved the introduction of heat-treated Factor VIII with remarkable speed.
- Funding was made available to cover the cost of heat treatment.
- SHHD provided, in addition to funding, such support as it appropriately could, given that the introduction of a heat-treated product raised issues which were fundamentally for the medical and scientific experts.

#### **The state of research**

49. Much of this topic is concerned with scientific and technical issues as PFC and other fractionators worked on various processes of heat treatment in order to inactivate viruses. For the purposes of this submission it is largely sufficient to refer to the account given in the Preliminary Report<sup>79</sup> and to the Briefing Paper<sup>80</sup> produced by Dr Foster of SNBTS. The following short general points about the state of research provide the necessary context.

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<sup>79</sup> Chapter 11.

<sup>80</sup> PEN.013.1309.

50. From the beginning of the 1980s fractionators were attempting to identify forms of heat treatment that would inactivate hepatitis.
51. The threat that LAV/HTLV-III posed to the integrity of blood products emerged suddenly, and with it the need to identify urgently a form of heat treatment that would inactivate it.
52. In Scotland there was a long-standing policy to achieve and maintain a state of self-sufficiency in blood products, in order to avoid the use of donations from what were perceived to be less safe parts of the world;<sup>81</sup> retaining self-sufficiency required the yield of blood products from blood donations to be satisfactory.
53. Any heat treatment procedure necessarily affected the yield: yield was therefore a crucial parameter in devising appropriate heat (or other inactivation) treatment: there would be little point in producing a perfect product if there was not enough of it to go round.<sup>82</sup>
54. The received wisdom until 1984 was that Factor VIII was a very unstable molecule, which was susceptible to damage if heat treated; steps therefore had to be taken to stabilize it against any measure of heat.<sup>83</sup> That was why the news from the Groningen conference in November 1984, of successful dry-heat treatment of Factor VIII for an hour at 68C or pasteurization at 60C, provoked such astonishment.<sup>84</sup>
55. Dr Foster's evidence and his Briefing Paper explain the various routes that PFC followed in seeking to devise an effective method of viral inactivation by heat treatment while not surrendering excessive yield. Apart from the work of the team at PFC, there was a fruitful exchange of ideas between PFC and BPL: while the

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<sup>81</sup> See e.g. Perry, Day 45 pp. 31-2.

<sup>82</sup> See e.g. Foster, Day 41 pp. 71, 124, 153; Perry, statement PEN.012.1759 at 1762 and Day 45 p. 18.

<sup>83</sup> Foster, Day 41 p. 116; Cuthbertson, Day 46 p. 22.

<sup>84</sup> Foster, Day 41 pp. 114-16.

two explored their own routes, lines of reporting between the scientists remained open, especially between Drs Foster and Smith.<sup>85</sup>

56. In light of the new information in November 1984 that HTLV-III in Factor VIII could be inactivated by dry-heat treatment, PFC moved immediately to introduce dry-heat treatment. Routine dry-heat treatment began on 18 November 1984; this extremely rapid introduction was possible because all the necessary equipment happened already to be in place.<sup>86</sup>

***The timescale for introducing the heat-treated product***

57. The timescale originally proposed by SNBTS in February 1984, to introduce a heat-treated product by April 1985, was extremely ambitious, even viewed with hindsight.<sup>87</sup> It was remarkably swift, not least in comparison with current norms, where development of a product through clinical trials and licensing to routine issue may be expected to take around five years.<sup>88</sup> In the event that timescale was of course superseded, since in light of advances in knowledge dry-heat treatment was instead introduced in November 1984.
58. As Dr Perry explained, once the basic development of the heat-treated product had been carried out at PFC, the rate-determining factor in moving on further to issue the product was the need to do clinical trials in patients.<sup>89</sup>
59. It would in theory have been possible to introduce heat treatment earlier, in terms of the availability of the necessary equipment. The medical and scientific evidence heard by the Inquiry indicates, however, that introducing heat treatment more rapidly could not be justified on the basis of scientific knowledge at the time. The main reasons identified in evidence were that the cause of AIDS had not been identified; the susceptibility of the virus (if that was indeed what it was) to

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<sup>85</sup> Foster, statement PEN.012.1438 at 1457, 1459 and Day 41 pp. 82, 140-41; Smith, statement PEN.012.1551 at 1556 and Day 59 pp. 46-7; Perry, Day 45 pp. 25, 70; Cuthbertson, PEN.013.0025 at 0030-31 and Day 46 p. 43; cf. Cash, Day 43 pp. 44-5.

<sup>86</sup> Perry, statement PEN.012.1759 at 1776-8; Foster, statement PEN.012.1438 at 1464; cf. Smith, Day 59 pp. 135-6.

<sup>87</sup> Foster, statement PEN.012.1438 at 1469-70 and Day 42 pp. 40-41. Cf. also Smith, statement PEN.012.1551 at 1560.

<sup>88</sup> Cuthbertson, PEN.013.0025 at 0037-8 and Day 46 p. 70.

<sup>89</sup> Day 45 p. 58.

heat treatment was not known; there were concerns that heat treatment might lead to the generation of inhibitory antibodies in the patients who were to receive the product; and there were also concerns about the solubility of heat-treated factor products.<sup>90</sup> As noted already, when the state of scientific knowledge rapidly advanced in autumn 1984, steps were very quickly taken to advance the introduction of heat treatment.

### ***Funding of heat treatment***

60. There are two distinct issues in relation to funding. The fundamental point, however, is that all SNBTS witnesses confirmed that progress with the heat-treatment project was not delayed by the need to obtain funding.<sup>91</sup>
61. First, SNBTS made a bid for £650,000 in order to fund heat treatment.<sup>92</sup> The bid was presented as funding that was necessary in order to implement the recommendations of the Medicines Inspectorate following their recent inspection of PFC. The bid was approved by the Blood Transfusion Service sub-committee of CSA at their meeting on 25 May 1983.<sup>93</sup> It was forwarded by the general administrator of CSA to SHHD under cover of a letter which recognized that the department 'will wish to give further consideration to certain of the proposals including their eligibility for funding from the source requested'.<sup>94</sup> SHHD evidently did not regard the heat treatment project as falling within the ambit of the Medicines Inspectorate's recommendations and declined to fund it on that basis; they did, however, make it clear that they were prepared to consider the matter further. It was suggested that CSA might wish to reconsider the position and re-submit details of estimated expenditure requirements for 1983/84 and later years.<sup>95</sup>

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<sup>90</sup> Foster, statement PEN.012.1438 at 1475-6; Perry, statement PEN.012.1759 at 1778-9; Cuthbertson, statement PEN.013.0025 at 0041-43; Ludlam, statement PEN.012.1688 at 1690-91; Smith, statement PEN.012.1551 at 1565-6; van Aken, statement PEN.012.1928-9 and PEN.012.1932 at 1937.

<sup>91</sup> Foster, statement PEN.012.1438 at 1470; suppl. statement PEN.012.1797 at 1803; Day 42 p. 14; Perry, Day 45 pp. 54-5; Cuthbertson, statement & Day 46 p. 71; Cash, Day 43 p. 79.

<sup>92</sup> Discussed in evidence by Perry, Day 45 pp. 46 ff.; Cash, Day 43 pp. 58 ff.

<sup>93</sup> SGH.001.9769; apparently the matter was 'hotly debated' in the committee: Cash, Day 43 p. 67.

<sup>94</sup> SNB.003.7641, 8 June 1983.

<sup>95</sup> SNB.011.1251, 20 September 1983.

62. The decision not to accept the bid as falling within the ambit of the Medicines Inspectorate's recommendations appears to have been entirely justified. Dr Cuthbertson described the presentation of the bid in this way as a 'stratagem' and in evidence explained that linking the two was perhaps somewhat expedient since the Medicines Inspectorate had not made any criticism of PFC manufacturing processes but only of its building and facilities.<sup>96</sup> In evidence Professor Cash appears to have agreed that the funding proposal was an attempt to link heat treatment to the budget for meeting the recommendations of the Medicines Inspectorate and that, when this approach was rejected, there was another funding avenue that could be followed.<sup>97</sup>
63. Second, SNBTS made a free-standing bid for the cost of producing heat-treated Factor VIII.<sup>98</sup> This funding consisted of £74,000 for equipment and £13,400 for recurring revenue costs. In February 1984 Dr Perry revised this funding proposal.<sup>99</sup> The bid was submitted to the Blood Transfusion Service sub-committee of CSA for their meeting on 22 February 1984. Approval in principle was given at that meeting. On 13 August 1984 Dr Perry sent a reminder to Mr Wooler of CSA about the need for the funding; he received a reply dated 17 August 1984 confirming that there was no difficulty about carrying the £90,000 expenditure over.<sup>100</sup>
64. Research carried on at PFC even pending approval of these sums. Since the heat-treatment process was still in the course of being scaled up, and the funds were required primarily for full-scale implementation of the treatment towards the end of the period 1984/5, the availability of these sums of money was not on the 'critical path' at that time;<sup>101</sup> Dr Foster and his colleagues continued with the programme; and they did not at that stage need any additional equipment.<sup>102</sup>

### ***Support from SHHD***

<sup>96</sup> PEN.013.0025 at 0033; Day 46 pp. 47-8. Cf. also Foster, Day 42 pp. 10-11; Perry, Day 45 pp. 52, 53, 56.

<sup>97</sup> Cash, Day 43 pp. 67-70, 73, 75, 126.

<sup>98</sup> SGH.002.0068; cf. Foster, Day 42 pp. 40-42.

<sup>99</sup> SNB.007.4276; discussed by Perry, Day 45 pp. 75-8 and Cash, Day 43 pp. 75-9.

<sup>100</sup> SNB.007.4523 and 4527; Perry, Day 45 pp. 84-5.

<sup>101</sup> Perry, statement PEN.012.1759 at 1775 and Day 45 pp. 54-5.

<sup>102</sup> Foster, Day 42 p. 72.

65. The issue of developing and introducing a heat-treated product was essentially a matter for the experts of SNBTS, especially the fractionators. It enjoyed the necessary support from SHHD, as the availability of funding shows. In particular, Dr Bell in SHHD was very supportive.<sup>103</sup> In a memorandum of 23 May 1984 he pointed out to departmental colleagues that he did not think SNBTS had effectively made the policy (as opposed to technical) case for funding the production of heat-treated Factor VIII. He explained that this was a genuine and important advance in therapy, whose objective was to reduce the risk of transmission particularly of hepatitis and which might also prevent the transmission of AIDS. A failure to bring this important technological advance about would be very difficult to defend publicly.<sup>104</sup> Speaking more generally, Professor Cash also described Dr Bell as 'immensely supportive' and commented on his attending SNBTS directors' meetings 'religiously'.<sup>105</sup>
66. At the same time, however, Professor Cash suggests that SHHD left SNBTS without active support in December 1984.<sup>106</sup> This does not fit with Professor Cash's otherwise enthusiastic endorsement of Dr Bell's positive influence; and nor does it find echoes in the evidence of other SNBTS witnesses. December 1984 was undoubtedly an anxious time, owing to the discovery that HIV had arrived in the Scottish donor population. But the key decisions in relation to introduction of a new heat-treated product clearly had to be taken by the experts, the fractionators in discussion with the clinicians.
67. It is not clear to what precisely the concern about lack of support relates. The necessary funding and equipment were in place. It may be related to the suggestion that there was a lack of clarity about potential legal liability in relation to blood products. If so, not only was that not an issue that was at the forefront of the mind of Dr Perry, who had the operational responsibility for PFC at this

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<sup>103</sup> The internal memo by Dr Bell, SGH.003.4922, taken together with Professor Cash's evidence, Day 43 esp. at p. 133, show that in spite of his occasional frustrations in dealing with requests or demands from SNBTS, Dr Bell conveyed nothing of this to Professor Cash.

<sup>104</sup> SGF.001.1986.

<sup>105</sup> Day 43 p. 77.

<sup>106</sup> Statement PEN.012.1912 at 1927; cf supplementary statement PEN.012.1909.

anxious time;<sup>107</sup> but in evidence Professor Cash also came to accept that the request for legal advice had been met: at a meeting of the Blood Transfusion Service sub-committee legal advice had been discussed, and it had been concluded by the national medical director among others that the assurances given by the legal advisers were satisfactory.<sup>108</sup>

68. The suggestion of lack of support may instead relate to a perception on Professor Cash's part that there was a lack of moral support, but it is not clear how SHHD could have offered more than it did. It could not have given a scientific or professional view that could have been of any comfort in taking the decision to issue the heat-treated product.<sup>109</sup> SHHD did convene an urgent meeting of haemophilia directors and SNBTS representatives, which took place on 29 November 1984.<sup>110</sup> Senior officials also kept the Minister informed of important developments at this time, in relation to clinical trials of the new heat-treated product, the discovery of infection of the 'Edinburgh cohort', and the expected timescale for issue of heat-treated Factor VIII.<sup>111</sup> Dr Perry copied his letter of 6 December 1984 regarding the issue of the first batches of the new Factor VIII product to Dr Bell.<sup>112</sup> The recommendation to introduce heat-treated products was indeed taken by experts, namely UKHCDO reference centre directors, UK blood transfusionists and senior fractionators from PFC and BPL.<sup>113</sup>

## **TOPIC B4**

### **Key points**

- There was consensus that it was necessary to evaluate the various test kits that were on offer before adopting them in practice.
- There was also consensus that the tests ought to be introduced throughout the UK at the same time.

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<sup>107</sup> Perry, Day 45 p. 117. As he pointed out, even with hindsight concerns over the regulatory process were not at the forefront of his mind.

<sup>108</sup> Day 43 pp. 117-120; SGH.001.8906.

<sup>109</sup> Day 43, pp. 109-10, 113-14 (contrast the position of NIBSC, who could offer a professional view, albeit they did so only unofficially).

<sup>110</sup> SNF.001.0255; cf. Ludlam statement PEN.012.0351 at 0354 (§16).

<sup>111</sup> SGH.002.6523, 26 November 1984; SGH.002.6513, 5 December 1984.

<sup>112</sup> SGH.002.6506; for further discussion of these points, see the Scottish Government letter to the Inquiry dated 4 May 2011, PEN.012.1731.

<sup>113</sup> *Ibid* §17; cf. Smith statement PEN.012.1551 at 1574.

- Evaluation of the tests was sponsored by DHSS and carried out at centres in England.
- SNBTS had originally intended to carry out its own evaluation but this did not in fact take place.
- Had SNBTS carried out its own evaluation and obtained satisfactory results with one or more of the test kits, it is a possible view that screening might have been introduced in Scotland before 14 October 1985.
- But this would have depended on numerous difficult issues first having been resolved: availability of tests to evaluate; satisfactory evaluation of the tests; an adequate confirmatory test; appropriate arrangements for donor counselling; availability of alternative testing facilities.
- It would also have involved departing from the consensus view that tests should be introduced throughout the UK at the same time, which was a matter of significant public policy given the issue of alternative testing.
- Funding did not play any part in the timing of the introduction of the tests.

### ***The need to evaluate the test***

69. There was consensus that it was necessary to evaluate the various test kits that were on offer before adopting them in practice.<sup>114</sup> In particular there was a concern about apparently high levels of false positive results in other countries (notably the USA); there was also a recognition that results obtained in another country might well not be replicated in the UK. The key issues are summarized in the advice Professor Cash gave to the Chief Medical Officer at SHHD in February 1985:<sup>115</sup> at that time introduction of the test would in his view be ill-advised because of the distress and suffering it would cause a number of donors and their families;<sup>116</sup> the lack of counselling facilities and appropriate technical back-up services to ascertain false positivity; and a concern about a reduction in usable donated blood. For those reasons the introduction of the test should be actively discouraged until such time as the government was advised that introducing it was in the best interests of the transfusion services; active steps should be taken to establish a national kit evaluation programme. Dr McClelland confirmed that

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<sup>114</sup> See e.g. Gunson/Smithies letter §4, SNB.006.5978, 3 July 1984.

<sup>115</sup> SNB.013.2233, 12 February 1985.

<sup>116</sup> Discussed further by Professor Cash, Day 48 pp. 69-71.

there was concern about the performance of the early tests and about both false positive and false negative results.<sup>117</sup>

70. In September 1984 DHSS established a working group – of the Advisory Committee of the NBTS - to consider the issues regarding the introduction of a test; Dr McClelland was a member, while Dr Bell was to attend on behalf of SHHD.<sup>118</sup> This group met for the first time on 27<sup>th</sup> November 1984<sup>119</sup>, but did not meet for a second time, presumably because the UK government was by then in the process of setting up a new advisory group, the EAGA<sup>120</sup>. That group met for the first time on 29<sup>th</sup> January 1985<sup>121</sup>. It was Dr Covell who represented SHHD at the meetings of the EAGA; his expertise lay in the area of communicable and sexually transmitted diseases.<sup>122</sup>

71. The contemporary documents show that Dr Scott, Dr McIntyre, Dr Bell and Dr Covell of SHHD were all closely engaged in the issue of introduction of the tests.<sup>123</sup> A series of internal documents discusses the practical issues that need to be resolved before the test can be introduced;<sup>124</sup> reference is made to the fact that the decision taken in England to introduce the test means that there is no practical alternative but to follow suit in Scotland. SHHD is keen to have Dr Cash's advice on the matter.<sup>125</sup> On 21 March 1985 a detailed briefing was submitted to Ministers and copied to a number of departmental officials summarizing the position: the need to screen blood but to do so only once the available tests have been evaluated and alternative testing facilities have been made available; the profound implications for individuals of false positive results and the need for further testing and counselling; the fact that the high cost of the

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<sup>117</sup> Day 50 p. 9.

<sup>118</sup> DHF.002.5897; SGF.001.0929.

<sup>119</sup> DHF.001.6037

<sup>120</sup> Preliminary Report, 8.120, p.222

<sup>121</sup> SNB.001.0002

<sup>122</sup> Professor Cash, while critical of this appointment in his written evidence (PEN.017.1038 at 1040) did not renew his criticism on Day 48 pp. 30-32, 64-5. Dr McClelland Day 50 p. 12 expressed no concern.

<sup>123</sup> Cash, Day 48 p. 64.

<sup>124</sup> SGH.002.7295, 7294, 7293, 7292, 7226 from February and March 1985; discussed in evidence by Scott, Day 49 pp. 107 ff.

<sup>125</sup> SGH.002 7293 and 7292.

test should not stand in the way of introducing testing.<sup>126</sup> The Secretary of State accepted the advice on 26 March 1985, so a decision in principle to introduce testing in Scotland was now in place.<sup>127</sup>

### ***A separate evaluation by SNBTS?***

72. SNBTS had originally intended to carry out its own evaluation of test kits but this did not in fact take place. The reasons for that are not entirely clear. On the one hand, Professor Cash notes in his statement that in early January 1985 the SNBTS directors had decided to abandon the notion of a joint UK approach and to mount their own evaluation of the test kits; this decision was relayed to SHHD on 24 January; and shortly afterwards Dr McIntyre made it clear to Professor Cash that SHHD was strongly opposed to SNBTS undertaking its own evaluation: SHHD had assured DHSS that they were content that DHSS manage evaluation of kits and that a UK-wide date for commencement of routine donation testing would apply. Dr Mitchell, Dr McClelland and Professor Cash thereupon agreed that the independent evaluation should not be done.<sup>128</sup>

73. On the other hand, the documents appear to suggest a somewhat different picture. There apparently had been an intention to evaluate kits at least in the West of Scotland.<sup>129</sup> However, Dr Mitchell cast some doubt on the practicability of any such evaluation, because of a lack of a sufficient number of kits to conduct it.<sup>130</sup> As noted above, on 12 February 1985 in writing to the CMO, Professor Cash advocated a national evaluation programme.<sup>131</sup> The minutes of the SNBTS Coordinating Group meeting on 19 February 1985 record that all available kits were to be evaluated under DHSS sponsorship by Middlesex Hospital and PHLS; that after a “full discussion” it was agreed that the proposal to evaluate kits in the West of Scotland should not be pursued; and that it was also agreed that no testing centre in Scotland would commence routine testing unilaterally under any circumstances and whatever pressure might be applied.<sup>132</sup> It must be doubted

<sup>126</sup> SGH.002.7226, 21 March 1985.

<sup>127</sup> SGH.002.7224.

<sup>128</sup> PEN.017.1038 at 1040 (§§2.07-08).

<sup>129</sup> Cf. Cash/Mitchell, SNB.005.9713, 25 January 1985.

<sup>130</sup> Evidence of Dr Mitchell, Day 51, pp.29-30; See also Dr Dow’s B4 statement PEN.017.1680

<sup>131</sup> Cf. Cash, Day 48 pp. 43, 85-6.

<sup>132</sup> SNB.003.9171 §9.

whether there would have been any need for a full discussion at this meeting if the matter had already been taken out of SNBTS's hands by SHHD. Moreover, a letter from Dr Bell to Professor Cash dated 6 March 1985, welcoming the SNBTS decision to hold off validating kits *until the protocols had been agreed through EAGA*, appears to be a response to an intimation of a decision by SNBTS, and does not suggest that SHHD had forbidden SNBTS to proceed with testing.<sup>133</sup> Equally, Dr McIntyre did not recall instructing Dr Cash to stand down.<sup>134</sup>

74. It is therefore far from clear that SHHD was responsible for terminating the proposed SNBTS study; although even if it had been considerations of duplication of effort and conservation of resources might well have justified that.

***Could SNBTS have introduced the test earlier than 14 October 1985?***

75. Had SNBTS carried out its own evaluation and obtained satisfactory results with one or more of the test kits, it is at least arguable that it would have been able to introduce screening with the tests before 14 October 1985, the date on which screening was introduced throughout the UK. Professor Cash was slightly cautious about this, describing it as a 'big job', but thought having regard to the quality of the SNBTS team and the position in various other countries that introduction in April or May 1985 might have been achievable.<sup>135</sup> But there are important qualifications to this.<sup>136</sup>

*Availability of the kits to test.* During 1985 there were supply difficulties, at least in relation to obtaining kits from Abbott to evaluate.<sup>137</sup> When Abbott kits were obtained, in March/April 1985, the results obtained were poor with many false positives, and DHSS did not approve this kit for use on blood donors. SNBTS obtained kits from Wellcome and Organon in about July 1985, but could only perform a "mini-evaluation" on these because

<sup>133</sup> SGH.002.7260; cf. Cash, Day 48 pp. 132-3.

<sup>134</sup> PEN.017.0552 §26; PEN.017.1836; he also took issue with the suggestion that SHHD had been 'hostile' to Professor Cash (a point in effect accepted by Cash, Day 48 pp. 84-5). None of the other witnesses was able to add much: Dr McClelland did not recall this issue: Day 50, pp. 40-42; neither did Dr Mitchell, Day 51, p. 33 or Dr Scott, Day 49 p.139.

<sup>135</sup> Cash, Day 48 pp. 185-7.

<sup>136</sup> Acknowledged by Cash, Day 48 p. 143.

<sup>137</sup> McClelland, statement PEN.017.1337 at 1361; Cash, Day 48 pp. 88/9; Mitchell, Day 51 pp. 267, 29.

supplies of kits were so limited<sup>138</sup>. So far as introducing the screening itself is concerned, Professor Weiss was of the view that sufficient supplies of tests for screening would not have been available before the end of May 1985.<sup>139</sup> On that view, there would be little scope for carrying out a thorough evaluation and introducing the tests much earlier than they were in fact introduced.

*Adequate confirmatory test.* Professor Tedder emphasized the importance of developing adequate confirmatory testing, in order to avoid screening donors, developing a large panel of donors who were repeat reactive on the screening test, and not knowing how to deal with them.<sup>140</sup> Dr Scott's memo of 8 February 1985 referred to the test then available as 'seriously unreliable'.<sup>141</sup>

*Donor counselling.* Introduction would in any event have had to await the availability of appropriate arrangements for donor counselling; clearly this issue intersects with that of ensuring by adequate confirmatory testing that the results of the initial screening test are accurate.<sup>142</sup>

*Alternative testing facilities at various regional centres.* These were clearly needed in order to avoid what was described as the 'magnet' effect, attracting people as donors solely because they wished to obtain an AIDS test, attracting therefore individuals who might be at higher than average risk of being infected, and thereby increasing the risks to the integrity of the blood supply.<sup>143</sup> This concern had been identified as early as July 1984.<sup>144</sup> Internal memos within SHHD indicate that this, together with the other logistical issues already mentioned, was regarded as a matter of considerable importance.<sup>145</sup> The territorial health boards were asked to put in place arrangements for alternative testing.<sup>146</sup>

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<sup>138</sup> Dr Dow, B4 statement, PEN.017.1680.

<sup>139</sup> Day 48 pp. 176-9.

<sup>140</sup> Day 49 pp. 76-8.

<sup>141</sup> SGH.002.7294. That view is supported by Dr Dow (PEN.017.1680, above), and Dr Cash (letter to the Lancet, SNF.001.3355 at 3357)

<sup>142</sup> McClelland, Day 50 pp. 76, 82.

<sup>143</sup> Tedder, Day 49 pp. 72-4; McClelland, Day 50 pp. 24, 57, 61, 76, 84-5.

<sup>144</sup> Fraser/DHSS letter, DHF.002.9126, 16 July 1984.

<sup>145</sup> See e.g. Davies/Scott memo SGH.002.7295, 7 February 1985; Macpherson memo SGH.002.7226, 21 March 1985 §§11-12; SGH.002.7225, 22 March 1985.

<sup>146</sup> Scott, Day 49 pp. 118-121, 123-4; Cash, Day 48 pp. 141-2.

76. There were therefore numerous challenges that had to be addressed before the test could safely be introduced. Dr McClelland produced an exhaustive list of what needed to be in place for testing to begin in his own centre.<sup>147</sup> He also observed that his recollection is that ‘we were quite pressured to meet the timescales [14 October 1985] once the two kits had been designated as approved for use’.<sup>148</sup>
77. On the evidence it therefore appears to be difficult to conclude with any conviction that the test could safely have been introduced in Scotland at a date much earlier than 14 October 1985.
78. The documents reflect a constant theme that it was important not to rush into testing without solving the various important logistical problems already mentioned. The suggestion that DHSS displayed a ‘laissez faire’ attitude in taking the view that the evaluation should not be rushed does not appear to be supported by the evidence. While Professor Cash was critical of delay in introducing the test, he too was clearly of the view that an effective evaluation of the tests was an essential prerequisite to their being introduced; and he was highly critical of others (such as Professor Bloom) who, in urging the rapid introduction of testing,<sup>149</sup> were in Professor Cash’s view giving insufficient weight to the need for confirmatory testing and donor counselling.<sup>150</sup> It was important, as Dr Mitchell emphasized, not to go ahead with a test which was not reliable.<sup>151</sup>
79. A comparison may be made with the situation in the USA. In spring 1985 SNBTS became aware that the pressure that US government was putting on the companies developing the test kits meant that the tests were being rushed to market before serious problems with false positive results had been addressed.<sup>152</sup> Given the level of distress and anxiety among donors, disruption to the blood supply, and unnecessary loss of future blood donors that a high rate of false positives would be likely to cause, SNBTS and the government might well

<sup>147</sup> PEN.012.1950; cf Day 50 p. 50.

<sup>148</sup> Statement PEN.017.1337 at 1353.

<sup>149</sup> See e.g. BMJ letter LIT.001.0333.

<sup>150</sup> See e.g. Cash statement PEN.017.1038 at 1041 (§2.09) and Day 48 pp. 108-9, 113-14.

<sup>151</sup> Day 51 p. 25.

<sup>152</sup> Cash, Day 48 p. 62; cf. discussion by McClelland, Day 50 p. 76 ff.

have been criticised had they rushed to introduce tests the reliability of which was suspect<sup>153</sup>.

### ***The UK dimension***

80. Since the magnet effect mentioned above would not respect the border between Scotland and England, there was much to be said on public policy grounds for fixing the same date for the introduction of screening throughout the UK. Dr Mitchell gave the example of a test being available in Dumfries but not in Carlisle.<sup>154</sup> Professor Tedder also referred to the anxiety that, if the same tests were not available at all donor centres, there might be a detrimental effect on the donor make-up in centres which did not have the test.<sup>155</sup>
81. There was the further issue of its being desirable to avoid a perception or the reality that people in one part of the UK were being treated differently from those in another: NBTS did express their concern about the possibility that testing might be introduced in Scotland before it was in England. Professor Cash recognized that this was a concern and he was an ardent advocate of getting those in the transfusion service in England and in Scotland to work together on the issues.<sup>156</sup> He also supported the proposition that testing should commence in each centre at the same time.<sup>157</sup> The same view was expressed by the regional transfusion directors.<sup>158</sup>
82. DHSS took the lead on the question when testing should be introduced. The magnet effect was a very important reason why it was appropriate that it should and why, broadly speaking, the approach taken in Scotland should be the same as that in England. As the Inquiry has seen in relation to other topics (such as C4 and C5), the notion that there should be a UK-wide approach was not set in stone: where local circumstances in Scotland demanded a different approach, officials in SHHD would be prepared to advise the Minister to that effect.<sup>159</sup> The

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<sup>153</sup> Compare SNF.001.3355 at 3357

<sup>154</sup> Day 51 p. 52.

<sup>155</sup> Day 49 pp. 19-20.

<sup>156</sup> Cash, Day 48 pp. 38-40, 59.

<sup>157</sup> Day 48 pp. 87-8.

<sup>158</sup> McClelland, Day 50 p. 37; cf. Mitchell, Day 51 pp. 45-6, 48-9, 51-2.

<sup>159</sup> Scott, Day 49 pp. 130-131.

series of memos from February and March 1985 referred to above indicates that SHHD was considering on its merits the appropriate line to follow in Scotland; the situation in England was of course an important element in that consideration.

### **Funding**

83. Issues of funding did not play any part in the timing of the introduction of the screening test.<sup>160</sup> Professor Cash explained that SHHD had set aside the money for screening so that it would be available when required (the position was apparently different in England).<sup>161</sup> An SHHD memo of February 1985 refers to the 'considerable financial implications' of introducing a test but notes that the financial angle cannot be the determining factor.<sup>162</sup> Professor Cash confirmed that SHHD did not attempt to influence the start date for testing by withholding funding<sup>163</sup>.

### **TOPIC B5**

84. The Scottish Government recognises that communication between doctor and patient is an important and sensitive topic. Good communication is fundamental to the clinical relationship, and a critical factor in obtaining informed consent to medical treatment or surgical procedures. The Scottish Government also recognises and welcomes the fact that attitudes to communication and consent have progressed significantly in the last 25 years. However, the quality and content of communications between doctor and patient, and the standard of communication which could reasonably have been expected at the time, are issues of good medical and clinical practice on which the Scottish Government does not think it appropriate to comment.

### **TOPIC B6**

85. In the mid-1980s HIV was a terrible and largely unknown disease. A diagnosis of AIDS was essentially a death sentence, and only a very few individuals diagnosed at that time remain alive today. We accordingly owe a great debt of

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<sup>160</sup> McClelland, Day 50 pp. 86-7; cf. Cash, Day 48 p. 107, departing from the comments in his statement PEN.017.1038 at 1041 (§2.09(f)).

<sup>161</sup> Day 48 pp. 127-8; statement PEN.017.1038 at §2.11.

<sup>162</sup> Davies/Scott memo SGH.002.7295, 7 February 1985.

<sup>163</sup> Day 48, p.126

gratitude to those individuals who were able to provide an insight into the suffering of those affected by the disease, and the ignorance and prejudice they sometimes experienced. It is a cruel irony that this disease was in many cases acquired as the result of otherwise life-saving treatment. Equally, the Scottish Government recognises that in providing such treatment, clinicians acted in good faith to administer what they considered to be the best available care. This Inquiry has heard evidence that treatment with factor concentrates represented a massive improvement in the quality of care for haemophiliacs. Such treatment offered the prospect of greatly improved quality of life, and greatly increased life expectancy for sufferers. Enthusiasm on the part of clinicians and patients for such treatment was understandable. The realisation by clinicians that their administration of such treatment had inadvertently caused harm and suffering must have been a harrowing one.

## **TOPIC C1**

### **Key points**

- As originally conceived there were sound or at least commendable penological reasons behind the collection of blood from volunteer prisoners.
- During the 1970s the main threat to the blood supply from prison donations was thought to be Hepatitis B, but that threat was thought to have been eliminated by the introduction in 1975 of sensitive tests for HBV. The government received expert advice at that time that there was no need to discontinue the collection of blood in prisons.
- There was a lack of knowledge about the causes and prevalence of HCV in the UK.
- While it is now clear that the majority of infections with HCV in Scotland were due to intravenous drug abuse, the link was not understood in the late 1970s. Drug abuse was not thought to be a major problem in Scottish prisons until the early 1980s, by which time SNBTS had begun to wind down its visits to prisons.
- Any perceived difficulty with prison donations was not brought to the attention of SHHD officials until 1983. SNBTS sought advice on the issue from the appropriate expert committee. It is not correct to assert that SNBTS were awaiting an answer on the issue from SHHD.

- During the period with which this Inquiry is concerned, SNBTS were not instructed or encouraged by SHHD or by Ministers at the Scottish Office to continue with a policy of collecting blood in prisons.
- Given their professional knowledge and clinical expertise SNBTS were best placed to decide whether or not it was appropriate to seek blood from volunteer prisoners.
- The use of blood from prison donations did not contribute to the infection of haemophilia sufferers with HCV.

### ***The policy of collecting blood from volunteer prisoners***

86. During the 1970s there appears to have been a view in Government that prisoners should be given the opportunity to volunteer as blood donors. The view appears to have been that prisoners were thus enabled to make some contribution to society, and that the sense of social responsibility thus engendered was likely to assist in their rehabilitation<sup>164</sup>. Moreover, some transfusionists took the view that prison sessions were valuable as a means of boosting supply during periods of particular shortage such as local or national holidays when regular donors might not be available to give blood<sup>165</sup>. There were thus good reasons for the policy of collecting blood from prisoner volunteers, at least as that policy originally appears to have been conceived. However, during the period with which the Inquiry is concerned, SNBTS were not instructed or encouraged by SHHD or by Ministers at the Scottish Office to continue with a policy of collecting blood in prisons<sup>166</sup>.

### ***The Advisory Group on Testing for Hepatitis B***

87. There was little evidence in the late 1970s to suggest that blood obtained from prisoners was more likely to transmit infections than blood from other donors. Hepatitis B was perceived to be the greatest threat to the blood supply at that time, and although the prevalence of HBV was known to be higher among prisoners than in the general population<sup>167</sup>, by 1975 a sensitive test for that virus

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<sup>164</sup> Statement of Dr Ewa Brookes, WIT.003.0057 at 0059, and see SGH.001.0572

<sup>165</sup> Evidence of Dr McClelland, Day 9, p.80; Dr Dow, Day 8, p.79

<sup>166</sup> Statement of Dr Graham Scott, WIT.003.0019, paragraph 13; evidence of Dr McClelland, Day 9, p.82-83

<sup>167</sup> Wallace et al (1972), SGH.002.9831, summarised in PEN.018.1521 at 1536

had been introduced and was thought to have largely eliminated any risk<sup>168</sup>. The relationship between infection with HBV and infection with NANB hepatitis was unclear at that time<sup>169</sup>, but it may be that elimination of HBV from the prison donor population also eliminated some NANB cases, particularly those associated with intravenous drug use.

88. Advice had been offered in 1975 by the Chief Medical Officer for England and Wales, Dr Yellowlees, that there was no need to discontinue prison sessions because of the availability of such tests<sup>170</sup>. That advice was derived, in turn, from a sub-group<sup>171</sup> of the Advisory Group on Testing for Hepatitis B Surface Antigen and its Antibody, the body set up to advise government on just such matters. The sub-group's advice was in line with the WHO's view at that time, which was that it was impossible to identify any group as posing a particularly high risk<sup>172</sup>, and that local circumstances had to be fully taken into account in deciding to disqualify any particular group of donors. As noted above, government health policy then, as now, proceeded largely on the basis of expert advice, and it was appropriate for the CMO to seek and to accept advice from a group of experts on the topic, as appears to have happened in this case.
89. The Advisory Group on Testing was chaired by Dr William Maycock of the Blood Products Laboratory at Elstree. In January 1975 Dr Garrot Allen of Stanford University School of Medicine wrote to Dr Maycock seeking information on the supply of factor concentrates in the UK but also to advise him that "most cases of post-transfusion hepatitis are caused by an agent other than hepatitis A or B" and that "whatever this agent may be it still seems to be more frequently encountered among the lower socio-economic groups of paid and prison donors"<sup>173</sup>.
90. In hindsight, it is unfortunate that the final report of the Advisory Group contained no reference to this advice, and that the possible prevalence of NANB hepatitis in the prison population does not appear to have been considered by the small

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<sup>168</sup> Compare evidence of Dr McClelland, Day 9, pp.88-9, 107

<sup>169</sup> And remains so.

<sup>170</sup> SGH.003.0187

<sup>171</sup> See SGH.003.0185; SGH.003.0259 at 0286

<sup>172</sup> LIT.001.3272 at 3298

<sup>173</sup> SGH.004.6061

group which advised in relation to prison donations. However, it should be borne in mind that in 1975 evidence was only just beginning to emerge in the USA about a possible NANB hepatitis<sup>174</sup>. A paper<sup>175</sup> proposing a paragraph which appears in the Advisory Group's final report<sup>176</sup> simply stated that "No evidence has been collected yet in the UK to substantiate the presence of a hepatitis C".

### ***Lack of knowledge about HCV in the UK***

91. Moreover, the prevalence of NANB hepatitis among the population generally, among the prison population, or among the important sub-group of injecting drug abusers was not fully appreciated during the 1970s and early 1980s. Even in the early to mid-1980s, cases of NANB hepatitis were thought to be rare in Scotland<sup>177</sup>, and "benign in most instances"<sup>178</sup>. Evidence about the serious long term effects of NANB hepatitis only started to accumulate in the mid to late 1980s, after the cessation of prison sessions.
92. One factor in SNBTS's decision finally to desist from holding donation sessions in prisons appears to have been the work of Drs Dow and Follett, which showed grossly elevated ALT levels in prisoners at a rate 10 times in excess of those in the general donor population<sup>179</sup>, but this work was not published until July 1984, by which time prison sessions had already ceased, and in any event, the relationship between ALT levels and the presence of HCV is not a straightforward one.

### ***Prisons and drug abuse***

93. It is now clear that the vast majority of HCV infections in Scotland were the result of intravenous drug abuse<sup>180</sup>. However, intravenous drug abuse appears to have been relatively uncommon for most of the 1970s, and it was only in the late 1970s and early 1980s that such drug misuse appears to have become more

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<sup>174</sup> See e.g. LIT.001.0137 and compare LIT.001.0254

<sup>175</sup> DHF.001.2819

<sup>176</sup> SGH.003.0079 at 0085

<sup>177</sup> Compare SGH.002.8040 at 8044

<sup>178</sup> LIT.001.0201

<sup>179</sup> SGH.002.8040

<sup>180</sup> See PEN.018.1561

widespread in Scotland<sup>181</sup>. This was the very time at which the Medicines Inspectorate – and apparently some transfusionists, for example in the South East of Scotland - began to query the appropriateness of collecting blood in prisons, and the practice was stopped shortly thereafter, the last prison session being held in March 1984 by West of Scotland BTS. Most of the other Regional Transfusion services ceased prison sessions during 1983; South East RTC stopped in April 1981.

94. Hepatitis B was associated with intravenous drug abuse, but there was no particular appreciation during the 1970s and even early 1980s that Non A Non B hepatitis was similarly associated, and the link between infection with HBV and infection with HCV remains unproven.
  
95. Prison medical officers were not always required to attend all donation sessions held in penal institutions<sup>182</sup>. However, prison sessions were conducted under the supervision of an SNBTS medical practitioner who had the final say on matters of donor selection<sup>183</sup>. Prisoners who attended for donation sessions were checked for heavy tattooing and needle marks, and were likely to be deferred as donors for those reasons, or if they showed signs of intoxication or drug use<sup>184</sup>. SNBTS were therefore best placed to make an informed decision as to the appropriateness in a medical sense of accepting donations from prisoners<sup>185</sup>. It was, in other words, a “professional” issue for SNBTS to consider; not a matter of policy for SHHD<sup>186</sup>.
  
96. There was no evidence that homosexual activity among prisoners took place at a higher rate than among the general population, as some of the contemporary correspondence suggests. While the percentage of prisoners found positive for HBsAg was higher than that found in the general population (0.65 as opposed to around 0.12), the percentage was considerably higher in homosexuals attending

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<sup>181</sup> Compare PEN.018.1561 at 1563

<sup>182</sup> Compare SGF.001.0086

<sup>183</sup> PEN.018.1521 at 1525

<sup>184</sup> McClelland, Day 9, pp.20-21 and compare SNB.002.5348 at 5352

<sup>185</sup> Evidence of Dr McClelland, Day 9, p.83

<sup>186</sup> See Professor Cash, Day 10, p.67, Dr McClelland, Day 9, p.83 and compare SNB.012.5017

an STI clinic in London at that time (1.34%)<sup>187</sup>. The incidence of Hepatitis B (and NANB hepatitis) among prisoners during the 1970s seems at least as likely to have been associated with unhygienic tattooing practices as with homosexuality<sup>188</sup>. Wallace et al attributed the high prevalence of HBV among prisoners to “social habits and hygiene”, a broad description possibly intended to be euphemistic, and certainly vague, which tends to suggest that they were really unsure of the true or dominant cause.

97. At this time, only HMP Barlinnie had full time medical officers. The remainder were serviced by part-time officials, usually GPs under contract to the prison, who were supported by full time prison nursing staff<sup>189</sup>. The Reports of the Chief Inspector of Prisons for 1981, 1982, and 1983<sup>190</sup> do not mention drug misuse among inmates at all. The first mention in these reports is in the Report for 1984<sup>191</sup> dated 1<sup>st</sup> October 1985, by which time all blood donor sessions in Scottish prisons had ceased.
98. The SHHD “Prisons in Scotland” Report for 1975 did not regard hard drugs as posing a problem in Scottish prisons at that time, recording only 5 cases of dependency on hard drugs<sup>192</sup>. Lest it be thought that this was a rose-tinted picture however, the report accepts that alcoholism was a serious issue among prisoners at that time<sup>193</sup>. The 1976 Report<sup>194</sup> noted that the number of cases of infective jaundice had increased. By that stage, as already noted, a sensitive test for Hepatitis B had been introduced, and was thought to have all but eliminated the risk of transfusion associated hepatitis. The statistics provided in paragraph 105 of the 1976 Report also bear out the idea that the abuse of “hard drugs” was not a significant issue among prisoners during the 1970s. The SHHD Report for 1980<sup>195</sup> records only 18 male cases of dependency on “hard drugs” although notes that there were many others who although not dependent on drugs at the

<sup>187</sup> Wallace et al (1972), summarised in PEN.018.1521 at 1536

<sup>188</sup> Compare e.g. evidence of Dr Mitchell, Day 9, p.181; Professor Leikola, Day 13, p.76

<sup>189</sup> see PEN.012.0645 at 0661

<sup>190</sup> PEN.012.0645, PEN.012.0677, and PEN.012.0701

<sup>191</sup> PEN.012.0720 at 0728

<sup>192</sup> PEN.012.0535 at 0559

<sup>193</sup> PEN.012.0535 at 0558

<sup>194</sup> Extract is PEN.012.0605 at 0607

<sup>195</sup> PEN.012.0631

time of admission to prison had a “clear history of drug abuse”. The figures for prisoners dependent on hard drugs for the period 1977 to 1980 are low, and in line with the figures disclosed in 1980. However, the Report for 1981 (published in August 1982) reports a “marked increase” in the numbers of addicts admitted – up to 86 from 18 the previous year. The Report for 1982<sup>196</sup> records the “steadily increasing numbers of admissions to local prisons who have been abusing drugs...usually hard drugs such as heroin and diconal...” but notes that that is a reflection of the increase in drug abuse in the wider community. By 1984<sup>197</sup> it is noted that “the alarming increase in the use of narcotic drugs in the UK is certainly mirrored in the number of admissions to penal establishments who are identified as having recently used these dangerous drugs of addiction.” The SHHD Report records in total 1163 prisoners, male and female, who fell into this category in 1984. Again however, by the time of the publication of this report (1<sup>st</sup> November 1985), all prison sessions had ceased. It may be notable that the SHHD reports for 1981 to 1984 make no mention of blood donations. The Reports appear to disclose a steadily declining pattern of donations in prisons, falling from 4644 pints in 1976<sup>198</sup> to 1,676 in 1980<sup>199</sup>. The absence of any reference to blood donations in the later SHHD reports may therefore reflect the fact that the Regional Blood Transfusion services had by this time begun to abandon prison sessions. West of Scotland BTS continued with prison sessions for the longest, and collected around 1,903 units of blood annually from 1982 to 1984.

99. Finally, while it is clear that donations from prisoners made a significant contribution to the blood supply during the 1970s<sup>200</sup>, the overall prevalence of Hepatitis C in the population at large, and the falling contribution to the general blood supply made by prison donations, suggest that removing prison donations from donor pool would have made no difference to the infectivity of pooled products<sup>201</sup>.

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<sup>196</sup> PEN.012.0693 at 0696

<sup>197</sup> PEN.012.0734 at 0749

<sup>198</sup> PEN.012.0605 at 0608

<sup>199</sup> PEN.012.0631 at 0641, and see the summary document by Gregor Mair PEN.012.1784

<sup>200</sup> Compare PEN.012.0605 at 0608

<sup>201</sup> Evidence of Dr Perry, Day 11, p.120

### ***SHHD involvement***

100. There was no documentary evidence that any perceived problem with prison donations was brought to the attention of officials within the Scottish Home and Health Department until the issue was raised at a meeting of the Regional Transfusion Directors on 29<sup>th</sup> March 1983<sup>202</sup>. Indeed the minutes of that meeting suggest that the issue was being raised only because the Medicines Inspectorate had commented adversely on the practice of holding blood donation sessions in prisons<sup>203</sup>. On receipt of their comments, the National Medical Director of SNBTS sought comments from Mr Watt at PFC, and asked Dr Ewa Brookes to “take the matter up”<sup>204</sup>. The Medicines Inspectorate in turn raised the issue with officials at DHSS, in or around July 1983<sup>205</sup>, and active consideration was given to the matter by DHSS officials<sup>206</sup>. Those officials consulted their counterparts at SHHD<sup>207</sup>. DHSS officials felt that if any policy decision was to be taken that prison sessions should be withdrawn, officials at the Home Office would probably have to be consulted because of the “importance placed on the social responsibility aspect of such sessions”. However, DHSS internal correspondence suggests that officials regarded the practice of collecting blood in prisons as being questionable, and shared the view of SHHD officials (and of SNBTS itself) that the question whether the practice should continue was one for individual RTDs<sup>208</sup>.

101. Dr Mitchell’s evidence<sup>209</sup> that SHHD was being “constantly asked” for their position on prison donations is not borne out by the evidence. Nor is there any evidence that their answer was “yes, it is accepted that people will collect blood from sessions at prisons.” It was for individual RTDs to make their own decision on prison donations, and ultimately, all did so. Dr Mitchell’s region, the West of Scotland, was in fact the last region to make the decision to cease prison sessions.

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<sup>202</sup> SGF.001.0234 at 0238

<sup>203</sup> SGF.001.0351 at 0352, and SGF.001.0086

<sup>204</sup> SNB.005.6703 – Cash letter to Watt, 5<sup>th</sup> July 1982

<sup>205</sup> SGH.001.0575, and SGH.001.0574

<sup>206</sup> SGH.001.0574

<sup>207</sup> SGH.001.0572

<sup>208</sup> SGH.001.0574; compare evidence of Dr Graham Scott, Day 11, pp.161, 166-167, and

PEN.018.1521 at 1525

<sup>209</sup> Day 9, p.160

102. The RTDs were initially unable to reach a consensus on the matter because of “different circumstances in the Transfusion Regions” and SNBTS quite properly sought guidance not from government officials but, through Dr Ewa Brookes, from the appropriate advisory committee, the Working Party on the Selection and Care of Blood Donors<sup>210</sup>. At the RTDs meeting of 13<sup>th</sup> September 1983 there were still some Transfusion Directors who felt that a “blanket decision to cease visiting prisons would be a mistake”<sup>211</sup>. There is accordingly no evidence to support the view that the RTDs were at that stage awaiting an answer on the issue of prison donations from officials at SHHD, as was put to Dr Scott by Counsel for NHS Scotland<sup>212</sup>. It was open to the RTDs to terminate prison sessions without awaiting permission to do so from government, and in fact all did so, some as early as 1981. There is no suggestion that officials on either side of the border made any attempt to prevent SNBTS from doing so. The DHSS’s own documentation suggests only that it envisaged “liaison” with the Home Office because the latter department had previously been in favour of holding prison sessions<sup>213</sup>. That in turn does not suggest that any requirement to consult with the Home Office posed any difficulty for the cessation of prison sessions, or delayed it in any way.

## **TOPIC C2**

### **Key points**

- The scientific justification for introducing surrogate testing in the 1980s was inconclusive.
- Research, ideally a full prospective study, was needed but the time and cost for this were prohibitive.
- SHHD medical officers kept abreast of the medical assessment of NANBH; they also kept abreast of medical views for and against surrogate testing, but these were sharply divided.
- Responsibility for deciding whether surrogate testing should be introduced in Scotland lay with the Scottish Minister responsible for health; in making his

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<sup>210</sup> SGF.001.0234 at 0238

<sup>211</sup> SNF.001.0072 at 0077

<sup>212</sup> Day 11, p.161

<sup>213</sup> SGH.001.0574

decision he relied on the advice of officials, who in turn relied on expert scientific and clinical advice; SNBTS was an important source of such expert advice.

- SHHD would have been willing to put in place funding for surrogate testing once persuaded by the medical evidence that this was an appropriate use of public funds.
- Neither SNBTS nor the wider scientific and clinical community gave clear or consistent advice to SHHD on this issue; nor did SNBTS submit to SHHD a clearly reasoned proposal for the introduction of surrogate testing.

### ***The scientific case for introducing surrogate testing***

103. Views were sharply divided on the question whether surrogate testing ought to be introduced in the 1980s. Within the transfusion services the English NBTS directors and some directors within SNBTS thought the introduction of surrogate testing in the UK could not be justified without further research. In general the introduction of testing did not enjoy much support in UK transfusion departments.<sup>214</sup>

104. Dr McClelland had in the early 1980s proposed a prospective study that would attempt not only to establish the prevalence of NANBH but also to identify the utility of excluding from the blood supply blood with ALT elevated beyond a certain level. He did not receive much support from professional colleagues for such a study, and the pressing need to deal with HIV led to the proposed study and more generally NANBH being lost sight of for a time.<sup>215</sup>

105. A prospective study to identify whether the American experience of the incidence of NANBH in recipients of blood or blood products was reproduced in Scotland would have been a massive undertaking, which would require substantial funding and other resources and also a great deal of time.<sup>216</sup> Such a study was needed in order to understand the significance of the surrogate test results.<sup>217</sup> In the absence of such evidence it was not possible to assess the benefit or

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<sup>214</sup> Mitchell, Day 65 pp. 26-7.

<sup>215</sup> PEN.017.1514; McClelland, Day 63 pp 80-84, 88, 90.

<sup>216</sup> McClelland, Day 63 p. 115; Gillon, Day 65 p. 87; Mitchell, Day 65 pp. 4-6; cf. memo of 1 Dec 1986, PEN.017.1554.

<sup>217</sup> Gillon, statement PEN.017.1931 at 1934-5.

effectiveness of testing, while at the same time the costs of such testing to the service, donors, and the country as a whole were evident.<sup>218</sup>

106. The later research proposal by Dr Gillon and Dr McClelland to study the prevalence of NANBH in donors was no substitute for a full prospective study. Dr McClelland acknowledged that it would not have added much to the possibility of making a rational decision about introducing surrogate testing or not.<sup>219</sup> Funding was not approved for it, because it was regarded as scientifically flawed, but in the circumstances the fact that it was not carried out does not appear to have been significant. Such a study was in fact carried out in the English centres by Dr Contreras, who found that NANBH was a “non-problem”<sup>220</sup>.

107. In the absence of a full prospective study, medical and scientific views on the value of surrogate testing remained sharply divided. The division of opinion is clearly seen in the contrasting letters sent by various transfusion directors to the *Lancet* in April and July 1987.<sup>221</sup> This was part of a continuing debate.<sup>222</sup> Whether to introduce such testing was a very difficult issue.<sup>223</sup> There was uncertainty about how the test would perform; and uncertainty about the impact on the donor population. Even in retrospect it is difficult to be sure, in light of these factors, whether testing should have been introduced. The benefit in terms of patient safety is unquantifiable.<sup>224</sup> Dr Mitchell did not regard the introduction of the test as warranted in terms of an improvement in patient safety; but he thought the need to compete with the commercial providers would justify introducing it.<sup>225</sup>

108. Professor Cash recognized that the question of surrogate testing was hugely important and very difficult:<sup>226</sup> the transfusionists had no notion of the real benefit that it would bring to patients in the UK; the cost of £800,000 would have to come

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<sup>218</sup> Gillon, Day 65 pp. 75-7, 120; cf. McClelland, Day 63 p. 103; Mitchell, Day 65 13-16.

<sup>219</sup> McClelland, Day 63 p. 119.

<sup>220</sup> Dr McClelland, Day 63, p.129

<sup>221</sup> LIT.001.0350; LIT.001.0346; LIT.001.0328

<sup>222</sup> So described by Cash in a letter of 8 July 1987, SNB.011.3846 (cf. Day 72 pp.1-2) -a characterization preferable to the ‘strident calls’ referred to in his supplementary statement PEN.017.1885 at 1889.

<sup>223</sup> Cash, Day 64 pp. 167-8; Gillon, Day 65 p. 72.

<sup>224</sup> Gillon, Day 65, pp. 76-8, 111, 119.

<sup>225</sup> Day 65 pp. 20-23, 57, 59, 61.

<sup>226</sup> Day 64 pp. 167-8.

from somewhere else in the NHS budget; and there would also be a cost in relation to attracting donors. His position in late 1986 was that further research was needed, because the risks simply were not known; only later did the SNBTS decide that the market in effect forced them to recommend the introduction of screening.<sup>227</sup>

109. The dilemma was clearly focused by Dr McClelland: 'on commercial competitive grounds we need to introduce screening but on scientific and value for money for the health service grounds, we should be opposing it'.<sup>228</sup> In essence Professor Cash said the same: that in 1987 SNBTS did not think surrogate testing should be introduced but thought it might have to be.<sup>229</sup> A DHSS memo of 29 January 1988 makes it clear that the reasons for introducing testing were considered to relate to commerce, competition or politics rather than to scientific rigour.<sup>230</sup> Professor Leikola agreed that the introduction of testing was properly described as an emotional rather than a scientific or logical reaction to the situation.<sup>231</sup>

110. In March 1987 the SNBTS Directors agreed to recommend to the SHHD that surrogate testing should be implemented from 1 April 1988. The minutes of the meeting at which that decision was taken do not spell out the reasons for it; Dr McClelland thought it was probably motivated primarily by awareness of the situation in the United States.<sup>232</sup> Professor Cash accepted that Dr Forrester, who attended the meeting representing SHHD, would have been aware that the directors were very uneasy about making the recommendation.<sup>233</sup> Dr McClelland had been an early advocate of the introduction of such testing and was of the view, when asked about the letter in the *Lancet* of April 1987 advocating a study on the incidence of acute post-transfusion NANBH, that such a study – which would take several years – would be too late. It was that sentiment that informed the letter of the SNBTS Directors to the *Lancet* in July 1987, that surrogate testing was 'irrational, perhaps, but inescapable'; it also made reference to

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<sup>227</sup> Day 70 pp. 168-9.

<sup>228</sup> SNB.006.0715, 15 April 1987; Day 63 p. 127.

<sup>229</sup> Day 70 pp. 188-9.

<sup>230</sup> PEN.016.0216.

<sup>231</sup> Day 71 p. 33.

<sup>232</sup> Day 63 p. 123.

<sup>233</sup> Day 72 p. 79; Day 70, p.189

impending strict liability legislation and the pressure that would arise from the use by commercial fractionators of tested plasma.<sup>234</sup> Dr McClelland had drafted the letter and, although many of his SNBTS colleagues had signed it, he thought most of them were still ‘pretty lukewarm’ about it; his own thinking was that resort to these additional arguments might perhaps succeed where appeal purely to patient safety had not and might influence those who formed opinion and advised the health departments in London and in Scotland.<sup>235</sup>

111. So far as Professor Cash was concerned, the main factor that led to the recommendation on 3 March 1987 was a realization that the rest of the world appeared to be heading in the direction of introducing testing, as well as current issues about product liability.<sup>236</sup> The RTDS themselves were “strongly” against the introduction of such testing because they did not see that it would have any clinical value<sup>237</sup>.

112. The Consumer Protection Act 1987, the prospective legislation implementing Directive 85/374/EEC in relation to product liability, was a factor potentially relevant to deciding whether or not to introduce testing. Professor Cash had been active prior to enactment of the 1987 Act in campaigning for the exclusion of blood and blood products from the scope of product liability, evidently owing to his concern that otherwise there might be no defence to a claim from a patient who had been harmed by receiving them.<sup>238</sup> SHHD took advice about this.<sup>239</sup> In particular officials in Scotland did relay these concerns to the DTI, which was the departmental sponsor of the Bill. The DTI did not accept the proposed exclusion; it was suggested that reliance could be placed on the defence of the state of scientific knowledge. The judgment of Mr Justice Burton in the *A* case subsequently concluded that reliance could not be placed on that defence, since the risk of transmission of hepatitis through blood and blood products was

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<sup>234</sup> Cf McClelland, Day 63 p. 130.

<sup>235</sup> Day 63 pp. 137, 142-3; Day 64 p. 112.

<sup>236</sup> Day 70 p. 175.

<sup>237</sup> Day 70, p.189. It is notable that at a meeting of the ACVSB on 21<sup>st</sup> May 1991 the members decided not to include ALT testing in the HCV protocol, because in their view ALT tests were not specific for HCV and there was a poor correlation between HCV antibody and ALT - SNB.001.9054 at 9057

<sup>238</sup> Day 70 pp. 179-83.

<sup>239</sup> Macniven, Day 65 p. 162-3.

known.<sup>240</sup>

113. While the evidence in relation to this matter is very limited, it appears that on taking advice SHHD were led to understand that supplying blood or blood products which had not been tested by means of surrogate tests would not expose the supplier to liability; accordingly this was not a factor that would dictate the introduction of such testing where other significant factors spoke against it.
114. Shortly after the SNBTS directors made their recommendation on 3 March 1987 Professor Cash advised Dr Gunson that it should not be taken too seriously and had been made with the SNBTS's budget bid in mind.<sup>241</sup> On 8 July 1987 Professor Cash also informed Dr Fraser that the SNBTS had no intention of introducing NANB surrogate testing unilaterally.<sup>242</sup>
115. The real reasons underlying the SNBTS Director's recommendation – namely considerations of legal liability, competition, and private sector access to blood – were well known to officials in SHHD. Duncan Macniven's evidence was that he understood the recommendation to have been made on the basis of such considerations<sup>243</sup>, and Dr Macdonald felt that the recommendation had been made 'for protective reasons'<sup>244</sup>. Therefore Professor Cash's suggestion that SHHD were not getting 'mixed messages'<sup>245</sup> may be correct, but the message was that the recommendation had been made for reasons other than clinical or scientific ones.
116. Indeed, in July 1987 the SNBTS Directors wrote to the *Lancet* that surrogate testing was 'irrational, perhaps, but inescapable' because of impending strict liability legislation and the pressure that would arise from the use by commercial fractionators of tested plasma. After the publication of this letter DHSS expressed concern and dismay; they interpreted the letter as representing SHHD policy, and

<sup>240</sup> Cf Macniven, Day 65 pp. 172-3; Cash, Day 70 pp. 179-183.

<sup>241</sup> SGH.001.6627, 27 April 1987; cf. Cash, Day 70 p. 191, acknowledging that SNBTS used PES as a method of floating a number of ideas over the years, even for things they did not really want.

<sup>242</sup> SNB.011.3846; cf. Mitchell, Day 65 pp. 35-9.

<sup>243</sup> Day 78, pp.13-14. See also Dr McIntyre's memo of 6<sup>th</sup> April 1987 - SGH.002.8127

<sup>244</sup> Day 66, p.128-9

<sup>245</sup> Day 72, p.81

SHHD had to reassure them it was not.<sup>246</sup> The reason for the concern was that, if testing began in Scotland, in England there would be no option but to follow.<sup>247</sup>

As this letter (and other evidence) shows, SHHD liaised very closely with DHSS in relation to surrogate testing and were conscious of the fact that NBTS directors south of the border were against the introduction of surrogate testing.<sup>248</sup>

117. Professor Cash explained that it was inconceivable that SHHD would have approved funding for surrogate testing in Scotland if it was not going ahead in England. That reality accorded with his own wish that centres throughout the UK should work as a team, and a concern that if they did not there could be damaging consequences, possibly involving litigation.<sup>249</sup>

### ***Practicability of introducing surrogate testing***

118. In practice it would anyway have been extremely difficult (if possible at all) to introduce screening in around April 1988: as Dr McClelland fairly acknowledged, SNBTS had not really thought through the implications of recommending the introduction of surrogate testing at that time, in terms of donor information and counselling.<sup>250</sup> He went on to say that SNBTS had not bottomed out the issue of donor counselling, although they knew that there would be a very significant burden of work; they had not prepared a management plan or costings or looked at the implications for hospital departments and general practitioners.<sup>251</sup> He thought they would have needed a few months for preparation and training before they could start testing.<sup>252</sup> Dr Gillon estimated that the counselling would have taken him half a day a week, time which he simply did not have.<sup>253</sup> Professor Cash also recognised that it would have been extremely difficult to introduce surrogate testing because of the difficulties which SNBTS were experiencing in collecting sufficient blood in the late 1980s. He went so far as to say that ‘there is

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<sup>246</sup> SGF.001.2085, 21 July 1987, memo by Dr McIntyre.

<sup>247</sup> SGF.001.2085, 21 July 1987, memo from Dr McIntyre to Mr Macniven; cf. Mitchell, Day 65 pp. 32-3.

<sup>248</sup> Macniven, Day 65 p. 180.

<sup>249</sup> Day 70, pp. 186-7.

<sup>250</sup> Day 63 pp 157-8; Day 64 p. 19.

<sup>251</sup> Day 64 p. 19.

<sup>252</sup> Day 64 p. 20.

<sup>253</sup> Day 65 p. 121.

no doubt at the end of 1987, if you had asked me, "What about non-A non-B," I would have said, "Go away".<sup>254</sup>

***Responsibility for deciding whether to introduce surrogate testing***

119. Ultimately the responsibility for deciding whether surrogate testing should be introduced in Scotland lay with the Scottish Minister responsible for health.<sup>255</sup> The Minister necessarily depended on advice given by the clinical and scientific community which would come to SHHD and would be relayed as appropriate from SHHD to him. Officials in SHHD required to take a view on whether there was sufficient evidence to make a recommendation to the Minister that testing should be introduced.<sup>256</sup> It is clear that the advice coming from the professional community of clinicians and scientists was neither clear nor consistent. In particular in the mid/late 1980s SHHD received from SNBTS no well-argued or reasoned advice about the desirability of introducing surrogate testing.<sup>257</sup>

120. The SHHD medical officers were generalists, but nevertheless had a good grasp of the issues surrounding NANB hepatitis and surrogate testing<sup>258</sup>. In this particular context they were guided to a large extent by the study carried out in the West of Scotland by Dr Dow<sup>259</sup>. That was at the time the only systematic study of the incidence of NANBH in Scotland. It concluded that post-transfusion NANBH did not appear to be a significant problem in the West of Scotland and that the introduction of surrogate testing was not merited.

121. It was widely recognized that the experience of NANBH in other countries such as the USA was quite different, and the absence of further evidence local to Scotland was therefore a serious gap. As noted already, the gap could be filled convincingly only by a full prospective study.

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<sup>254</sup> Day 72, p.40

<sup>255</sup> Macniven, Day 65 p. 140; cf. Cash, Day 70 p. 185.

<sup>256</sup> Macniven, Day 65, p. 141.

<sup>257</sup> McClelland, Day 63 pp 132-3; Day 64 p. 100.

<sup>258</sup> Notwithstanding the terms of the – DHSS produced - briefing paper SGH.002.8012 – Dr Macdonald was confident in the knowledge and ability of the medical officers under him – see Day 66, pp.119,147

<sup>259</sup> Dr Forrester also sought advice from Dr Dan Reid, an expert in communicable diseases at the Ruchill hospital – see SGH.002.8187, and Dr Forrester, Day 66, pp.6-7

122. In his report on the SNBTS directors' meeting of 26 March 1986 Dr Forrester explained that he had made enquiries into the possibility of a test for NANBH; that he had discovered that the number of cases in Scotland was likely to be exceedingly low<sup>260</sup>; and that he had indicated to the directors that SHHD was open to proposals for funding research in the field, if it was required to determine the true size of the problem and the likely effect of any proposed remedy.<sup>261</sup>
123. In a number of SHHD memoranda NANBH is characterized as 'relatively benign'. Dr Forrester noted on 12 June 1986 that the condition is 'not as a rule serious' but that there may 'be a tendency for it to become chronic, and the long-term outlook is inevitably not yet known';<sup>262</sup> on 26 January 1987 he referred to it as 'relatively benign';<sup>263</sup> and on 9 February 1987 he described it as being 'relatively benign despite some risk of cirrhosis of the liver in the long term'.<sup>264</sup> As Dr Forrester explained in a supplement to his oral evidence, in medical circles 'benign' may be used to refer to a form of a fatal disease that takes longer to prove fatal than another form and does so in fewer cases; it was in that sense that he used the word in his memoranda. He accepted that in ordinary language no form of such a disease would be called 'benign'.<sup>265</sup>
124. These views appear to be consistent with respectable (albeit not unanimous) scientific and medical opinion among specialists. For example, Dr Gillon explains in his statement that in 1981 and for many years thereafter there was a body of opinion which disputed the seriousness of chronic NANBH.<sup>266</sup> Dr McClelland notes (referring to the period 1980-1988) a persisting belief among most SNBTS

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<sup>260</sup> Dr McClelland said Dr Forrester may have misunderstood the figures he had been presented with – Day 63, p.120. However, while the figures mentioned in his report of the first meeting of the newly reconvened UK Working Party on Post Transfusion Hepatitis on 24 November 1986, PEN.017.1554, seem low, they appear to refer to the annual figures for reported cases, rather than to actual prevalence, and are entirely consistent with the figures in Dr Dow's thesis, and Dr Dow's article in the *Lancet* for 13<sup>th</sup> June 1987. Dr Forrester's note that the 1985 figures had seen a "sharp decline" in the number of cases is also consistent with Dr Craske's report at the meeting of the Haemophilia Reference Centre directors of 9<sup>th</sup> January 1986 that the number of reported hepatitis cases – presumably for 1985 - had dropped, possibly because of the efforts by then being made to prevent unsuitable blood donors from donating - see LOT.003.2693 at 2695

<sup>261</sup> SGH.002.7496, 26 March 1986 §6.

<sup>262</sup> SGH.002.8142.

<sup>263</sup> SGH.003.1657.

<sup>264</sup> SGF.001.2261.

<sup>265</sup> PEN.018.1481.

<sup>266</sup> PEN.017.1931 at 1934.

(and NBTS) transfusion professionals that NANBH was a much less common consequence of transfusion than it appeared to be in the USA and that it was generally not a particularly serious condition.<sup>267</sup> Dr Smith emphasized how little pressure there was even from those treating haemophilia and their patients to take NANBH seriously before 1983; and explained that the view that it could have severe long-term sequelae was not widely held.<sup>268</sup> Dr Charles Hay's evidence<sup>269</sup> was that only after 1985 was there gradual acceptance, even among haemophilia doctors, that the condition was less benign than had been thought, and that a significant minority of patients went on to develop serious liver disease. An Ortho paper of February 1990 still described NANBH as 'a mild subclinical hepatitis'.<sup>270</sup>

125. In November 1986 at a meeting of the UK Working Party on Transfusion-Associated Hepatitis, the chairman (Dr Gunson) advised the SHHD observer, Dr Forrester, that he would not recommend the screening of all blood donations, even if it were free of cost.<sup>271</sup> At that meeting the decision was made to proceed not with a full prospective study but instead with a study of donors positive for ALT or core antibodies; Dr McClelland found it difficult in retrospect to understand this decision.<sup>272</sup> Quite apart from the fact that the various letters to the *Lancet* in 1987 indicated an absence of consensus in the medical and scientific community, the message that appears to have been conveyed to the SHHD observer at the SNBTS directors' meeting of March 1987, when introduction of screening was recommended, was that there were concerns about possible legal liability.<sup>273</sup> Professor Cash accepted that it was for SNBTS to make a reasoned case to government that surrogate testing should be introduced and that this had not been done.<sup>274</sup> It was recognized within SHHD in 1987 that there was a need for evidence going beyond Dr Dow's study,<sup>275</sup> but as mentioned earlier the difficulty was in obtaining cogent evidence within a reasonable period. In the circumstances it does not appear unreasonable for SHHD to have remained of

<sup>267</sup> PEN.017.0754 §10.1; cf. Day 64 p. 23.

<sup>268</sup> Statement PEN.012.1551 at 1554; cf. also pp. 1567 and 1570.

<sup>269</sup> Day 83, p.99, 148-150

<sup>270</sup> SNF.001.1628 at 1631.

<sup>271</sup> PEN.017.1554 §5.

<sup>272</sup> Day 64 pp. 118-19.

<sup>273</sup> SGH.002.8127, minute by McIntyre of 6 April 1987; cf. McClelland, Day 64 pp. 106-11.

<sup>274</sup> Day 70 pp. 177-8; Day 72 p.70.

<sup>275</sup> See Dr Forrester's memo of 20 August 1987, SGH.002.8079.

the view that such an expensive innovation should await the results of the proposed research project.<sup>276</sup>

126. In 1986, in their budget request to the Scottish Office, the SNBTS sought £810,000 to introduce surrogate testing for NANBH in 1987/88. Mr Murray explained the general procedure for putting forward bids for funding.<sup>277</sup> He also explained why this bid had not been successful: Mr Murray and his medical colleagues were agreed that on the information available to them the introduction of testing could not be justified.<sup>278</sup> The reasons are as set out by Dr McIntyre in a memo of 6 April 1987 which refers to the low impact of NANBH in the West of Scotland: expense; the fact that screening would not abolish the transmission of NANBH; a loss of a perceptible amount of 'innocent' blood; and the desire to await DHSS thinking on the subject (DHSS had by now proposed research).<sup>279</sup> For all those reasons the view taken in SHHD was that research should come first and a decision whether or not to introduce screening subsequently.<sup>280</sup> Mr Macniven stressed the importance of ensuring that funding was available if the department was persuaded that testing ought to be introduced; funding should not be the obstacle.<sup>281</sup>

### **TOPICS C3 and C3A**

#### **Key points**

- The choice of appropriate blood product to treat haemophilia A during the period 1985 to 1987 was a matter for the treating clinician.
- The dissemination of guidance to clinicians on the appropriate choice of blood product during this period was primarily a matter for senior haemophilia clinicians and the UKHCDO.
- It would not have been helpful or appropriate to issue a CMO letter to clinicians seeking to give guidance as to the appropriate product for use in such circumstances.

<sup>276</sup> As recorded in SGH.002.8125 of 9 April 1987.

<sup>277</sup> Statement PEN.017.1755 §§8 ff.

<sup>278</sup> Murray statement §14; Macniven, Day 65 pp. 157-8

<sup>279</sup> SGH.002.8127; cf. Preliminary Report §9.49.

<sup>280</sup> Memos of 7 April 1987, SGH.002.8126; 9 April 1987, SGH.002.8125

<sup>281</sup> Memo of 2 October 1987, SGH.002.8076; Day 65, pp. 184-5.

- Questions of funding and co-operation between PFC and the CBLA/PFL did not delay the development of Z8.
- It is doubtful whether the issue of compensation for volunteers in clinical trials delayed the introduction of Z8 to any material extent.

### ***The development of Z8***

127. The Inquiry heard detailed evidence from Dr Foster about PFC's efforts during the period 1984 to 1987 to develop a high purity, wet-heated hepatitis safe product using the NYU method, and about the subsequent decision to discontinue work into pasteurisation and concentrate on a dry-heat treated product similar to 8Y. They were working in conditions of considerable uncertainty as to the efficacy of heat treatment as a means of inactivating HCV, and at the very frontiers of knowledge about the FVIII molecule. While any judgment as to the justification for and reasonableness of their actions is a matter for the Inquiry, taking into account all the available technical evidence, we note Professor Van Aken's view was that PFC could not have done anything more to produce a hepatitis safe product at an earlier stage<sup>282</sup>.

128. Co-operation on technical matters between PFC and its English counter-parts appears to have been close and fruitful<sup>283</sup>. While technology could not be directly copied, and results in one laboratory were not always easily reproducible in another, informal meetings and discussions took place on a regular basis, and each "side" fully briefed the other on the lines being followed. It was just such co-operation that led to the development at PFC of Z8, a product similar, although not identical, to the English 8Y FVIII product. Discussions in 1984 aimed at more formal links between PFC and CBLA, and to establish a new UK committee on blood transfusion research, appear to have come to nothing, but that did not in practice seem to cause any difficulty in maintaining close and productive co-operation between scientists in Scotland and England<sup>284</sup>.

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<sup>282</sup> Day 62, p.40

<sup>283</sup> See generally evidence of Dr Foster and Dr Smith, days 56,57, 59, 60

<sup>284</sup> Foster, PEN.017.1556 at 1567; Perry, PEN.017.1219 at 1226; Cuthbertson, PEN.017.1200 at 1204; cf also C3 Statement of Mr Murray - PEN.017.1594; C3 Statement of Mr Macniven PEN.017.1604, and Dr Forrester's memo SGH.002.4672 – the "Punch and Judy" memo.

### ***Issues of funding and compensation***

129. There is no suggestion that the technical development of Z8 was delayed because of any lack of funding or support from government during that period. The question of compensation for volunteer recipients of trial products latterly caused some difficulty, but it does not appear that it ultimately caused any delay to the treatment of patients throughout Scotland.
130. PFC's products were very much at the "cutting edge" of pharmaceutical blood products. Clinical trials were necessary to test their suitability and efficacy. Some clinicians, notably Professor Ludlam, were concerned that provision should be made for the possibility that volunteers in such trials might suffer harm as a result of testing new products.
131. The issue appears to have been first raised by Dr Ludlam (as he then was) at a meeting of the Joint Directors on 14<sup>th</sup> November 1983<sup>285</sup>. Dr Cash agreed to raise the matter with the CSA and to liaise with SHHD.
132. Dr Ludlam raised the matter again at the next meeting of the Joint Directors on 2<sup>nd</sup> February 1984<sup>286</sup>. Although Dr Bell was "not in a position to provide directly relevant advice" at that stage he mentioned the compensation arrangements for blood donors throughout the UK, presumably as a possible model for a compensation scheme for FVIII trials. Dr McClelland was to put a paper forward to the BTS Sub-committee of the CSA.
133. On 11<sup>th</sup> March 1985, Dr Cash wrote to Mr Mutch of the CSA proposing a compensation scheme for participants in *all* BTS procedures, not just clinical trials of PFC products, under reference to the arrangements of which Dr Bell had reminded the Joint Directors at the meetings of 1<sup>st</sup> November 1983 and 2<sup>nd</sup> February 1984<sup>287</sup>. This was a rather wider scheme than that originally sought by Dr Ludlam.

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<sup>285</sup> SNB.001.5188 at 5189

<sup>286</sup> SNB.001.5252 at 5255

<sup>287</sup> SGH.003.1964

134. On 15<sup>th</sup> March 1985 Dr McIntyre wrote to Mr Davies of SHHD<sup>288</sup> in fairly forthright terms indicating that the clinicians concerned wished the legal position on compensation to be stated quite clearly and to be reassured that compensation would be paid without “prolonged legal wrangling”. He indicated that he and his medical colleagues felt that this was “a matter of some importance”. He wrote to Mr Davies again on 28<sup>th</sup> March 1985, indicating that the matter had been given a “measure of urgency” by the AIDS/Factor VIII issue.<sup>289</sup> He appears to have been referring only to Dr Ludlam’s narrower request for a compensation scheme at this point.
135. However, it rapidly became clear that Treasury approval would be required for any compensation scheme, and concern was expressed within SHHD as to the breadth of the scheme proposed by Dr Cash.<sup>290</sup> It is here that the whole issue really appears to have become bogged down – did SNBTS/PFC wish Dr Ludlam’s narrower or Dr Cash’s wider scheme, and if the latter, what procedures was it to cover, who was it to cover<sup>291</sup>, and in what circumstances?
136. At this stage, officials at SHHD were in no doubt that the issue was being dealt with at the correct level – i.e. within the CSA – and were awaiting proposals for a detailed scheme for which approval was sought<sup>292</sup>. However, it took a long time for the boundaries of the scheme to be properly defined, and SHHD officials were still awaiting clarification of the matter from the CSA and/or Dr Cash in December 1986, almost two years later.
137. On 16<sup>th</sup> August 1985, Mr Murray of SHHD wrote an internal memo to Mr Davies noting that the questions raised by Dr Cash raised wider issues than those pertaining only to the BTS<sup>293</sup>. Accordingly, at the subsequent BTS sub-committee meeting, Mr Morison of SHHD undertook to take the scheme forward with DHSS, but indicated that the precise boundaries of the proposed scheme would have to

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<sup>288</sup> SGH.003.1969

<sup>289</sup> SGH.003.1957. Dr McIntyre had by this time received a further letter from Dr Cash, conveying Dr Ludlam’s continued concern about the issue – SGH.003.1958

<sup>290</sup> SGH.003.1950

<sup>291</sup> SGH.003.1969

<sup>292</sup> Evidence of Mr Murray, Day 61, p.116

<sup>293</sup> SGH.003.1933

be clarified by the CSA before the scheme could be taken forward. He also noted that the scheme would require to be considered in a GB context<sup>294</sup>. It can be appreciated that a scheme compensating only Scottish volunteers or patients might be considered inequitable (and unjustifiable in terms of administrative efficiency) south of the border.

138. Thus, the focus of officials became wider, in part because of the terms of Dr Cash's letter of 11<sup>th</sup> March 1985, and in part because a scheme confined narrowly to participants in clinical trials of FVIII in Scotland would be difficult to justify to Treasury at a national level. But in widening the focus, the view perhaps became less sharp, losing sight of the particular proposal or request originally made by Dr Ludlam.

139. At all events, the CSA appeared to have the matter in hand as at September 1985<sup>295</sup>, and Mr Murray wrote to Alun Williams at DHSS in November 1985 inviting consideration of a blanket approval of compensation for volunteers who suffered injury through participation in clinical trials or BTS procedures.<sup>296</sup> No response was forthcoming from DHSS and Mr Murray wrote a reminder to them on 11<sup>th</sup> February 1986<sup>297</sup>.

140. Matters then went quiet for some time. The next event of note is the meeting of the BTS sub-committee of the CSA on 20<sup>th</sup> August 1986. At that meeting it was noted that Dr Cash had had a useful dialogue with the legal adviser concerning compensation arrangements and agreed that the general manager of the CSA should now "pursue the bringing forward of firm proposals"<sup>298</sup>. The matter accordingly rested with the CSA and Dr Cash at that time, and SHHD awaited clarification of the "boundaries" of the scheme from the CSA<sup>299</sup>.

141. The issue then appears once again to have gone into abeyance until 11<sup>th</sup> December 1986 when Dr Ludlam wrote to Dr Cash complaining of

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<sup>294</sup> SGH.003.1927

<sup>295</sup> SGH.003.1926

<sup>296</sup> SGH.003.1925

<sup>297</sup> SGH.003.1924

<sup>298</sup> SGH.002.0455 at 0456

<sup>299</sup> SGH.003.1920

“procrastination” by SHHD in relation to compensation<sup>300</sup>. It would appear that Dr Ludlam’s letter prompted Dr Cash to contact Dr McIntyre with a view to agreeing a scheme.<sup>301</sup>

142. By this time, however, PFC’s dry-heat treated product, Z8 was ready for use in clinical trials. The first Z8 appears to have been issued on around 22<sup>nd</sup> December 1986<sup>302</sup>. It was shortly after this point, in January 1987, that Dr Ludlam intimated his refusal to participate in trials of Z8 unless a compensation scheme was agreed<sup>303</sup>. He had been aware that Z8 was nearing readiness since early December 1986 at least<sup>304</sup>. His refusal appears to have caught even Professor Cash off guard.<sup>305</sup>

143. Once it was drawn to their attention that the matter had become critical, SHHD officials acted very quickly. Dr Forrester indicated to his administrative colleagues on 7<sup>th</sup> January 1987 that a scheme to cover FVIII clinical trials was required urgently<sup>306</sup>. He also spoke to Dr Ludlam by telephone on that date, and was reassured because the latter had indicated that if SHHD could provide a date by which a compensation scheme would be in force, he would begin recruiting volunteers at once<sup>307</sup>.

144. A proposal for the necessary scheme was ready and submitted to the DHSS by 12<sup>th</sup> January 1987<sup>308</sup>. It was processed and submitted to Treasury on the same day<sup>309</sup>. At this stage all participants in this exercise, both at SHHD and DHSS were clearly treating the matter as extremely urgent.<sup>310</sup>

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<sup>300</sup> SNB.005.8711

<sup>301</sup> SGH.003.1919

<sup>302</sup> SNB.009.4073 But this appears to have been only the 75°/72 hour product, not the safer 80°/72 hour product – see SNF.001.3022

<sup>303</sup> Dr Ludlam’s letter to Dr Cash, intimating his refusal is dated 5<sup>th</sup> January 1987, but it is clear that SHHD had a little prior warning of Dr Ludlam’s intentions – see SGH.003.1919

<sup>304</sup> See SNB.005.8711

<sup>305</sup> SGH.003.1907. Although Professor Cash had been on notice since early December 1986 that a crisis was imminent – see SNB.007.6274

<sup>306</sup> SGH.003.1912

<sup>307</sup> SGH.003.1912; and SNF.001.3020

<sup>308</sup> SGH.003.1883

<sup>309</sup> SGH.003.1891

<sup>310</sup> See e.g. SGH.003.1891

145. Although Treasury officials were initially cautious<sup>311</sup>, they were quickly persuaded of the necessity for the narrower scheme put forward by SHHD, and at least in relation to Scotland<sup>312</sup>. Treasury approval for the scheme was granted on 5<sup>th</sup> February 1987<sup>313</sup> and Mr Murray wrote to Dr Cash on the 6<sup>th</sup> February confirming that the SHHD had approved compensation arrangements for patients taking part in clinical trials<sup>314</sup>. Trials appear to have begun very shortly after that<sup>315</sup>.

146. Thus, it would appear that there was a short delay in implementing clinical trials of the new product, probably of about a month to six weeks. That in turn meant that particular patients may have received treatment with Z8 slightly later than they otherwise would have done. Fortunately, it is unlikely that there was any delay in the phased introduction of Z8 for all patients in Scotland<sup>316</sup>.

147. While it is accepted, as it must be, that the issue of compensation took a long time to resolve, it is regrettable that the matter was only raised at the last possible minute to bring the matter to a head. As the speed of subsequent events demonstrates, SHHD could almost certainly have ensured that a compensation scheme was in place as soon as or very shortly after the first vials of Z8 were issued in late December 1986, had they been made aware of the urgency of the situation in early December 1986. The situation was particularly anxious because, as Professor Ludlam also knew, stocks of the earlier NYU product were being run down, and would be largely exhausted by February 1987<sup>317</sup>. As Professor Cash put it in his letter of 7<sup>th</sup> January 1987, “the game...being played [was] getting perilously near to Russian Roulette”. Why did the whole issue take so long to resolve? Mr Murray said that “in reviewing the papers it would appear that there was a fragmentation of attention – meetings of joint directors, BTS sub-committee, SHHD, CSA, admin and medical officers, the answer to your question

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<sup>311</sup> SGH.003.1890

<sup>312</sup> SGH.003.1879; SGH.003.1873; SGH.003.1871

<sup>313</sup> C3 Statement of Duncan Macniven, PEN.017.1866 at 1867

<sup>314</sup> SGH.003.1870

<sup>315</sup> SGH.003.1853

<sup>316</sup> PEN.017.1219 at 1225; Evidence of Professor Ludlam, Day 58, p.129

<sup>317</sup> The timetable had been fixed from about July 1986 – see Dr Perry, Day 58, pp.45 - 56

lies ... in those structures".<sup>318</sup> There is little doubt that matters seemed to stick at the level of the BTS sub-committee and the CSA. SHHD were represented on that committee and on the board of the CSA. However, it would appear that officials in SHHD were unaware until January 1987 how deeply the narrow issue of compensation for clinical trials was felt by the haemophilia clinicians. They acted extremely quickly once that became plain. Moreover, it may be that Professor Cash and officials at the CSA did not treat with sufficient urgency the need to place before SHHD a concrete scheme supported by sufficient reasoning which could be submitted to DHSS and Treasury at an earlier stage. Certainly it is plain that officials at SHHD were unclear as to the scope of what was being proposed. It was not for them to dictate the scope of a compensation scheme, and it is unfortunate that proposals were not brought forward earlier.

### **Guidance**

148. There is no indication that any attempts were made to involve government in securing supplies of 8Y in Scotland, or that any of the medical officers or officials in SHHD were aware that some supplies of 8Y could be, or were being sent north of the border. It should be borne in mind that 8Y was a scarce product, and that supplies were insufficient to the needs of patients in England & Wales, let alone those of patients in Scotland. While Professor Ludlam was able to obtain a small supply for some Scottish patients under the aegis of further clinical trials, a more general scheme of supply would almost certainly not have been available for Scotland, given the separate arrangements for the blood transfusion service north of the border, and the scarcity of the English product<sup>319</sup>.

149. The appropriate choice of product to treat haemophilia during the period of scrutiny was primarily a matter for treating clinicians.

150. The dissemination of guidance to clinicians on the appropriate choice of blood product during this period was primarily a matter for senior clinicians, and the

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<sup>318</sup> Mr Murray, Day 61, p.143

<sup>319</sup> Dr Smith was clear that supplies of 8Y would have been insufficient to meet English demand if purchases of commercial products had ceased – Day 60, pp.31-34

UKHCDO<sup>320</sup>. That organisation had previously prepared and disseminated guidance to clinicians on AIDS,<sup>321</sup> although this does not appear to have been revised since its issue in 1984. SHHD also hosted a biannual meeting of the Scottish Haemophilia Directors and Regional Transfusion Directors which provided a forum for the dissemination of advice or guidance among clinicians.

151. Dr Ludlam suggested in his evidence on the C3A topic that it would have been appropriate for the CMO to issue guidance on the issue of the appropriate product with which to treat a previously untransfused patient during the period to April 1987 when hepatitis safe FVIII was not generally available in Scotland.<sup>322</sup> Dr Ludlam's evidence<sup>323</sup> gives some idea of the range and difficulty of situations which might require to be dealt with. Any guidance, even from expert clinicians in the field, would run the risk of being dangerously prescriptive or unhelpfully vague. Dr Macdonald explained that CMO guidance would generally be issued in relation to broad issues such as the provision of information on infectious diseases; vaccination and immunization; and the acceptability of blood donations from various groups of donor. His view was that it was for the medical profession to evolve treatment policies, no doubt taking into account the variety of circumstances with which clinicians might be faced. He felt that, in view of the sensitivity over the boundary between medical and public policy, it would be neither helpful nor acceptable for government to issue guidance about clinical treatment. If asked as CMO, he would have declined to do that.<sup>324</sup>

## **TOPIC C4**

### **Key points**

- The decision when to introduce the test for HCV was taken in Scotland by the Minister of State.
- The decision was based directly on advice from SHHD but ultimately on the expert advice obtained from ACVSB; SHHD kept abreast of the deliberations

<sup>320</sup> Evidence of Professor Ludlam, Day 55, pp.59-61

<sup>321</sup> SGF.001.2388

<sup>322</sup> Day 55 pp. 124-8.

<sup>323</sup> Day 55, pp.48-50, and 59

<sup>324</sup> PEN.018.0620. Dr Ludlam himself seemed unsure whether the question was one of medical, rather than public policy – compare Day 55, p.62, 125-126

about when testing for HCV should be introduced; they did so in particular by participation in ACVSB.

- Funding for HCV testing was approved by SHHD for the financial years 1991/92 and was accordingly in place for testing to begin in April 1991.
- SHHD, in common with DHSS and leading figures in SNBTS and NBTS took the view that it was appropriate for HCV testing to begin in Scotland at the same time as it began in England.
- Various factors caused delay in introduction of testing: among them were the need to obtain and to evaluate confirmatory tests; to secure adequate supplies of test kits; and once a second-generation test had been developed to evaluate it too.
- A factor that may have contributed to delay in England but not in Scotland was the need to secure funding for the various regional centres that were to carry out the testing.
- Testing could have been started in Scotland earlier than 1 September 1991, since the infrastructure and funding were in place, but the prevailing view in SNBTS and NBTS remained that testing should begin in Scotland at the same time as it began in England; SNBTS did not advise SHHD to adopt any other course.
- The SHHD submission recommending introduction of the test in Scotland was put to the Minister once there was a firm date for him to approve; the fact that the submission was made only in July 1991 did not delay the starting date, since the funding was already in place. In any event, the inclusion of an item for testing in the 1991 PES constituted de facto Ministerial approval, since the Minister would have had to sign off on an item in the PES bid for the funding<sup>325</sup>.

***The procedure for deciding if and when testing for HCV should be introduced***

<sup>152</sup>. In 1989 DHSS established ACVSB, a committee of experts to advise it on the virological safety of blood. There were two members from Scotland, as well as an observer from SHHD, Dr McIntyre. SHHD kept abreast of the deliberations about testing for HCV. They relied on ACVSB for expert advice on when such testing

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<sup>325</sup> Tucker, Day 69, p.121; McIntosh, Day 70, pp.75-76

should be introduced and on the technical questions on which introduction depended, such as the availability and evaluation of test kits.

153. Some concern has been expressed about the fact that the proceedings of ACVSB were confidential.<sup>326</sup> It does not seem that in practice this can have been a very significant issue. First, when they thought it appropriate, members of ACVSB did divulge matters that had arisen in the meetings to colleagues whom they thought needed to know about them.<sup>327</sup> Second, SHHD, when asked if this confidentiality could be waived, confirmed that it could: the contents of minutes of ACVSB could be disclosed (but not copied) to SNBTS directors.<sup>328</sup> Professor Cash said that on rare occasions he was shown the minutes.<sup>329</sup> He also received various written reports.<sup>330</sup> It is also notable that the issue does not appear to have been raised again with SHHD after Mr Panton had confirmed that minutes could be circulated.

154. On the central question whether HCV testing should be introduced, a number of issues had to be resolved: first and foremost, the need for a confirmatory test; the need, if an American (Ortho) test was to be used, for the reassurance that it had obtained FDA approval; and pilot studies of the test in the UK. This was the position recorded in the minutes of ACVSB of November 1989.<sup>331</sup> An export licence for that test did not become available until the end of November 1989. As Dr Perry explained, without a confirmatory test, the test was dangerous and its introduction would not be in the public interest.<sup>332</sup> The minutes of subsequent ACVSB meetings reveal differences of emphasis among the members of the committee on matters of timing and scientific rigour but a general understanding that the likelihood was that an HCV test would be introduced in the UK. The determining factor, according to Dr Perry, was the availability of a confirmatory test.<sup>333</sup> By 24 April 1990 Dr Perry and Dr Gunson were satisfied that there was

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<sup>326</sup> See e.g. Perry, Day 68 pp. 141 ff.

<sup>327</sup> Dr Perry and Dr Mitchell: see Perry, Day 68 pp. 100, 125.

<sup>328</sup> SNB.002.4627, 13 Feb 1990.

<sup>329</sup> Day 72 p. 105.

<sup>330</sup> As mentioned above in Perry's evidence; cf. Cash, Day 72 p. 146.

<sup>331</sup> SNB.001.9563 at 9566, ACVSB meeting of 6 Nov 1989 §23; cf. Perry, Day 68 p. 50.

<sup>332</sup> Day 68 p. 53.

<sup>333</sup> Day 68 pp 66-7.

sufficient data to warrant taking a decision in principle to introduce HCV testing, but the majority of ACVSB and the Department of Health preferred a more cautious approach.<sup>334</sup> By 2 July 1990 ACVSB was willing to recommend to Ministers that HCV testing should be introduced, but that a pilot study using the Ortho and Abbott tests should first be carried out to decide which was the better test for the regional transfusion centres. On 21 November 1990 ACVSB recommended the introduction of HCV testing as soon as practicable; individual centres would decide which test to use. While the minutes of the meeting do not mention a target date, Dr McIntyre's note of the meeting notes that as being 1 April 1991.<sup>335</sup>

155. In January 1991 the Department of Health approved the introduction of HCV testing on a date yet to be fixed, since some testing laboratories would require new equipment. 1 April 1991 was suggested as the target date for the earliest possible introduction, with regional transfusion centres to come into line thereafter. Mr Tucker of SHHD pointed out to a colleague in SHHD that to delay for the slowest could mean a long wait.<sup>336</sup>

156. By February 1991 the date that was under consideration in the Department of Health was 1 July 1991.<sup>337</sup> That is also reflected in an internal SHHD memo between Mrs Falconer and Mr Hogg stating that the Department of Health had unofficially indicated the hope that testing would start on 1 July 1991.<sup>338</sup> By March 1991 it had emerged that 1 July was not practicable for NBTS; Dr Gunson was going to advise the Department of Health that the date should be delayed until an evaluation of the new screening tests had been completed. The delay caused concern in SHHD: Mr Panton noted 'This is worrying ...'.<sup>339</sup> Contrary to Professor Cash's witness statement, there is no evidence to support the suggestion that SHHD were party to a contrived further delay in introducing

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<sup>334</sup> SNF.001.1710; Perry, Day 68 pp. 99-101.

<sup>335</sup> SGH.002.8501.

<sup>336</sup> SGH.002.7890, 21 January 1991, memo to R Panton (SHHD).

<sup>337</sup> PEN.016.0236, 5 Feb 1991.

<sup>338</sup> SGH.002.7886 (commented on in their respective witness statements, PEN.017.2146 at 2151 and PEN.017.2120 at 2123).

<sup>339</sup> SGF.001.2026, 28 March 1991.

testing.<sup>340</sup> In fact, as Mr Panton's note indicates, SHHD themselves became aware of the further delay only at the end of March 1991.<sup>341</sup> Equally, in evidence Professor Cash departed from the view expressed in his statement that by March 1991 SHHD had been consulted and had agreed to a DHSS-inspired and unnecessary delay.<sup>342</sup>

157. It seems likely that it should have been possible to achieve a starting date earlier than 1 September 1991. Dr McClelland explained that what he regarded as stalled decision-making seems to have centred around the ACVSB and ACTTD, one example being the decision that the start must wait for the better test kits and their evaluation; since other countries did start testing before 1 September, in terms of the availability of equipment and test systems an earlier start date could have been achieved. The question whether Scotland should have started before England is a different question.<sup>343</sup>

158. While the precise explanation for the slippage in the date for introducing testing, from April to September 1991, remains elusive, it seems likely that it was the advent of a second-generation test, and the need to evaluate it, that was a – or the – major factor in the delay. There was also a problem with availability of test kits.<sup>344</sup> Dr Mitchell was clearly of the view that it made no sense to start testing with a first-generation test only to replace it shortly afterwards with a second-generation test – after all, the reason that it was being replaced was that it was no good;<sup>345</sup> on the other hand, Dr McClelland thought that the introduction of improved tests was an entirely routine and unproblematic matter,<sup>346</sup> although it is fair to say that in relation to the first and second generation of tests for HIV he recognized that, where a second-generation test was on the way, work put into a first-generation test could be a huge waste of effort and potentially quite

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<sup>340</sup> Statement PEN.017.2094 at 2104-5 §35(2).

<sup>341</sup> Cf. Cash, Day 72, pp. 165, 169

<sup>342</sup> Statement PEN.017.2094 at 2104 §33; Day 82, p 23.

<sup>343</sup> Day 69 pp. 62-3. On that different question, see below.

<sup>344</sup> See e.g. PEN.016.0166 of 4 April 1991, in which Dr Gunson, writing to the NHS procurement section, notes that timing slipped because of unavailability of test kits; to accommodate slippage he had postponed introduction until 1 September 1991.

<sup>345</sup> Day 69 pp. 188-9.

<sup>346</sup> Day 69 p. 75.

misleading.<sup>347</sup> Dr McClelland found it difficult to understand an apparent lack of urgency about introduction of the tests; the best explanation he was able to offer was that NANBH was regarded as an American problem, and that in the relevant professional communities across the UK there had been a degree of failure to internalize the scale of the issue.<sup>348</sup>

### ***The UK dimension***

159. The date for introduction of HCV testing was set by DHSS, once they were satisfied that the regional transfusion centres were able to carry it out; the evaluation of second-generation tests had been completed; and the advisory committee had signalled that they were happy with that.<sup>349</sup>

160. When to introduce the test in Scotland was a matter for the Minister of State, whose decision was based directly on advice from SHHD and ultimately on the expert advice obtained from ACVSB. The Department of Health decision was crucial for Scotland too, because there was a consensus among Ministers, their officials, and the medical and scientific community that it was appropriate for HCV testing to begin in Scotland at the same time as it began in England. That view was based on and strongly supported by leading figures in SNBTS, as well as by NBTS. It was also the clear view of ACVSB that the decision was a UK decision and should be implemented in a co-ordinated manner across the UK.<sup>350</sup> Given the UK context, it is fair to say that the Department of Health took the lead in the process, with the advice of ACVSB.<sup>351</sup>

161. So far as the practicability of introducing testing is concerned, Dr Gillon indicated in response to a query from Professor Cash in November 1990 that the earliest date on which the Edinburgh centre would be able to start testing was 25 February 1991.<sup>352</sup> In practice, what was described as an evaluation of tests in the Glasgow centre involved testing of every single donation from about April

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<sup>347</sup> Day 50 p. 44.

<sup>348</sup> Day 69 pp. 67, 77.

<sup>349</sup> Tucker, Day 69 pp. 127-8.

<sup>350</sup> Cf. Perry, Day 68 p. 36.

<sup>351</sup> Tucker, statement PEN.017.2060 §13; cf. Perry, Day 68 p. 38.

<sup>352</sup> SNB.004.7202

1991.<sup>353</sup>

162. Although it might have been practically possible for HCV testing to be introduced earlier in Scotland than the rest of the UK, Dr Perry could not imagine circumstances in which that would have occurred without causing a major problem.<sup>354</sup> Nonetheless, given that testing had started earlier in Newcastle and given that there was an extended study of the tests in the Glasgow centre (which covered half of the Scottish population), it was becoming increasingly difficult to reconcile and sustain the policy of a common starting date.<sup>355</sup> Dr Perry recalls a very substantial discussion on the points at the SNBTS board meeting on 11/12 June 1991, albeit the minutes record only that routine donation testing was to begin on 1 September 1991. Dr McClelland's recollection was that from the time of that board meeting, he and his staff proceeded as quickly as they could; and he thought there were records of their testing towards the end of July or early in August 1991.<sup>356</sup>

163. Dr McClelland recognized that from the point of the view of the individual patient and his or her family, the policy of adhering to a common start date was a bad thing; but he did not describe it as a mistake. As he explained, there were many cogent reasons for having a common starting date: there were downsides in having a fragmented introduction in a small compact country like the UK; 'postcode prescribing' was undesirable and inequitable; there was the prospect of bad publicity, damage to reputation, and the possibility of litigation.<sup>357</sup> During this period there was an increasing awareness of the regulatory environment and of risks in relation to treatment and product liability, and the threat of litigation if it emerged that a patient in one city was getting a test for a virus while a patient in another city was not.<sup>358</sup> Dr McClelland's own view was nonetheless that it would have been better to manage a phased introduction in particular areas, and to present that as being a positive rather than a negative thing.<sup>359</sup>

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<sup>353</sup> McClelland, Day 69 pp. 69-70.

<sup>354</sup> Day 68 p. 128.

<sup>355</sup> Perry, Day 68 pp. 128-9.

<sup>356</sup> Day 69 p. 61.

<sup>357</sup> Day 69 pp. 64-5

<sup>358</sup> Day 69 p. 86.

<sup>359</sup> Day 69 pp. 66-7.

164. Professor Cash in particular advocated the importance of holding a UK line. His correspondence with Dr Gunson in 1989 shows that they were working together on the introduction of screening and that this was precisely what Professor Cash wanted; as he wrote to Dr Gunson, 'We will not move unilaterally unless instructed to do so by SHHD, thus close collaboration seems certain'.<sup>360</sup> Although in his written statement Professor Cash appears to suggest that this approach was imposed by government, in oral evidence he accepted that he thought the principle of simultaneous introduction was right and had subscribed to it.<sup>361</sup> The same understanding appears from the minutes of the SNBTS directors' meeting in September 1989,<sup>362</sup> and in Professor Cash's letter to the directors of 27 November 1990, which emphasizes the importance to everyone of a UK simultaneous start date.<sup>363</sup> There are many other instances in the evidence that show this. One is a letter in January 1991 expressing a firm commitment to starting testing on the same day as NBTS colleagues.<sup>364</sup> As he and others explained at numerous points in the evidence, Professor Cash had a strong belief in the importance of teamwork and commonality of action within the service.<sup>365</sup> Against this consistent picture from the evidence, it cannot be accepted that in 1991 Professor Cash would in fact have urged that it was necessary to reconsider the policy of a common UK starting date; there is no other evidence to support that suggestion and much that is against it.<sup>366</sup> Professor Cash himself accepted that it was possible that a concern that Scotland was being delayed by difficulties in England may not have been made known to SHHD.<sup>367</sup> Even in late March 1991, Professor Cash was writing to Mr McIntosh advising him that he and Dr Mitchell had at a meeting of ACTTD supported the proposal to delay the 1 July start date until evaluation of the new test had been completed, which might delay the start to September.<sup>368</sup> In April 1991, after he had been informed that a

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<sup>360</sup> SNB.008.2606, 28 July 1989; Day 72 pp. 126-7.

<sup>361</sup> PEN.017.2094 §13; Day 72, pp. 128-9.

<sup>362</sup> SNB.002.4517; Day 72 p. 131.

<sup>363</sup> SNB.005.2555; Day 72 pp. 147-9.

<sup>364</sup> SGH.002.7887, 24 Jan 1991.

<sup>365</sup> Cash, (e.g.) Day 72, pp. 183-4; McClelland, Day 69 pp. 82-3; cf. Mitchell, Day 69 p. 186.

<sup>366</sup> Cash, Day 72 pp. 170-173; Day 82 pp. 56-8, 75-8. At p. 84 Professor Cash completely accepts that there is no sign of communication of these concerns to SHHD or the health Minister.

<sup>367</sup> Day 82 pp. 102-6, 120.

<sup>368</sup> SGF.001.2026, 27 March 1991; Day 82 pp. 50-52.

starting date of 1 July was not going to be possible, he wrote to Dr Gunson stating that the new starting date of 1 September had the SNBTS directors' fullest support.<sup>369</sup> In May 1991 he wrote a letter to Dr Lloyd in Newcastle, which was extremely critical of the fact that in Newcastle the decision had been taken to introduce HCV testing before all other centres in the UK were ready to do so.<sup>370</sup> The letter emphasized the importance of co-operation and teamwork, which a decision in Scotland to proceed unilaterally would clearly undermine. The minutes of the board meeting of 11/12 June 1991 made no reference to the need to approach SHHD in order to express SNBTS concern about delay or the need to introduce screening in Scotland immediately.<sup>371</sup>

165. Mr McIntosh was critical of the persistence of the 'UK solidarity' line, particularly given that Newcastle had struck out on its own in April 1991, and from May 1991 Glasgow was in practice testing all donations.<sup>372</sup> He explained that he and Dr McClelland had argued strongly at the SNBTS board meeting on 11/12 June 1991 that SNBTS was in a position to move immediately to implement full testing throughout Scotland and so needed very good reasons to postpone such implementation.<sup>373</sup> Mr McIntosh's recollection was that at the meeting it was agreed that he should write to SHHD seeking clarification that Ministers did wish to adhere to a uniform starting date, even though SNBTS was ready to implement testing immediately.<sup>374</sup> No copy of this letter has been discovered, and Mr McIntosh's own evidence was that the most likely explanation for that is that for some reason it was never sent.<sup>375</sup>

166. Clearly, the commencement of testing in Scotland depended on Ministerial approval and on the necessary finance having been made available. But those in turn depended on the information and advice being presented to SHHD (and through SHHD to the Minister), in particular by SNBTS.<sup>376</sup> As Dr McClelland

<sup>369</sup> SNB.006.3958, 5 April 1991.

<sup>370</sup> SNB.011.8726.

<sup>371</sup> Cash, Day 82 pp. 115-116.

<sup>372</sup> Day 70 p. 35; witness statement PEN.017.2126 §5.3.

<sup>373</sup> Statement PEN.017.2126 §5.11; Day 70 pp. 60-62.

<sup>374</sup> Statement PEN.017.2126 §§ 5.12-15; Day 70 pp. 62ff.

<sup>375</sup> Day 70, pp. 65-9.

<sup>376</sup> Cf. McIntosh, Day 70, pp. 85-6, recognizing that it was for SNBTS to be very clear in their recommendations to SHHD and the consequences of not accepting them.

explained, had SNBTS taken the view that it was important that testing should be introduced more urgently, it could have worked harder on influencing SHHD and seeking to have the Minister authorize testing at an earlier date.<sup>377</sup> This accords with Mr Tucker's evidence, that SHHD would want advice from the transfusion service about exactly when they would be ready to begin testing.<sup>378</sup>

167. As Mr Tucker explained, the general approach in SHHD was to follow England where it was sensible to do so but not otherwise; there was a general desire within SHHD to avoid duplication of work done in DHSS; DHSS was also able to put more pressure on the Treasury; and both SHHD and DHSS drew advice from the same experts on ACVSB.<sup>379</sup> If Scottish expert advice contradicted the advice from England, the issue would have been put to Ministers, but that did not arise in relation to this issue.<sup>380</sup> Mr McIntosh put forward essentially the same view, that it was open to Scotland to move separately.<sup>381</sup> If the missing letter drafted by Mr McIntosh in June 1991 had indeed reached SHHD, on the evidence just mentioned it would have prompted SHHD to consider whether adherence to a common starting date with the rest of the UK was appropriate; given the potential political sensitivities, it is likely that that question would have had to be drawn to the attention of the Minister. In fact, there is no evidence that that occurred.

168. Similarly, there is no evidence that SNBTS urged that the issue of a common start date should be reconsidered. As Mr McIntosh put it, SNBTS ought to have done more to set out clearly and unambiguously for CSA, SHHD and for Ministers, the shape and size of the HCV problem and the key performance indicators that their strategy was aimed at: in short, SNBTS did not lobby SHHD hard enough.<sup>382</sup> His view was that he, as general manager, should have generated a consensus among his SNBTS colleagues, in order in turn to generate an instruction from SHHD to SNBTS on how to proceed.<sup>383</sup> This is consistent with the fact that SNBTS was authorized to commence testing on the

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<sup>377</sup> McClelland, Day 69 pp. 76-7.

<sup>378</sup> Day 69 pp. 119-120, 143-4.

<sup>379</sup> PEN.017.2060 §13.

<sup>380</sup> Ibid.

<sup>381</sup> Day 70 pp. 20-21 and pp. 130-131.

<sup>382</sup> Statement PEN.017.2126 §7.13.2.2; Day 70 p. 118.

<sup>383</sup> Day 70 p. 95.

very date that they had themselves chosen.<sup>384</sup> Mr McIntosh considered that if the arguments (about departing from the common stating date) had been put forward to Ministers, they would have listened attentively and might have taken a different course, particularly in the latter part of the period.<sup>385</sup>

169. This evidence is to be preferred to the picture painted in oral evidence by Professor Cash, apparently suggesting that Mr Tucker at SHHD ought in about March 1991 to have convened a meeting to explore the problems of delay arising south of the border, and that at that meeting Professor Cash would himself have argued that 'we shouldn't be delayed'.<sup>386</sup> The evidence already mentioned indicates that SHHD relied on advice from the experts in relation to the timing of the introduction of the test and the underlying technical issues that indicated one starting date or another; and Professor Cash himself suggests in the same passage of evidence<sup>387</sup> that it was for Mr McIntosh of SNBTS to brief colleagues in SHHD about the issues. That, it is submitted, is the way in which matters ought to have and ordinarily did proceed: SNBTS and other experts put their views and concerns forward to SHHD to consider and decide.

### ***The role of SHHD***

#### ***Funding***

170. The commencement of testing in Scotland depended on Ministerial approval and on the necessary finance having been made available.

171. Funding for HCV testing had been approved by SHHD for financial year 1991/92; the PES survey for that year had been approved by Ministers and the funds were available for testing to begin on 1 April 1991.<sup>388</sup> As Mr Tucker explained, if a decision had been taken to introduce screening when funds had not already been reserved for that purpose, it would have been necessary to find the necessary sums by looking in turn at the CSA budget, the budgets of other SHHD divisions, and then the Scottish Office budget more generally. There was therefore room for

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<sup>384</sup> Statement §7.15.

<sup>385</sup> Day 70 p. 132.

<sup>386</sup> Day 72 pp. 157-60.

<sup>387</sup> p. 160.

<sup>388</sup> Tucker, Day 69 p. 118. As already noted, approval of the item in the PES bid for testing constituted *de facto* Ministerial approval for testing.

manoeuvre, though in fact it was not needed, since the test was introduced only in financial year 1991/92, by which time the funds had been approved for it.<sup>389</sup> Mr McIntosh, who was at the time general manager of SNBTS, recognized that there was a degree of flexibility in the budget and, most importantly, that finance was not in fact an obstacle in introducing the test in Scotland.<sup>390</sup> He knew as the financial year 1991/92 began on 1 April 1991 that he was already fully financed for HCV testing.<sup>391</sup>

### *Setting the date*

172. The SHHD submission<sup>392</sup> was put to the Minister once there was a firm date for him to approve for the introduction of HCV testing in Scotland. The fact that the submission was made to him only in July 1991 did not delay the starting date, since as a result of the success of the PES bid the funding had been in place since 1 April 1991. Since that constituted approval in principle, there was no need to go to the Minister in July 1991 for that approval: the money was there, and the fact that this would proceed on a UK basis was also agreed.<sup>393</sup> Only the date remained to be fixed. On 26 July 1991 the Minister approved the submission and the introduction of testing on 1 September 1991.<sup>394</sup>

## **TOPIC C5(b)**

### **Key points**

- From the advent of testing for HCV in 1991 until at least 1994, there was no expert agreement as to the necessity or utility of a look-back exercise; no attempt was made to inform or persuade government officials in Scotland that a look-back exercise was necessary, desirable, or feasible; the advice from the principal advisory committee to Ministers, including Scottish Office Ministers, was that look-back should not proceed at that time.
- Once a local exercise had proved the feasibility of lookback, and it was clear that appropriate treatment was available to those identified as being HCV positive, the

<sup>389</sup> Day 69 pp. 112-14; statement PEN.017.2060 §§25-6.

<sup>390</sup> Day 70 pp. 29-30 (His references to financial pressures at pp. 47, 50-51 refer to the position in England.)

<sup>391</sup> Day 70 pp. 73-6.

<sup>392</sup> SGH.002.7828, 24 July 1991.

<sup>393</sup> Tucker, Day 69 p. 121.

<sup>394</sup> SGH.002.7817.

Scottish Office was convinced this should be done nationally, and legal advice indicated that Scottish Ministers had a duty to ensure this happened.

- Having decided that a look-back exercise was necessary, Scottish Ministers would if necessary have been prepared to take the exercise forward in Scotland even in the absence of approval of a similar scheme for England & Wales.
- SHHD and Ministers would have been prepared to do so in this instance because they were given clear and persuasive clinical advice that it would be appropriate to do so.

### ***The period 1991 – 1993***

173. Prior to 1994, the attitude of officials within SHHD was coloured by the view, commonly held among transfusionists, that look-back was logistically too difficult, and that because there was no real evidence-based treatment for HCV<sup>395</sup>, the exercise would cause patients distress and anxiety for no real benefit.<sup>396</sup> The latter point also convinced Professor Cash that look-back would not be appropriate at that time<sup>397</sup>. Dr Gunson and the English RTDs in particular were unenthusiastic about instituting a look-back programme<sup>398</sup>.

174. The ACVSB committee met on 25<sup>th</sup> February 1991<sup>399</sup>, and decided that look-back should not be undertaken “as a service”. Dr McIntyre of SHHD was present as an observer. As Professor Cash accepted in evidence<sup>400</sup>, that committee was a UK committee and provided advice to Scottish Ministers as well as Ministers in England & Wales. Thus, at this stage, advice to Ministers was that look-back should not go ahead<sup>401</sup>.

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<sup>395</sup> Although early results from an Interferon trial in the USA were available from 1986 (Hoofnagle, LIT.001.3806), referred to in Professor Hayes’ report (PEN.018.8240), those results do not appear to have been well known in the UK in 1990/1991 (see Professor Cash in evidence (Day 85, p28) and the efficacy of Interferon treatment remained controversial even in 1994 (compare PEN.018.0001). Treatment with Interferon was not generally available in the UK until 1995-96 (PEN.018.1186 at 1213).

<sup>396</sup> SNB.008.4848

<sup>397</sup> Day 85, pp.26-28

<sup>398</sup> Day 85, p.10

<sup>399</sup> SNB.001.8934

<sup>400</sup> Day 85, p.32

<sup>401</sup> Dr Keel, Day 86, p.110

175. During this period, few other countries had decided to carry out a look-back exercise. The United States in particular had decided not to do so<sup>402</sup>. Some in Scotland felt, however, that look-back should at least be attempted. Dr Gillon had formed an ad-hoc working party to develop protocols for HCV testing and donor counselling. The Working Party's report to the National Medical Director, dated 23<sup>rd</sup> November 1990 included a clear recommendation that look-back should be instituted<sup>403</sup>.

176. On 12<sup>th</sup> March 1991, Professor Cash wrote to Dr Gillon indicating that in his view, there should be no look back "in the light of national events".<sup>404</sup> Dr Gillon was "appalled" by this decision. He understood that the decision not to institute look-back had been taken partly on ethical grounds, but took the opposite view<sup>405</sup>. Accordingly, at some point between March and September 1991 he decided that his region, South-East BTS, would go ahead with look-back in spite of the UK decision not to do so<sup>406</sup>. While his programme became known as a pilot study, in reality it was no such thing.

### **1993-1994**

177. Matters continued on this basis until 1993, when Professor Cash's interest in the topic was once again piqued when he attended a symposium at which improved treatments for HCV were discussed<sup>407</sup>. The MSC committee of SNBTS discussed the "principles of look-back" at its meeting of 10<sup>th</sup> November 1993, but it was felt that further discussion was required, and Dr McClelland was to circulate look-back information produced by SERTC. It is unclear whether this was information arising from Dr Gillon's "pilot study" but it does not appear that such information was forthcoming before the next meeting of the MSC committee in May 1994<sup>408</sup>. Meantime, Professor Cash wrote to Dr Gunson on 18<sup>th</sup> November 1993 indicating

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<sup>402</sup> Dr Gillon, Day 86, p.33-34

<sup>403</sup> SNB.001.8779

<sup>404</sup> SNB.005.1689

<sup>405</sup> Day 86, p.31

<sup>406</sup> Dr Gillon, Day 86, p.32

<sup>407</sup> SNB.005.2107

<sup>408</sup> Dr Keel, Day 86, p.143-4

that the Scottish RTDs had “stepped back” from introducing look-back until such time as further UK deliberations had taken place.<sup>409</sup>

178. By the time of the next meeting of the SNBTS MSC on 18<sup>th</sup> May 1994, the results of Dr Gillon’s look-back scheme were available, albeit that these were not published until later<sup>410</sup>. Although the minutes<sup>411</sup> of that meeting do not reflect the fact, the vast majority of the meeting was given over to consideration of the issue. Dr Gillon gave a presentation on look-back which made a powerful impression on Dr Keel, who had recently taken over Dr McIntyre’s responsibility for blood transfusion issues at SHHD. In the light of Dr Gillon’s work, she was “absolutely convinced” that look-back was feasible, and indeed that it was “the right thing to do for a whole raft of reasons”<sup>412</sup>.

179. Her first reaction appears to have been that look-back was really a matter for SNBTS to take forward if they thought fit. She doubted whether SHHD truly had a locus in the matter and thought it might really be an issue for the professional judgment of the transfusionists. However, the matter was somewhat sprung upon her at the meeting of 18<sup>th</sup> May<sup>413</sup>; she was a relatively inexperienced SHHD medical officer at that time; and understandably she was concerned that there might be wider issues which would require to be considered by SHHD and in the UK context. She accordingly asked SNBTS to give her an opportunity to consult with her colleagues before taking matters forward. She was clear on leaving the meeting, however, that having heard Dr Gillon’s presentation it was up to her to persuade her policy colleagues that look-back was the right thing to do<sup>414</sup>.

180. Matters then took an unexpected turn thanks to Mr McIntosh’s memo indicating that SNBTS proposed to start look-back on 1<sup>st</sup> June<sup>415</sup>. This seems to have come as a surprise even to his colleagues.<sup>416</sup> A meeting between SNBTS and SHHD

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<sup>409</sup> SNB.005.5560

<sup>410</sup> LIT.001.3802, published 21<sup>st</sup> July 1994, the study having been completed in 1992 (Gillon, Day 86, p48).

<sup>411</sup> SNB.009.9331

<sup>412</sup> Day 86, pp.130, 157

<sup>413</sup> Dr Keel, p.124

<sup>414</sup> Day 86, p.135

<sup>415</sup> SNB.008.4779

<sup>416</sup> Professor Cash, Day 85, p.101

representatives took place on 24<sup>th</sup> May, at which, in spite of Mr McIntosh “jumping the gun”<sup>417</sup> SHHD officials gave SNBTS representatives a “sympathetic hearing” on look-back<sup>418</sup>. Indeed, it appears clear that SHHD agreed at that meeting – at least in principle - that SNBTS should take steps to implement a look-back exercise, subject to SNBTS producing written details of the mechanics of a look-back exercise<sup>419</sup>.

181. It would appear however, that at that stage it was envisaged that the look-back would be taken forward on a UK-wide basis<sup>420</sup>, and as at 30<sup>th</sup> May the issue was being taken forward by SHHD and the Department of Health on that basis, consistently with the long-held view that in matters related to blood transfusion policy there ought to be a common approach north and south of the border<sup>421</sup>.

182. By the time of the general issues meeting of 21<sup>st</sup> September 1994<sup>422</sup>, SNBTS had “still not produced suitably detailed papers on the costs and consequences of a look-back”, and it was noted that although hepatologists appeared to be in favour of look-back, the Department of Health was apparently not taking the matter forward. SHHD were to monitor the situation.

183. Mr McIntosh produced a summary document on 23<sup>rd</sup> September 1994 as to the costs and consequences of look-back – apparently in response to observations at the general issues meeting on the 21<sup>st</sup>. In it he indicated that SNBTS anticipated being able to have all their preparations in place “within weeks rather than months” from being given the go ahead<sup>423</sup>, and putting the cost at around £50,000 in respect of which funds had already been set aside from non-recurring sources.

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<sup>417</sup> Professor Cash, Day 85, p.98

<sup>418</sup> SNB.008.4783

<sup>419</sup> SNB.009.9601 – Dr Keel’s MSC action list dated 21<sup>st</sup> June 1994 shows that she had by that stage contacted DHSS about the scheme, the condition precedent for which that SHHD would by that time have agreed that SNBTS should implement a look-back policy

<sup>420</sup> Compare PEN.018.0001 at 0004

<sup>421</sup> SNB.008.4784. The arguments in favour of such an approach have rehearsed elsewhere in this submissions.

<sup>422</sup> SGH.004.0840

<sup>423</sup> SNF.001.2187

184. At a meeting of the government's advisory committee, the ACMSBT, on 29<sup>th</sup> September 1994, reasons were put forward why a look-back exercise should probably be instituted at that stage. It is worthy of note, however, that even at that stage, there was strong dissent from that view, notably from Professor Zuckerman. Although some members noted that discussions on look-back were quite far advanced in some regions, for example West Midlands, the matter was deferred to the next meeting of the ACMSBT<sup>424</sup>. Dr Keel could not be present at that meeting.

185. At the next SNBTS general issues meeting, on 14<sup>th</sup> October 1994<sup>425</sup> it was noted that a decision on look-back from the ACMSBT was awaited but that committee was not expected to consider the matter again until December. As noted above, Dr Keel was already entirely persuaded of the necessity of carrying out a look-back exercise and, along with Dr Perry, expressed some doubt as to the ACMSBT's locus in the matter, since look-back was not strictly a matter of blood safety. While she recognised that in hindsight this was a "nitpicking" point, a much more serious issue lay behind the making of it, which was Dr Keel's apprehension that, notwithstanding Dr Gillon's findings, the UK committee might decline to proceed with look-back. She thought that this would have been an undesirable outcome for Scotland<sup>426</sup>.

### ***A decision for Scotland***

186. At around this point SHHD officials decided that it would be appropriate and helpful to obtain legal advice. In broad terms, that advice was to the effect that, standing the feasibility of a look-back exercise, Ministers had a duty to begin look-back as soon as possible<sup>427</sup>. However, it seems clear that SHHD officials, and in particular Ministers' principal medical adviser in the blood transfusion area, Dr Keel, were already persuaded that a look-back exercise was both feasible and necessary from an ethical point of view. The legal advice obtained simply

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<sup>424</sup> PEN.018.0001

<sup>425</sup> SGH.004.0803

<sup>426</sup> Day 86, p.145-6

<sup>427</sup> SNB.008.4848. A copy of the actual legal advice received cannot now be found.

confirmed that view, and informed the letter which was subsequently issued by Lord Fraser to his English counterpart (see paragraph 188).

187. The cost-effectiveness and therapeutic benefits of look-back were unproven at this stage. Indeed, apart from one recent study<sup>428</sup>, most of the evidence suggests that there was and is no benefit to patients in terms of mortality and morbidity from look-back. Accordingly, it is doubtful whether, ethical questions aside, look-back could have been regarded as cost-effective<sup>429</sup>. Nevertheless, SHHD officials were convinced that look-back was appropriate and recommended its implementation in Scotland, in spite of delays south of the border.

188. Accordingly on 21<sup>st</sup> December 1994, Mr Tucker of SHHD wrote to Mr McIntosh of SNBTS instructing him to take look-back forward “as expeditiously as possible”<sup>430</sup>. The next day, 22<sup>nd</sup> December 1994, Lord Fraser, the Scottish Minister of State with responsibilities for Health, wrote to Tom Sackville<sup>431</sup>, his English counterpart, making the points that:-

- (i) Look-back was feasible and practicable
- (ii) Treatment was now available, and that
- (iii) Failure to do so might result in legal liability.

189. Lord Fraser also noted that that the ACMSBT committee had recommended uniform introduction throughout the UK, but indicated that in the light of the legal advice received, he considered that he had “little choice” but to instruct SNBTS to proceed as expeditiously as possible to take forward look-back for all areas in Scotland.

190. The decision to go ahead with look-back in Scotland is a striking example of an instance in which SHHD and Ministers acted quickly and decisively when provided with clear and persuasive evidence and advice on a particular topic, even in the face of delays south of the border.

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<sup>428</sup> PEN.018.0507

<sup>429</sup> See generally Dr Gillon, pp.77-83

<sup>430</sup> SNB.008.4847

<sup>431</sup> SNB.008.4848

**TOPIC C6**

191. The HCV virus was discovered relatively recently, although it is clear that it had been silently present in the blood supply for many years prior to its identification. It is a matter of regret that science in this instance was unable to produce a test for the disease, or treatment for it at an earlier stage, in spite of the best efforts of the best minds. Similarly, it is unfortunate that the full seriousness of the condition took so long to be fully recognised by scientists and clinicians. As the Inquiry has heard, however, the nature of the disease is such that the impact of infection can only be properly seen after many years. Once again, the Scottish Government would wish to acknowledge the courage of those who have been infected and their family members who came forward to provide this Inquiry with an insight into the suffering of those affected by HCV, and the prejudice they sometimes experienced because of the association of liver disease with alcohol abuse. As with HIV, this disease was a disease acquired in many cases as the result of otherwise life-saving treatment, and as with HIV the deep dismay and distress of patients and their families as a result of these infections are understandable. Once again, however, the Scottish Government recognises that in providing treatment, clinicians acted in good faith, and in understandable ignorance of the possible seriousness of the condition. The consequences of these infections have been tragic, and it is earnestly to be hoped that this Inquiry will provide some resolution for patients, families and clinicians alike.