Witness Name: Professor Aileen Keel
Statement No: WITN5736003
Exhibits:
Dated: 13 July 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR AILEEN KEEL

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 08 April 2022.

I, Professor Aileen Keel, will say as follows: -

Section 1: Introduction

Q1. Please set out your name, address, date of birth and professional qualifications.

A1. My name is: Aileen Keel
My business address is: GRO-C
DOB: GRO-C 1952
My professional qualifications are: MB ChB, FRCPath, FRCP (Glasgow and Edinburgh), FRSCE, FRCGP, MFPH.

2. **The Inquiry has seen a copy of your CV (PRSE0001988) and understands you held the following roles; please confirm whether this is accurate:**

i) Senior House Officer then Registrar (General Medical Rotation), Southern General Hospital, Glasgow; August 1977 to July 1979
ii) Lecturer in Medicine, University of Aberdeen; August 1979 to July 1981
iii) Honorary Registrar in Haematology, Royal Infirmary Aberdeen; August 1979 to July 1981
iv) Leukaemia Research Fund Fellow, Royal Hospital for Sick

Children, Glasgow; January 1981 to January 1983
v) Registrar in Haematology, Royal Infirmary, Glasgow; February 1983 to August 1986
vi) Various locum posts at Consultant and Senior Registrar level in haematology at St Mary's Hospital, London and Middlesex Hospital, London; September 1986 to June 1987
vii) Consultant Haematologist and Director of Pathology, Cromwell Hospital, London; July 1987 to May 1989
viii)Honorary Consultant Haematologist, Central Middlesex Hospital, London August 1988 to February 1992
ix) Honorary Research Fellow, Middlesex Hospital, London; August 1988 to February 1992
x) Senior Medical Officer, Scottish Department of Health; March 1992 to December 1998
xi) Honorary Consultant Haematologist, NHS Lothian from 1995
xii) Principal Medical Officer, Scottish Department of Health; December 1998 to June 1999
xiii)Deputy Chief Medical Officer, Scottish Executive Health Department; June 1999 to 2014
xiv) Acting Chief Medical Officer, Scottish Government; April 2014 to April 2015.
xv) Director of Innovative Healthcare Delivery Programme at the Usher Institute of Population Health Sciences and Informatics at the University of Edinburgh.

A2. There are two posts missing from my CV:

(i) August 1976 to February 1977- JHO (medical) Victoria Infirmary, Glasgow

(ii) February 1977 to July 1977 –JHO (surgical) Dumfries and Galloway Royal Infirmary.

I recently (1/05/22) stood down as Director of IHDP and now act as Senior Adviser to the Programme.

3. Please confirm whether you attended the following committees/working groups and add any relevant other working parties or committees which you attended or to which you belonged:

i) Advisory Committee on the Virological Safety of Blood

ii) Scottish National Blood Transfusion Service Medical and Scientific Committee
iii) Scottish National Blood Transfusion Advisory Committee
iv) Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation
v) Working Group on Blood and Blood Products
vi) Coagulation Factor Working Party.

A3. I confirm that I attended the committees and working parties listed.

4. Please confirm whether you have provided evidence to or have been involved in any other inquiries, investigations, criminal or civil litigation in relation to HIV and/or Hepatitis B and/or Hepatitis C infections and/or vCJD in blood and blood products, and please provide details of your involvement.

A4. I gave evidence, on behalf of the Scottish Government, to the Penrose Inquiry into the transmission of blood borne viruses to people in Scotland in the course of NHS treatment, the final report for which was published in 2015.

5. Please describe your clinical experience in relation to the treatment of patients with bleeding disorders, and in relation to blood borne viruses (in particular hepatitis), before joining the Scottish Office.

A5. I started training in haematology in 1979 and all of my subsequent NHS clinical jobs involved an element of managing patients with bleeding disorders. During the course of my training, I became increasingly aware of the risks of viral transmission through use of blood and blood products, particularly after the discovery of HIV in 1984 and HCV in 1989.

6. You have previously explained to the Inquiry that you worked with Professor Ludlam at the Edinburgh Royal Infirmary (ERI) in a weekly general haematology clinic, from April 1995 (WITN5736001).

a) Other than your work at the ERI, what were your professional connections with Dr Ludlam? Did you work on any committees or working groups together?
b) Did you ever undertake clinical work at Yorkhill Hospital, in particular the care of patients with bleeding disorders, and/or with Dr Willoughby?

What if any knowledge or experience did you have of the approach to the treatment of such patients at Yorkhill?
c) You co-authored the publications "Alternating Chemotherapy for Childhood Hodgkins Disease" (Lancet) 1982 and "Early Management of Acute Leukaemias" (Emergencies in Medicine, Pitman Press) 1984, with Dr Willoughby. What was your professional relationship with Dr Willoughby?

A6.

a) I regularly attended meetings of the Coagulation Factor Working Party which was chaired by Professor Ludlam and involved SNBTS and Haemophilia Directors from Scotland and Northern Ireland.

b) Between January 1981 and January 1983, I worked at Yorkhill Hospital as a Leukaemia Research Fund Fellow. This was a trainee post in paediatric haematology under Dr Willoughby's supervision and the majority of my time was spent in looking after children with leukaemia or other malignancies. Most of the care of haemophilia patients was undertaken by other staff members, including Dr Willoughby. Occasionally I was required to prescribe FVIII concentrates to patients. I was aware at the time that Dr Willoughby preferred to use commercial concentrates rather than PFC products.

c) Dr Willoughby was my line manager.

Section 2: Scottish Home and Health Department and Scottish Department of Health

7. Please describe the organisational structure at the Scottish Home and Health Department (SHHD) and Scottish Office during your time there.

A7. The Scottish Home and Health Department was part of the Scottish Office. Post devolution in 1999 it was renamed the Scottish Executive, subsequently Scottish Government, which included the Health Department (now Health and Social Care Directorate General). The Chief Medical Officer, Deputy Chief Medical Officer and Senior Medical Officers provided clinical advice to policy officials and Ministers. The teams and Divisions responsible for blood safety and infected blood moved around several times over the years within the Health Department. If you require more information on any specific points, you may wish to ask the Scottish Government if they can provide further details.

8. Please describe your role, functions and responsibilities as Senior Medical Officer (SMO), Principal Medical Officer (PMO), Deputy Chief Medical Officer(DCMO) and Acting Chief Medical Officer (ACMO).

A8. In my roles as SMO, PMO, DCMO and Acting CMO I provided advice and support to Ministers in my areas of responsibility, including handling of long term strategic planning and immediate issues/problems of the day. At the beginning of my civil service career, I had a relatively limited portfolio, but this grew over the years. As DCMO and Acting CMO I had to have an awareness of all health-related matters.

A8. In your draft statement, you state that you had a *'relatively limited portfolio, but this grew over the years.'*

a) Did you hold any responsibility for blood and blood products as SMO and/or PMO?

   I held responsibility for blood and blood products as both SMO and PMO.

b) Was blood and blood products your area of responsibility as DCMO?

   Yes.

9. Please explain the position of the DCMO and Chief Medical Officer (CMO) within the Scottish Office/SHHD, and the administrative structures that were in place to

(i) support the DCMO and CMO for Scotland, and
(ii) administer health policy more generally.

A9. The CMO is the most senior medical adviser in SG and is supported by a team of consultant level doctors, as well as a private office of administrators. The DCMO by definition has to be able to deputise for the CMO as required. Both posts require strong links to policy teams in health and to other relevant government departments, as well as the NHS.

10.Please explain the role that the DCMO and CMO played in:

a) Advising ministers;

b) Formulating and implementing policy;

c) Recruiting and managing medical and administrative civil servants;

d) Advising doctors and other medical practitioners;

e) Providing information and advice to patients, and/or the general public.

A10.

a) and **b)** In terms of advising Ministers, the DCMO and CMO would be required to provide authoritative medical advice and contribute to the formulation and implementation of policy. Once an issue was identified as having the potential to impact population or individual health, the CMO and DCMO would discuss with policy colleagues and contribute to Ministerial briefings at all stages, gathering intelligence through relevant networks. If communication was required with the NHS or other health-related bodies, often this would be in the form of a CMO letter.

c) The DCMO and CMO had overall responsibility for medical recruitment, but administrative colleagues were usually involved at the interview stage of any appointments.

d) and **e)** The DCMO and CMO would be involved in advising NHS clinical colleagues on relevant issues, through the issuing of CMO letters, which were regarded as authoritative advice from the centre, to be implemented by the service. Advice to patients and/or the general public was largely the responsibility of Health Boards.

11. Please describe how relationships between the medical and administrative civil service were managed within the SHHD/Scottish Office.

A11. Different line management arrangements were in place for medical and administrative civil servants, given that they operated in different teams. To make a success of joint working on decision making/ policy development required credibility, mutual respect and the ability to work across boundaries. In my experience this was almost invariably the case.

12. How were information and issues brought to your attention as DCMO? In particular, please explain:

a) What criteria determined whether a matter was of sufficient importance to be brought to your attention?

b) Who would make those decisions?
c) How effective the process was, in your experience, in ensuring that you were suitably informed of the key issues relevant to your post during the period of your tenure as DCMO for Scotland?

A12. I had a variety of intelligence gathering networks, clinical and non-clinical, e.g. through DH and the devolved administrations and contact (both formal and informal) with internal and external sources. As DCMO I met regularly with NHS Board CEs, Medical Directors and DsPH, as well as the Scottish Academy of Medical Royal Colleges etc. Importantly, I had weekly meetings with all of the departmental doctors to catch up on headline issues. I had an "open door" policy with departmental and external contacts and was often contacted directly by Medical Directors and DsPH seeking advice.

a) Any issue of potentially adverse impact on health, at population or individual level, would be brought to my attention.

b) An ethos of open exchange encouraged colleagues to let me know about any issues on their radar screens.

c) In my experience the processes described above were highly effective in keeping me informed.

13. Please describe how SSHD officials brought information or issues to the attention of ministers. In particular please explain:

a) What criteria determined whether a matter was of sufficient importance to be brought to the attention of ministers?
b) Who would make those decisions?
c) How effective the process was, in your experience, in ensuring that ministers were suitably informed of the key issues with which the SSHD was concerned?

A13.

a) I'm afraid I cannot answer that question as I would be speculating. Given I was not a policy official, the Inquiry may wish to ask one of the officials at the time as they may be better placed to give a view on this question.

b) See a) above.

c) At this distance, it is difficult to comment accurately. Ministers certainly received many submissions on issues relating to infected blood, which I was copied into.

14. How did your role change when Scotland devolved and some powers previously held at Westminster were transferred to the Scottish Executive?

A14. My recollection is that the main change post-devolution was that there was much more face to face briefing of Ministers.

15. Please explain how relationships between the Scottish Office/SHHD and the Scottish National Blood Transfusion Service were managed. How effective was communication between the organisations?

A15. SO/SHHD had regular meetings in St Andrews House with key SNBTS colleagues. In addition, I regularly attended meetings of the SNBTS Medical and Scientific Advisory Committee and had ad hoc meetings with SNBTS colleagues as required. Communication between the organisations was highly effective.

16. Please explain how relationships between the Scottish Office/SHHD and the Common Services Agency were managed. How effective was communication between the organisations?.

A16. I have no clear recollection of how relationships between SO/SHHD and the CSA were managed. The CSA CE would have attended departmental meetings between Board CEs and senior colleagues, and departmental "sponsors" of the various CSA divisions would have met regularly with the heads of those divisions, as described above for SNBTS. In that instance, communication was highly effective.

17. What if any contact would SHHD officials (including the DCMO and CMO) have with the DCMOs or CMOs for England, Wales and Northern Ireland?

A17. In the early years following my initial appointment, there were a number of CMO England led meetings of civil service doctors between DH and the devolved administrations, where we did a "show and tell" on some key issues. Kenneth Calman had been CMO Scotland prior to being appointed as CMO England. When he demitted office, those meetings were discontinued. The four CMOs met formally four times a year, rotating host countries.

18. Please describe in broad terms the relationship between the SHHD/Scottish Office and the Department of Health in London (DH) in respect of health

policy in Scotland during your time as SMO, PMO, DCMO and ACMO, with particular reference to policy related to blood and blood products. In particular please consider the following:

a) How much oversight if any did the DH retain over health policy decisions made in respect of Scotland? Please provide any relevant examples.
b) To what extent did the SHHD/Scottish Office interact with and influence the DH on matters relating to blood and blood products?
c) To what extent did the SHHD/Scottish Office attempt to align its policies and activities with those of the DH on such matters?
d) How would disputes between the DH and the Scottish Office/SHHD be resolved? Please provide any relevant examples.

A18.

a) In my experience DH did not have any "oversight" of policy decisions made in respect of Scotland, either pre or post devolution. From its inception the NHS in Scotland has always differed substantially from that in England, e.g. structure and funding mechanisms. There was, however, a general desire across all four countries to act on a UK basis in relation to policy decisions in key areas on such things as blood and blood products.

b) SHHD/SO interacted closely with DH in relation to blood and blood products, principally through representation on decision making bodies such as ACVSB and MSBT. Any differences in approach between Scotland and England would be aired and resolved in those committees, or in follow up discussion/correspondence.

c) As indicated above, there was a general, four country, desire for decisions around blood and blood products to be made on a UK-wide basis, to provide a consistent approach wherever possible. For example, it was viewed as important to have a standardised approach to the testing regime for Transfusion Transmissible Infections applied to blood donations, to avoid potential public and clinician confusion and allow "mutual aid" in times of shortages.

d) See answer at b) above. One example which comes to mind is that of ALT testing, which was proposed by BPL when it was embarking on an alliance with a commercial plasma

processing company (Miles) – see para 32 below. As indicated, there was a difference of approach between Scotland and England. The Scottish view ultimately prevailed.

Section 3: Hepatitis/developments in product safety 1992 - 1994

19. On 28 March 1992 an article was published in the Lancet describing an outbreak of Hepatitis A amongst patients with haemophilia in Italy, all of whom had been treated with Factor VIII concentrate manufactured in Italy, using donations from the USA and Italy (SBTS0000026_027). The plasma had tested negative for HBsAg and anti-HIV and was treated with solvent and detergent. The authors of the article had recommended haemophilia centres consider vaccination of IgG antibody seronegative patients with haemophilia and the use of alternative concentrates.

a) Were you aware of this article or the outbreak? If so, what action did you or the Scottish Office take?
b) Did you give any advice on the issue?
c) What was your general view at this time of the risks of hepatitis transmission from plasma?

A19.

a) I have no recollection of the Lancet letter.

b) I have no recollection of giving any advice on the issue. In March 1992 I would have been in post in SOHHD for only a few weeks.

c) I was aware of the risk of transmission of hepatitis (and other) viruses from plasma.

20. The Coagulation Factor Working Party produced an annual report on 15 May 1992 (PRSE0004830). By way of background, you were listed as in attendance at the meeting of the Coagulation Factor Working Party on 1 May 1992 (SBTS0000260_016).

a) Please explain your understanding of the decisions made about the source of Factor VIII concentrate and the planned transition from the use of "Lille VIII" concentrate to "Tartan VIII".
b) What were the differences between each product and the reason

behind the planned changes?

A20.

a) Lille VIII was HP FVIII manufactured in Lille from French plasma. Tartan FVIII was HP FVIII manufactured from Scottish plasma in the PFC, using the Lille technology. My recollection is that SNBTS were not in a position to immediately swap technologies, in the interests of maintaining FVIII supplies in Scotland. Therefore, there needed to be a transition period, involving a Semi-Tartan FVIII product, which was manufactured from Scottish plasma in Lille. Each of these new products also had to undergo clinical trials in Scottish patients, to determine their safety and efficacy.

b) My understanding, having revisited the relevant documents, was that SNBTS had for some time been keen to develop a new, high purity (HP) FVIII product. This would have had the clinical benefit of minimising the protein load associated with less pure products, and therefore the risk of the patient developing FVIII inhibitors.

21. In the meeting of 1 May 1992, the minutes record that "*no Z8 had been manufactured from HC-tested plasma and accordingly could not be issued by the SNBTS after 31 December 1992 unless current CPMP proposals were altered. It was agreed that the Haemophilia Directors would discuss this and report back to the SNBTS*". Were you involved in discussions about how to resolve this issue, and if so, what options were discussed?

A21. I have no recollection of being involved in discussions around the Z8 issue.

22. On 12 May 1992 there was a meeting of the SNBTS Medical and Scientific Committee (SBTS0000452_096). You attended the section of the meeting regarding the Protein Fractionation Centre. Dr Perry raised an issue with acceptance of plasma for fractionation: there appears to have been a difference in approach between the exclusion of patients from plasma pools and removal from the donor register following "ELISA positive" and HCV positive screening results. It was proposed that Scotland pursue a separate policy from England and Wales "*particularly because of donor counselling concerns*" and the Committee agreed to obtain expert opinion, liaise with the Scottish Office and research the practicality of the proposal. What liaison took place and what was the outcome of the discussions? You may be assisted by the following documents: (SCGV0000057_057, ARCH0003309_001, SCGV0000121_074,

SCGV0000196_015) What was the Minister's final decision on whether anti-HBc testing should be introduced by the SBTS, and what input did you have into that decision?

A22. The MSC minutes of 12 May 1992 indicate that Professor Cash was to contact Dr Eddie Follett, head of the Regional Virus Laboratory at Ruchill Hospital, Glasgow, and that he would also liaise with the Scottish Office over policy. He subsequently wrote to the CMO on this matter. SCGV0000057_057 seems to be about Dr Perry contacting the MCA on the matter of HAV (**not HCV**) transmission by coagulation factor concentrates, but I am confident that he was also in touch with the MCA on the issue of products manufactured from non HCV tested plasma prior to January 1993. Indeed, my email to the CMO on 18 August 1992 [SCGV0000163_006] confirms this to be the case.

The outcome of these discussions was a policy decision and recommendation to the Minister to agree with the SNBTS proposal to continue to produce specialist products from existing non HCV tested stocks from 1 January 1993 to 31 December 1995 at the latest, seeking approval from the CSM to release product to the market place, on a case by case basis [SCGV0000121_074].

I assume the reference to **anti-HBc** testing in this paragraph is a typographical error and the final question relates to the ongoing manufacture of special products by the PFC from non HCV tested donors, as mentioned above? The Minister agreed with the recommended decision. As in all such matters, I would have provided the necessary clinical advice to develop the policy decision to support SNBTS' proposal. I would have pointed to the strong safety record of PFC's manufacturing processes in reducing the risks of viral transmission, as well as the threat to continuity of supply if this policy was not implemented.

A22. In your draft statement, you state that *'I assume the reference to **anti-HBc** testing in this paragraph is a typographical error and the final question relates to the ongoing manufacture of special products by the PFC from non HCV tested donors, as mentioned above.'* Please can you clarify which document you are referring to here?

I am referring to the reference in the final sentence of question 22.

23 Dr Cash and Dr Kendell wrote to each other on the same issue on 14 May and 1 June 1992, copying you in (SBTS0000058_075, SBTS0000002_033). Dr Kendell said he

understood Dr Cash's concerns about the potential effects on volunteers and that he had asked you to "*discuss the problem with her opposite numbers in the Department of Health and try to find out whether we can get the present December 1992 deadline extended*". On 17 August 1992 you wrote to the CMO providing an update on the issue (SCGV0000163_006).

a) Please explain the difference between the English and proposed Scottish approach, and the rationale behind the differing approaches?
b) What did you understand the donor counselling concerns to be?
c) To what extent was cost a factor in deciding which approach to take?
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d) What did you understand Dr Cash to mean when, in his letter to Dr Kendell, he said that potential supply difficulties "*could be politically very embarrassing, not least because it will concern anti-Rh(D) immunoglobulin made from the plasma of immunised male volunteers and use in mothers for the prevention of haemolytic disease of the unborn*"?
e) Did you speak to your opposite number in DH, and what was the outcome?

A23.

a) The English proposed to exclude all HCV ELISA positive donations, whether confirmed or not, from plasma pools. Scotland proposed subjecting ELISA positive donations to further testing, using RIBA/PCR. If confirmatory testing was negative, those donations would be included in plasma pools.

b) In terms of donor counselling, it would be difficult to be clear with donors what (if any) the implications of a positive ELISA test were, if no confirmatory test had been done, as a proportion of ELISA tests would be false positives.

c) I have no recollection of cost being a determining factor in terms of testing.

d) Professor Cash is referring to Anti-D immunoglobulin, manufacture of which requires the immunisation of male adult volunteers with Rhesus positive red blood cells (a medical intervention), to prevent/treat haemolytic disease of the new born. Both of these might be

perceived as emotive areas, particularly the latter. If supplies of Anti-D were not maintained, this could result in the death of babies.

e) Given that the CMO had asked me to contact DH about the issue of extending the CPMP deadline of December 1992, I would have done so. However, I have no recollection of the outcome of that conversation.

24. It appears that Dr Perry expressed concern that plasma products made from material not screened for anti-HCV would not be usable after 31 December 1992 and this would lead to the destruction of considerable amounts of plasma. The Committee agreed he should look into this further (see further SBTS0000375_082) and Dr Cash should write to the CMO to express the concerns held by the Committee. Were you involved in advising the CMO on this issue? What was your view?

A24. My briefing note to the CMO of 18 August 1992 [SCGV0000163_006] uses the phrase "As you are aware…" at para 2, in relation to HCV testing of plasma for fractionation. Clearly, therefore I was involved in advising the CMO. My view was that the SNBTS proposals in this area were entirely logical.

25. What was the impact of the transition to HCV-tested plasma on stock levels and cost from 1992? You may wish to consider SBTS0000376_031.

A25. Dr Perry's letter of 22 September 1992 was in response to my queries around the **potential** impact on product supply in the event that the CPMP recommendation had to be followed to the letter. This would have resulted in the loss of significant stocks of specific immunoglobulin products, such as anti-D, which could not be retrospectively tested for HCV. Replacement costs of these products would have been considerable, and in some instances, products would have been unavailable in the quantities needed to supply the Scottish population. In the event, none of this came to pass because of Ministerial agreement to adopt the approach outlined in Mr Tucker's submission of 24 December 1992 [SCGV0000121_074].

26. On 19 July 1992 Dr Cash wrote to Dr Kendell regarding the Advisory Committee on Safety of Blood, expressing his concerns about the adequacy of SNBTS input into the Committee and the openness of its output (RCPE0000203_002). He also advised that steps should be taken to invite members of the Committee to declare any financial interest in commercial institutions contributing to the safety of blood. Dr Kendell's reply to Dr Cash is dated 3 July 1992 (SBTS0000645_016). You were not copied into either of

these letters, but Dr Kendell stated that you could be the point of contact if Dr Cash wished to raise any matter at a subsequent meeting.

a) Were you aware of the difficulties between SNBTS and the ACVSB?
b) Was information sharing a problem?
c) Did you know of any member's financial interests, and do you know what Dr Kendell meant when he said he was assured the issue of financial interest would "*shortly be solved anyway*"?
d) Did you receive requests from SNBTS to raise matters at the ACVSB and if so, what was the nature of these requests?

A26.

a) I was aware of difficulties between Professor Cash and ACVSB. He was not a member of the Committee, although two of SNBTS' staff were (Drs Mitchell and Perry). I gained the impression that Professor Cash felt that he should be on the Committee, particularly as his opposite number in England was a member.

b) I was not aware of any problems with information sharing.

c) I had no knowledge of members' financial interests and I don't know what Dr Kendell meant.

d) I have no recollection of being asked by SNBTS to raise matters at ACVSB.

27. On 7 September 1992 Dr Cash wrote to Dr Gunson, copying you in, about the discussion at the Advisory Committee on Transfusion Transmitted Diseases on 3 September 1992 and expressed views about Bio Products Laboratory being motivated by market forces rather than the welfare of blood donors (SBTS0000376_028).

a) Were you familiar with the issues he raised?
b) What was your own view about the difference between approaches of the SNBTS and BPL?
c) In your view, did the manner in which the organisations were funded create any difference in approach?

A27.

a) It is not clear to me, given the passage of time and the somewhat cryptic nature of his letter, what issues Professor Cash is referring to.

b) My recollection is that BPL was established on a commercial basis unlike the PFC, which was/is centrally funded. BPL cross charged the NHS for blood and blood products, whereas SNBTS did not. I supported the central funding approach, with SNBTS' principal aim being the achievement of self -sufficiency in the provision of safe blood and blood products for Scotland.

c) BPL were much more likely than SNBTS to purchase commercial products to cover shortages in blood products.

28. The minutes of the Coagulation Factor Working Party on 22 January 1993 (LOTH0000051_054) record that "*Factor VIII concentrates may transmit HAV and that this was of major concern to haemophilia directors*". This issue was also raised again in a meeting of the SNBTS Scientific and Medical Committee, held on 9 and 10 March 1993, at item 4.2.9 (STHB0000677).

a) Did you share this concern?
b) Were any steps taken by the Scottish Office to inform patients of the potential risk or to encourage clinicians to inform patients?
c) What steps, if any , were being taken by the Scottish Office at this time to assist SNBTS enable the second viral inactivation step?

A28.

a) I shared the general concern (held in particular by haemophilia and BTS doctors) that blood products were capable of transmitting infection, as had been clearly demonstrated in the mid-80's by HIV transmission. This had resulted in strenuous efforts by BTS across the UK to develop effective viral inactivation processes. However, in this specific case of HAV transmission, I was reassured that:

i) the implicated product (Octoplas) was subject to very different viral inactivation processes from those used by the PFC
ii) there had been no reports of HAV transmission by PFC or Lille HP FVIII.
iii) batches of PFC HP FVIII had been tested for HAV and were PCR negative.
iv) PFC colleagues were fully involved in the investigations at European level into the possible cause of the Octoplas problem. At that stage this was far from clear.

b) As indicated above, there was no evidence that there was any risk arising from PFC products that merited communication to clinicians or patients.

c) SNBTS efforts to develop a second viral inactivation step that did not result in major reduction in product efficacy were strongly encouraged by the Scottish Office, in the pursuit of ever increasing safety.

29. On 26 March 1993 you wrote to Mr Paton regarding CPMP's position statement on HAV, issued on 17 March 1993: there had been four published reports of outbreaks of HAV in haemophiliacs (SCGV0000121_081). Please explain the rationale behind your view at that time that the "*failure of the solvent detergent method is far from proven*". What did you and Dr Perry conclude about the overall level of risk? A briefing note by Dr Perry dated 2 April 1993 may also assist (SCGV0000121_078).

A29. My view would have been based on discussions with Dr Perry and others which indicated that the jury was out on the cause of the Octoplas problem. At that point it was not at all clear whether it was due to failure of the solvent detergent/ion exchange methods used in its production. Potential alternative explanations included use of donor plasma with a high virus load, or failure of GMP steps, e.g. sewage contamination of the manufacturing plant. Based on the evidence provided by the PFC (and itemised in Dr Perry's briefing paper), I concluded that the risk of transmission of HAV by PFC products was extremely low. In addition, the surveillance programme in place to monitor possible virus transmission by the new HP FVIII product was extremely robust.

30. On 12 October 1993 you wrote to Mr Panton, to inform him of the view of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation that anti-HBc testing should not be introduced (SCGV0000196_034). The meeting took place on 4 October 1993 (MHRA0020214).

a) Did this represent your own view?
b) What was your understanding of the rationale behind this decision?

A30.

a) Yes.

b) My understanding, based on the evidence presented, was that:

i) the number of "window period" cases likely to be detected by anti-HBc testing was small.
ii) the associated costs at £3m annually would represent a very significant opportunity cost for the NHS.
iii) the standardisation of available tests was not satisfactory, and suitable confirmatory tests were not available.
iv) use of the test was far from widespread in Europe and the EC and WHO did not include it in their guidelines for viral testing.

31. The minutes of the SNBTS Medical and Scientific Committee, held on 17th August 1994 (STHB0000683), recorded that it was not thought appropriate to gain informed consent pre-blood transfusion, although it was the clinician's responsibility to advise on risk. Did you have any input into this discussion? What were your views on this approach?

A31. I do not recall having any input to the discussion. I agreed with the decision not to introduce formal consent to blood transfusion on the grounds that clinicians already had a duty to advise patients on the risks of transfusion. I supported the intention to reinforce this message through the BCSH. In addition, I was aware of the general clinical consensus, supported by legal advice, that the introduction of formal consent to transfusion would not be appropriate. My recollection is that the view of clinicians at that point was that the process of formalising consent to transfusion would be logistically difficult in terms of NHS processes and would not add value to the existing duty on doctors to inform patients of the risks of transfusion.

32. In a memo from you to Mr. G. Wildridge dated 17 August 1994 (SCGV0000053_094) you gave your view on a number of developments related to commercial involvement in BPL and reorganisation of transfusion centres. At point (iii) you explained your view that ALT testing had no scientific rationale for introduction in the UK. Please explain your view. What were the perceived benefits and drawbacks of ALT testing? Why did you describe the proposal to introduce it as "*extremely controversial*" with blood transfusionists?

A32. It appeared to me that BPL were proposing to introduce ALT testing simply to align with their new commercial partner's (Miles) testing requirements. HCV testing had been introduced three years earlier, and the clinical consensus was that this was a far more effective means of detecting HCV than using a surrogate marker such as ALT. The latter is by no means specific for HCV (or indeed any other virus) and can be elevated for a whole variety of reasons, including excess alcohol consumption and obesity. This view, I understood, was shared by

transfusionists in many countries where ALT testing was still in place, in spite of the introduction of HCV testing. There appeared to be absolutely no clinical rationale behind BPL's recommendation to introduce the test.

Section 4: Look-back exercise relating to HCV infection from blood transfusion/products

33. When you took up your post as Senior Medical Officer in 1992, were you aware that a decision had been taken that a lookback exercise would not be undertaken "in the light of national events" despite Dr Gillon preparing an "idealised procedure" for the lookback exercise in November 1990 and the SNBTS Medical and Scientific Committee considering that careful consideration should be given to such an exercise occurring? NHBT0000073_028, PRSE0000348, PRSE0001573, SBTS0003086_004 and PRSE0003568 may be of assistance.

A33. I was unaware of the decision not to undertake a lookback exercise at the time I took up post as SMO in 1992. I have no clear recollection of when I became aware of the decision.

34. If you were aware of that decision, what was your opinion as to whether a lookback exercise should have been undertaken once testing for hepatitis C was available?

A34. See above answer.

35. Please explain your understanding as to:

a. why the SNBTS and the Scottish Office considered and discussed conducting a lookback exercise before the rest of the UK;
b. why, ultimately, the Scottish lookback was not conducted in 1993; and
c. why it was delayed until 1995.
The following documents may be of assistance: PRSE0003635, DHSC0003512_164, PRSE0003928, DHSC0003555_083, PRSE0003685, NHBT0097145_001, PRSE0002093, DHSC0003555_085, PRSE0000874, PRSE0001781, PRSE0002454, DHSC0032208_136, WITN4461155, SBTS0003812_004, SCGV0000165_085 and DHSC0002551_110.

A35.

a) My understanding is that the SE Scotland RTC had an interest in pursuing lookback, originally as a research project. When this project demonstrated feasibility, SNBTS began to discuss the idea of extending it to the other Scottish RTCs, and Professor Cash also began to discuss the idea with his opposite number in the NBA. These discussions predated my appointment to SHHD. However, clearly SNBTS/Scotland was "ahead of the game" in terms of demonstrating the feasibility of conducting a lookback.

b) It is clear from a number of the documents referenced that SNBTS, although keen to pursue lookback, was having to engage in a detailed exploration and discussion of the numerous practical issues which needed to be addressed before proceeding. SNBTS MSC minutes of November 1993 indicate they did not feel in a position to make an organisational policy decision, and that further internal discussions were required. At that point the matter of a **national** policy decision had not been raised with SHHD.

From a personal point of view, it was only at the SNBTS MSC meeting on 18th May 1994, when I heard Dr Gillon give a presentation on the SE Scotland pilot, that I realised that a national lookback exercise would be feasible. At that point I immediately started to put the wheels in motion in terms of achieving an SHHD policy decision in this area.

c) Throughout this whole period there was a desire across the UK BTS to proceed on a four country basis. The other UK countries would have faced very similar practical/logistical issues to those being encountered in Scotland. To ensure that the lookback proceeded as far as possible on an equitable and uniform basis, all of these had to be resolved before it could commence.

36. At the meeting of the Advisory Committee on the Microbiological Safety of Blood on 29 September 1994 (page 4 of PRSE0003670), it was noted that *"approaches to institute HCV lookback in Scotland had been resisted, and it was important that a UK wide approach was adopted"*. Please set out your understanding as to: who had made these approaches; who had resisted them; and why these approaches had been resisted.

A36. I can't answer this question directly, but Mr Tucker's comment may relate to external pressure, possibly from lobby groups, to proceed with a Scottish lookback, in advance of any UK-wide lookback.

37. Were you involved in the decision that a national lookback should be commenced in January 1995? If so, please describe your involvement and set out your understanding of why that decision was taken. PRSE0001046, PRSE0003115, NHBT0009383, PRSE0001386, STHB0000683 may be of assistance.

A37. I was involved in the decision to start the national lookback in January 1995, through a variety of mechanisms, e.g. participation in discussions in advisory committees, as well as directly with SHHD and SNBTS colleagues. The decision to undertake the lookback in the first place was based on changing perceptions of the impact of HCV, the emerging availability of treatment, and the SE Scotland study which demonstrated feasibility. In deciding on a start date, all involved were conscious of the significant practical issues that the UK BTS would have to address (see 35 above). Dr Gillon's paper in Transfusion Medicine in 1994 acknowledges that lookback is "time consuming and difficult", even in a well- supported and integrated service such as that in the SE Scotland RTC.

38. What involvement, if any, did you have in the press briefing, Epinet message and Scottish CMO letter that was utilised to announce the lookback process? What consideration, if any, was given to whether the briefing and letter gave the impression that all patients would be identified by the lookback process? Please consider DHSC0002552_250, DHSC0002551_056, PRSE0000412, SCGV0000165_066, SBTS0003833_322 and HHFT0000002_002.

A38. I have no detailed recollection of my involvement in any of these specific activities. However, undoubtedly, I would have been involved in briefing colleagues, including the CMO, and commenting on drafts. I disagree that the communications give the impression that all patients would be identified through the lookback exercise. Indeed, Dr Metters' press briefing of 11th January 1995 uses the phrase "many, but not all" in relation to individuals who would be identified.

39. Why, to the best of your knowledge, was the decision taken to limit the lookback exercise to those donors who had returned to give blood after September 1991? What consideration, if any, was given to how recipients who had been infected by a donor who had not subsequently donated might be identified? Please consider NHBT0009715, SBTS0000462_085, SBTS0000462_011, DHSC0020692_118, DHSC0004469_013, SBTS0000518, DHSC0002555_010, STHB0000687 and SBTS0003816_083.

A39. My recollection is that there was general agreement that extending the exercise to recipients of blood donated by donors who did not return, would be logistically extremely difficult for the BTS. The view was that any benefit would be disproportionate to the effort required by both the BTS and the wider NHS. Instead, it was agreed that individuals who had received a transfusion prior to HCV testing being introduced in 1991 should be offered a test, as the most effective way of addressing this issue.

40. Please consider SBTS0000463_005, NHBT0088395 and DHSC0004026_032. What consideration, if any, was given to how to identify recipients of infected blood who had not been successfully traced because of problems with records or due to administrative difficulties such as a change of address or name?

A40. I have no clear recollection of the discussions on this point. However, the MSBT minutes of June and October 1998 indicate that documentation and traceability issues arising from the lookback exercise were being given high priority. The BTS were required to produce this documentation in order to demonstrate that every reasonable effort had been made to trace such individuals.

41. What consideration was given to providing further information and / or training to GPs about hepatitis C to assist them in identifying recipients of infected blood? SBTS0003833_421 may be of assistance.

A41. SBTS0003833_421 is a reply from me to Dr Ian Kerr, an Edinburgh GP, whom I presume was writing to me in an official capacity (I don't have access to his original letter). It appears that he was requesting additional resources for Primary Care to contribute to the lookback exercise. I highlighted the fact that approximately 300 patients were expected to be identified across Scotland, so the anticipated burden for any individual practice was not likely to be onerous. In addition, there had been very few queries to SHHD from GPs. Against this background, it was not felt necessary to provide additional information and/or training on HCV to GPs.

42. In October 1995 a decision was taken not to undertake a lookback of recipients of DEFIX who did not have haemophilia. Who made that decision and why? SBTS0003833_084, DHSC0002557_023, STHB0000687, DHSC0003533_123, DHSC0002557_005 and LOTH0000053_101 may be of

assistance.

A42. The DEFIX decision was made by the UK Ad Hoc Working Party on HCV Lookback. The lookback's terms of reference covered only blood and unfractionated blood products, not coagulation factors. Dr Gillon was a member of the group, and agreed with its decision. The Working Party pointed to the enormous logistical difficulties involved in extending the lookback, particularly to DEFIX, whose major use in the NHS was for the reversal of coumarin anticoagulants such as Warfarin. Tracing such patients would require the manual searching of many thousands of patient records as there was no central data collection in this area. In addition, intrinsic to the whole lookback exercise was the ability of patients not covered by its remit to request an HCV test, if they felt that they were at risk of infection.

43. What impact did the risk of legal liability have on the decisions that were made in relation to the nature and extent of the HCV lookback exercise? SCGV0000227_075 may be of assistance.

A43. My recollection is that the risk of legal liability was not a major determining factor in relation to the nature and extent of the lookback exercise, once the policy decision had been made to undertake it. However, I was aware that our legal advice had consistently been that lack of resources would not be a justification for limiting such an exercise.

44. In 1996 and 1997, correspondence suggests that discussions were ongoing about retaining the archive of blood samples (SCGV0000112_131, SCGV0000112_062 and SCGV0000098_166). By letter dated 2 June 1997, Dr McClelland asked for your advice about what to do with the large archive of blood samples held in South East Scotland dating from April 1984 onwards (SCGV0000112_070). Dr McClelland in his evidence to the Inquiry stated that they *"did not, at that time, get the support we needed to establish a proper archive"*.

a) What discussions, if any, did you have with Lynda Towers, Gary Wildridge and/or others about the need to retain archive samples? In your answer please consider SCGV0000112_060.

b) When did the policy in relation to sample retention change? Why did it change?

c) Was it the case (and if so, why) that no support was provided to the South East transfusion service to enable them to retain the archive of samples?

d) What if any consideration was given at that time to the fact that the lookback exercise had been unable to trace a number of recipients of infected blood?

A44.

a) I have no recollection of discussions with Linda Towers and Gary Wildridge on the matter of sample retention. However, from the minutes of a meeting with SNBTS in November 2003, I am recorded as having given SNBTS advice to continue to retain archive samples indefinitely.

b) I cannot recall when this policy changed. I assume it was because of doubts about the ongoing reliability of tests in aging samples and the issue of SNBTS storage capacity.

c) I have no recollection of whether additional support for the SE RTC to retain archive samples was provided. This would have been an internal management decision for the SNBTS/CSA, not for SHHD.

d) My recollection is that the inability to trace a number of recipients of infected blood was largely due to hospital records issues and patient traceability in tracing patients, e.g. patients' change of name/address, rather than an inability to trace archive samples.

45. Why, to the best of your knowledge, was a decision taken to consider the HCV lookback exercise to be closed when a number of patients had not been traced? What relevance to the decision was the issue of providing further resources? (PRSE0003277, PRSE0003957, PRSE0000262, PRSE0004337 and DHSC0004026_033 may be of assistance).

A45. The lookback was closed when a number of patients had still not been traced because, in spite of very significant efforts by SNBTS, activity had tailed off. Over a period of many months, no new patients had emerged in Scotland, MSBT agreed that all reasonable efforts had been taken to trace components and that the tracing exercise could stop. In my view the issue of providing further resources was not a major factor in this decision. SNBTS were instructed to ensure that the reasons for non follow-up of components and recipients were clearly documented and justified on the Lookback Register.

46. On page 7 of SCGV0000044_024 (a briefing to ministers in January 2005,

copied to you) it is stated that "SNBTS conducted a lookback exercise in the early 90s to trace people who might have been infected. The exercise was conducted when a test became available to screen donations". Hepatitis C screening of donations commenced in September 1991. The SNBTS lookback exercise was not commenced until January 1995. Why was the Minister given "the line to take " that the lookback had commenced when a test became available? Do you consider that the "line to take" was accurate and/or candid? Please explain your answer.

A46. I believe this "line to take" was inaccurate, probably due to a less than full grasp of the detail of the chronology around the setting up of the lookback exercise. As highlighted at paragraphs 35 and 37 above, a policy decision was only made in mid-1994 in Scotland to conduct the lookback, following the pilot study in SE Scotland. Thereafter, significant planning had to be undertaken to ensure that the other parts of Scotland, as well as the rest of the UK, were in a position to participate. This required time to ensure that the lookback was conducted as equitably and uniformly as possible.

47. In a letter dated 1 November 1999, (page 1, at paragraph 3 of HSOC0020371), Dr Bill Smith asked for you or the Protein Fractionation Centre to *"trace through invoices/records or any other documentation to find out whether or not some of the blood products from the allegedly less than safe plasma might have found their way to Wales"*. Did you do this? If so, what were your findings?

A47. I would have asked SNBTS/PFC to investigate the allegation (arising from an article in the News of the World) that "unsafe" Scottish plasma products might have found their way to Wales. I have no recollection of the outcome of that exercise.

48. To the extent not already set out above, please describe your involvement in:
a) the decision-making as to whether, and if so when and on what terms, a lookback exercise should be undertaken;
b) the carrying out of the lookback exercise in Scotland.

A48.

a) and **b)** As outlined at paragraph A35. b) above, at a meeting of the SNBTS MSC in May 1994, Dr Gillon gave a presentation (under AOB) on the pilot lookback study in SE Scotland.

I realised that if such a study was feasible in one part of Scotland, it should be feasible in other parts of the country. I immediately set the wheels in motion within SHHD to achieve a policy decision in this area and agreement that the lookback would be conducted on a UK-wide basis. Thereafter I was fully involved in the practicalities of designing and implementing that policy decision, taking account of the considerable logistical challenges that the exercise would present to the UK BTS.

Section 5: Variant CJD

Early understanding of vCJD

49. Please consider the following documents: minutes of a meeting of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation on 2 May 1996, which you attended as an observer (SBTS0000518 point 6.9 onwards); letter dated 13 May 1996 from Dr Metters to Dr Will, copying you in, regarding the outcome of the meeting on 2 May 1996 and Dr Will's study at Western General Hospital, Edinburgh (DHSC0032286_084); letter dated 14 May 1996 from Dr Kendell to Sir Kenneth Calman (Chief Medical Officer for England), copying you in (DHSC0020783_065); minutes of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 18 November 1996 (NHBT0006005); minutes of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 25 March 1997 in particular at items 7.1-7.33 (NHBT0006016); a letter from you to the CMO dated 24 November 1997 to inform him of the outcome of the UK Haemophilia Centre Directors Organisation Extraordinary Executive Committee meeting on CJD and Treatment of haemophilia (SCGV0000112_056); minutes of the Coagulation Factor Working Party meeting 2 December 1997 (GRAM0000005_002).

a) What was your understanding at this time of the risks of transmission of the new vCJD by blood and blood products?
b) Did you agree with the approach of continuing to wait for more definitive evidence that vCJD was transmissible by blood?

c) What actions, if any, did the SHHD/Scottish Office take in response to the issues raised in the meeting of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation on 2 May 1996?

A49.

a) vCJD had only been discovered in 1996 and very little was known about its transmissibility in humans. However, the theoretical possibility of transmission of sporadic CJD by blood

transfusion had been considered for a number of years, and therefore it seemed to me entirely logical to extend that consideration to vCJD.

b) Yes, particularly given SEAC's view that there was no evidence of any human transmission of vCJD by blood transfusion.

c) Dr Will's proposal to set up a pilot research lookback study was considered at the MSBT meeting on 2 May 1996 and the four UK BTS were tasked with working with the CJDSU to develop a study protocol. SHHD would have encouraged SNBTS to fully engage with that exercise. The first draft of the study protocol was in fact produced by Dr Gillon, Dr Will and Dr Hewitt from the NBA and considered at the next meeting of MSBT in July 1996.The CMO's minute to Sir Kenneth Calman on 14th May reinforced the message that Scotland was well aware of the need to be proactive in building the evidence base in this area.

50 Please consider the Minutes of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting on 2 July 1996, in particular item 5 (SBTS0000519).
a) Were you aware of the advice from Professor Ian Kennedy that recipients of blood from a CJD patient should not be informed and the position should be reviewed once a diagnostic test or effective intervention was found?
b) What was your view on this?

A50.

a) I was not at the MSBT meeting on 2 July 1996. As far as I can remember, I was unaware of Professor Kennedy's advice until I read the minutes.
b) I agreed with his view. It seemed to me that telling individuals that they **might** be at risk of an infection which had a universally fatal outcome, but no diagnostic test and certainly no treatment, would not be the right thing to do.

51. On 6 October 1997 the Chief Medical Officer in England issued a statement on CJD and acknowledged the potential for transmission through blood (DHSC0041442_171). Please consider the following documents which discuss the issues surrounding vCJD after the CMO (England) statement: Spongiform Encephalopathy Advisory Committee (SEAC) meeting on 24 October 1997 (DHNI0000041_075); the minutes of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation

meeting on 27 October 1997, particularly at section 5 (SBTS0000522); letter from you to Dr McGovern dated 31 October (NHBT0009040); letter from Dr Metters to Dr Robert Will dated 5 November 1997, copying you in, which sets out the SO's approach as of that date (NHBT0009036).

a) What steps were taken to monitor vCJD in donor and patient populations at this time?

b) What steps were taken to reduce risk to recipients of blood products at this time?

c) How effective was the communication between SEAC and the Scottish Office, and the MSBT and the Scottish Office, during this time?

d) How did the Scottish Office get updates regarding the progression of the understanding of vCJD and the risks it posed?

A51.

a) The CJDSU was the UK body which registered and monitored CJD cases. As part of the CJDSU's pilot research study mentioned above, Dr Will informed the NBS of any cases of CJD (including vCJD) who were known to have donated blood. In October 1997, I asked that these notification arrangements be formalised, and Dr Metters wrote to Dr Will to that effect. Part of the new formalised arrangements was that redacted (i.e. patient's identity removed) letters were also sent by CJDSU to the relevant health department. By 6 March 1998, an SOP had been developed by SNBTS and CJDSU covering the new arrangements.

b) Given emerging experimental (animal) evidence that vCJD theoretically could be transmitted by transfusion, SEAC recommended that an overall risk assessment be undertaken. The UK BTS had already begun to plan for the introduction of leucodepletion of blood donations as a (possible) risk reduction measure and this carried on in parallel with the risk assessment. At that point there were many unknowns and the scientific basis for leucodepletion was very fragile. It was introduced on a UK-wide basis in October 1999. Also in 1999, the use of UK plasma in the manufacture of blood products was abandoned.

In December 1997 a policy of withdrawal/recall of blood components and tissues from patients who had gone on to develop vCJD was instituted. Over subsequent years, additional precautionary measures were introduced, including deferral of previously transfused donors in 2004.

c) SEAC was the overarching advisory group in relation to CJD. I had no direct contact with the committee - that would have been between the public health side of the Scottish Office and SEAC, given that its considerations went much wider than blood and blood products. However, there was close liaison between me and my public health colleagues in this

area. In addition, there were clear and direct lines of communication with MSBT and relevant DH officials which I found to be very effective.

d) In relation to vCJD and blood transfusion risks, my updates following MSBT meetings would have been the main means of briefing SO colleagues in this area. The wider risks arising from vCJD (e.g. dietary spread) would have been communicated by public health colleagues from e.g. SEAC and the ACDP TSE subgroup.

A51. In your draft statement, you state that '*In relation to vCJD and blood transfusion risks, my updates following MSBT meetings would have been the main means of briefing SO colleagues*'. Please could you provide more details about how regular and detailed these updates were.

I would have provided a written update to policy colleagues following each MSBT meeting (I recall these were held three or four times a year) on the key points (eg vCJD) on the agenda, supplemented by verbal briefing as required.

Proposed ban on UK blood products

52. Please consider the following documents: minutes of the United Kingdom Haemophilia Centre Directors Organisation (UKHCDO) Executive Committee meeting, 20 November 1997 (BART0000953); letter from Scottish Chief Medical Officer David Carter to Trevor Jones of Lothian Health, dated 15 December 1997 (SCGV0000116_061); minutes of Coagulation Factor Working Party meeting, 16 January 1998 (GRAM0000008); letter from Professor Franklin to Professor Carter dated 19 January 1998 (SBTS0003131_028); nvCJD Project Action Note by Professor Franklin dated 10 February 1998 (NHBT0001283_003); a note made by you of a meeting between Scottish Office Department of Health and the Haemophilia Society on 28 January 1998 (SCGV0000116_086); memo from John Aldridge to Mr Galbraith and the Secretary of State dated 19 February 1998 (DHNI0000042_071); Note of meeting of SODOH, SNBTS representatives and others on 17 February 1998 (SBTS0003131_080); Memo from Dr Metters to the Secretary of State dated 20 February 1998 (DHSC0004390_118);

Letter from Michael Palmer to Mr Galbraith dated 23 February 1998 (DHSC0004390_109); a letter to Medical Directors from David Carter regarding the announcement of further precautionary measures on blood products, dated 26 February 1998 (LOTH0000670); Scottish National Blood Transfusion Service Procedure for responding to information supplied by the CJD surveillance unit dated 6 March 1998 (NCRU0000111_067).

a) **What was your view on the proposed ban on UK albumin?**
b) **Did you share any of Professor Franklin's concerns about the impact on the patients if the risk of nvCJD transmission through blood products did not eventuate, and if so, what were those concerns?**
c) **What were the Scottish Office doing around this time to address these competing risks and assess the safety of UK sourced plasma in respect of vCJD transmission?**
d) **What were the differences between the English and Scottish Health Department positions on the issue of ban of blood products (both generally, and in respect of albumin alone)?**
e) **Did the Scottish Office consider it was able to deviate from the recommendations of (i) CSM and (ii) CPMP on the safety of products?**

A52.

a) I believed that the safety record of albumin manufactured from UK plasma was excellent and that a move away from use of UK plasma in this regard was unnecessary, in the absence of a CSM pronouncement.

b) I shared Professor Franklin's concerns. At that point we were all very much trying to balance the theoretical risk of transmissibility of vCJD by blood transfusion against the real, and quantifiable, risk of eroding the donor base and risking the blood supply. This would have had serious implications for surgical practice as well as continuity of supply of many plasma products.

c) Given that the risk of transmission was at that point entirely hypothetical and that there was no diagnostic test for vCJD, it was extremely difficult for the Scottish Office to assess the safety of UK sourced plasma in respect of vCJD transmission. However, we were well aware of ongoing efforts within SNBTS to devise ways of demonstrating that PFC

procedures were capable of removing PrP. PFC were also part of a collaborative European study looking at similar areas.

d) Scotland was keen to avoid a wholesale ban on use of UK plasma. Informed by experts in SNBTS/PFC, the Scottish Office believed that the importation of US plasma, given its donor base epidemiology, carried with it quantifiable risks of transmission of infectious agents, e.g. HIV, HBV and HCV. The risk of vCJD transmission by blood/blood products was, by contrast, hypothetical. In addition, it was pointed out that there was no guarantee that the US would not in time also develop a vCJD "problem". Specifically on albumin, SNBTS highlighted its excellent safety record. It seemed to some SNBTS colleagues that England were more keen to move to non-UK plasma fractionation because of commercial reasons relating to the viability of BPL.

e) The Scottish Office did not consider deviating from the CSM recommendations, but was aware that compliance with CPMP recommendations was not mandatory in the UK.

Sourcing blood products from the USA

53. Please consider a briefing note for you from Dr Perry, dated 30 March 1998, regarding SNBTS's view on recommendations to be made at the upcoming CSM meeting (SBTS0003200_049). On 30 March 1998 Peter Foster (Protein Fractionation Centre) sent an email to Dr Perry, setting out the points he felt you should argue at the upcoming Committee on Safety of Medicines (CSM) meeting on vCJD risk (SBTS0003200_050). The minutes of the meeting of the Committee on Safety of Medicines Working Group on TSE and Variant CJD on 1 April 1998 are MHRA0009404.

a) How did you view the suggestion of the Haemophilia Directors that if sufficient recombinant Factor VIII could not be sourced, they would want to use concentrates from US plasma?

b) What was your view on the recommendations at 6.1 and 6.2 of the 1 April 1998 meeting?

A53.

a) The Haemophilia Directors' suggestion seemed to me somewhat lacking in logic, given the increased risk of viral transmission from products made from paid donor plasma, of which they were well aware.

b) I was disappointed that the Committee felt unable to wait a bit longer for the outcome of the PFC partitioning studies, before coming to the decision to ban the use of UK plasma.

54. What role did you have in the decisions made to import FFP? You may find SCGV0000097_039, SCGV0000211_024 and SCGV0000098_139 of assistance.

A54. Once the CSM had made its decision, I and policy colleagues would have supported SNBTS in their efforts to source plasma from outside the UK. PFC had already begun to explore options prior to the CSM's decision.

TMER

55. In 2002 you were notified of the fact that the SNBTS was not willing to participate in the TMER as a result of ethical issues. How was this resolved? You may find NCRU0000298_011 of assistance.

A55. I'm afraid I have no recollection of how the TMER issue was resolved. My colleague Dr Peter Christie (an SMO on the public health side of the house) was in the lead on this matter.

56. In 2004 you expressed concerns about the ethical position relating to patients who had been identified as being at increased risk of vCJD and so placed on a register, being unaware of this fact - SCGV0000098_166 page 2. What steps did you take to bring an end to this arrangement?

A56. Again, I have no recollection of the steps I took, other than that I would have spoken to Dr Christie (recorded as an action in the minutes of the meeting). Dr Christie was the departmental clinical link to the CJD Incidents Panel, and as such would have been in the lead in resolving the matter.

Information provided to patients who had potentially received vCJD contaminated blood products

57. In a meeting of MSBT on 26 February 1998 the issue of informing patients who had received vCJD implicated blood or blood products was considered at item 3.5 (SBTS0000523). The minutes refer to the ethical advice of Dr Winyard issued to NHS Trust Medical Directors on 6 February 1998 (BART0002418). Dr Robinson of the National Blood Service wrote to you on 2 March 1998 enclosing a position statement on the advice to be given to patients in response to a request from you (NHBT0021927_177,
NHBT0001722).

a) Was Dr Winyard's advice, or the position statement, adopted by the Scottish Office?

b) If not, what was the Scottish Office policy sharing this information with patients?

A57.

a) I have no precise recollection of the mechanisms used in Scotland to adopt Dr Winyard's advice, but it **was** adopted. At that point the whole of the UK agreed that patients who had received vCJD implicated blood or blood products should **not** be informed, as:
i) the risk of vCJD transmission was entirely theoretical;
ii) there was no diagnostic test or treatment available;
iii) the disease was likely to have a long incubation period and any individual who was informed would face a lengthy period of anxiety and uncertainty.

b) See above.

58. You attended a meeting on 16 June 2000 to discuss the management of patients who receive blood from donors who later develop vCJD, attended by a number of UK organisations (NHBT0009063_002). Two ethics experts attended the meeting and the issue of information provided to patients was considered.

c) What was the advice of the ethics experts on this issue?
d) Did the Scottish Office seek its own separate advice?
e) What approach was decided on at the 16 June 2000 meeting?
f) Did you agree with this approach and did the Scottish Office adopt it?

A58.

c) The minutes of the meeting do not attribute comments to specific individuals and I don't recall the advice of the ethics experts. However, I do recall that there was a lengthy discussion of the complex ethical issues at play in this area. The group ultimately decided that donor screening processes should be adapted to allow for the provision of further information to implicated donors if they wanted it. It was also agreed that the ten recipients of implicated blood/products who were not eligible to donate, should not be informed.

d) I do not recollect the Scottish Office seeking separate advice.

e) See c) above.

f) Yes, I agreed with the suggested approach and my recollection is that it was adopted by the Scottish Office.

59. On 29 October 2002 you wrote a letter on behalf of the CMO, authorising Directors and doctors to tell patients about potential vCJD exposure (BHCT0004027). why was the decision taken to communicate this information taken at that time? You may find WITN3496016, SCGV0001064_135, and GGCL0000152_001 of assistance.

A59. I have no clear recollection of why the decision was made to inform patients that they had been exposed to vCJD implicated products at that time. However, clearly the ethical issues around whether patients should be informed or not had not been resolved. From the documents referenced, it would appear that advice was awaited from CJD Incidents Panel which was in the process of consulting on interim guidance. The latter had been issued for consultation in November 2001, but a year later was not still forthcoming. In the meantime, UK Haemophilia Directors were being informed by the UK BTS about implicated batches of coagulation factors, and were understandably keen to know whether and how recipients of those products should be informed. In the absence of the long awaited CJD Incidents Panel advice, I suspect that the decision was arrived at in Scotland to change the previous advice.

60. It appears that Haemophilia Directors had raised this issue earlier that year. On 5 March 2002 Dr Ludlam raised the issue with you by email and enclosed a draft letter to send to patients (DHSC0038507_067). Why was authorisation to inform patients not given at this time?

A60. My recollection is that authorisation was not given to the Scottish Haemophilia Directors to inform recipients of implicated products in March 2002, because I was hopeful that we would soon be in receipt of definitive advice from the Incidents Panel referred to above.

Notification exercise from September 2004

61. The SNBTS Notification of vCJD Risk Group held its first meeting on 7 June 2004 (SBTS0003136_123). The minutes indicate that the purpose of the group was to identify recipients of plasma products believed to be at risk of carrying vCJD. The CMO had requested the Scottish Centre for Infection and Environmental Health coordinate the identification of at-risk patients in cooperation with HPA in England. You did not attend these meetings, but it may assist to see the minutes of the last three meetings of the Group: 9 August 2004 (NCRU0000146_119); 16 August 2004 (SBTS0003136_059); 30 August 2004 (NCRU0000146_116). Please explain what input you or the Scottish Office generally had into the notification processes discussed in the meetings. Who was ultimately responsible for ensuring patients were notified that they had received products at risk of carrying vCJD? How was the Scottish Office kept informed of the work of the Group?

A61. I do not recall having any direct input into the work of the SNBTS Notification of vCJD Risk Group. The notification process was UK-wide, and SCIEH had been tasked by the CMO to coordinate the Scottish element. Drs Hester Ward and Martin Donaghy from SCIEH would have been fully involved in developing the details of the notification processes. They would have briefed policy officials and the CMO and me on progress both in the group and across the UK.

The clinicians responsible for the identified patients (mainly Haemophilia Directors) would ultimately have been responsible for ensuring that patients were notified that they had received "implicated" products.

62. Please consider a document drafted by Sandra Falconer (SEHD Health Planning and Quality Division) regarding the notification of patients who had received plasma products manufactured from the plasma of donors who subsequently developed variant CJD, dated July 2004 (NCRU0000143_175): "*The Minister notes the content of this minute and confirms he is content for Scotland to fall in line with the HPA proposal for notification and handling*". The Inquiry understands that the documentation sent to patients and clinicians in the 2004 notification exercise was (CVHB0000011_003). Did you agree with its adoption by Scotland?

A62. I agreed that the documentation should be adopted in Scotland. It had been developed collaboratively by the HPA, with significant input from SCIEH and the UKHCDO.

63. By June 2004 there had been two possible cases of vCJD transmission by blood: see the Extraordinary Meeting of the Advisory Committee on the Microbiological safety of Blood and Tissues for Transplantation attended by you on 29 June 2004 (DHSC0038559_048). Please also consider a chain of emails exchanged on 29 June 2004 between Ed Davis, Dr Peter Christie, and you (NCRU0000146_041).

a) Please explain what you understood by Mr Davis' suggestion that "*the 'umbrella' approach to haemophiliacs was clearly Scotland's preferred solution*".
b) Please explain, within your email to Hester Ward, what proposal you were taking to Ministers and what you intended to recommend.
c) What was known about the 'Glasgow case' at this time?
d) How long had the Scottish Office been aware that the Glasgow case was or might be a case of vCJD transmission through blood product?
e) What did the Scottish Office do with this information once in possession of it?
f) Were there any differences in approach between England and Scotland?
g) To what extent was the HPA leading the Scottish approach at this stage?

A63.

a) The "umbrella" approach refers to the fact that UK Haemophilia Directors wanted to inform all of their patients, even those not implicated in the current incident, to avoid the need to repeatedly contact patients when future notifications occurred.

b) I think my email to Dr Ward refers to the umbrella approach covered above. I supported the Haemophilia Directors' position, and would have recommended that to Ministers.

c) I recall very little about the "Glasgow case", other than what I have gleaned from the referenced documents - the key point being that the unit of blood had been transfused prior to the introduction of leucodepletion. My public health colleague Dr Christie appears to have been in the lead on this matter

d) and e) I do not recall how long the Glasgow case had been known to the Scottish Office, or what was done with the information when it was received.

f) As far as I can recall, the approach taken in England was the same as in Scotland.

g) My recollection is that this was a collaborative joint approach by the HPA and SCIEH.

64. There was a formal announcement by health ministers of further risk reduction measures on 19 July 2005 (NCRU0000145_009), an associated news release dated 20 July 2005 containing a quote from you (SCGV0001058_095), and a letter on the same topic sent on 19 July 2005 (SCGV0001022_008).

a) **What role did you have in these events?**
b) **What prompted this announcement?**
c) **Please explain what steps were being taken to ensure patient safety at this stage.**

A64.

a) From revisiting the papers, it appears that I directed the coordinated Scottish response that was needed from HPS, SNBTS, Health Boards and GPs in relation to the new advice from the CJD Incidents Panel.

b) The announcement was prompted by the Incidents Panel's advice that donors who had donated blood to patients who subsequently developed vCJD, should now be contacted.

c) The contacted donors were advised that they were considered "potentially at risk from vCJD for public health purposes". They were informed that they could no longer donate blood, tissues or organs and that they should inform clinicians before undergoing medical, surgical or dental procedures in order to avoid onward transmission of vCJD. This further precautionary measure was in addition to the raft of risk reduction measures already in place in relation to vCJD and blood transfusion, including withdrawal of blood components/products and tissues obtained from any individual who later developed vCJD (December 1997); importation of plasma from USA and Germany for manufacture of plasma products (1998); leucodepletion ((October 1999); importation of FFP from the US for patients born on or after 1 January 1996 (August 2002); deferral of previously transfused (since 1980) donors (April 2004); and promotion of appropriate use of blood in the NHS.

65. Please consider the minutes of an SNBTS meeting on 16 March 2005(SCGV0000098_227). The paper by Marc Turner referred to at paragraph 2.2.2 is a Brief for the Scottish Executive Health Department dated 8 March 2005 SCGV0000098_054). What was your understanding of Keith Thompson's advice that

"*SNBTS had taken the decision not to proactively inform recipients of exported blood products of the outcome of the vCJD risk assessment*" (paragraph 2.2.1 of the minutes?

A65. I was not at the meeting of 16 March 2005, and am unable to comment on the meaning of Keith Thomson's comment.

66. To what extent were these notification exercises a joint enterprise between the four nations? You may find NHBT0031730_002, DHSC0032258_062 NIBS0000665, HCDO0000869_008 of assistance.

A66. The notification exercises needed to be a joint enterprise between the four nations, not least because, in times of shortages, blood/blood products crossed borders. In addition, Scotland manufactured factor concentrates for Northern Ireland. Sir Liam Donaldson's letter of October 2005 indicates that the four CMOs had been jointly considering the new advice from the Incidents Panel.

Deferral of donors

67. What role did you play in the decision of SNBTS to defer donors who had received transfusions? You may find SCGV0000096_014,SCGV0000211_024 and SCGV0000098_139 of assistance.

A67. As my 2001 minute to policy colleagues following a recent MSBT meeting indicates, the question of whether previously transfused donors should be deferred from further donation had been discussed for some time. I was involved in these discussions through my membership of MSBT. It was recognised that such a policy would have a major impact on the blood supply, and the question of how that could be made up was a major issue. One option under consideration was importation of units of blood from abroad, where SNBTS had undertaken some exploratory work. In 2004, I suggested that they be encouraged to revisit this work, as the policy was again under consideration. It would have been more feasible for Scotland to make up supplies in this way than England, where the larger number of units required would not have been available from abroad.

Purchase of Life Resources

68. You attended a meeting with the SNBTS on 17 January 2003 in which the Department for Health (England) purchase of Life Resources was discussed (SCGV0000097_026). Bob Stock referred to SNBTS's contribution to parliamentary questions about the purchase of Life Resources. The parliamentary questions referred to appear to be those asked by Pete Wishart (SNP North Tayside) and were answered on behalf of the

Secretary of State on 14 January 2003 (DHSC0006216_026). There is an accompanying background document by an unknown author (DHSC0006216_028).

a) Were the Scottish Executive involved in the decision to purchase Life Resources?

b) Were you involved in any discussions (not amounting to decision making) with your England counterparts about the purchase? If so, please explain those discussions.

c) What was your view on whether paid donation was justified in circumstances where stocks were low?

d) How was the decision reached to source Anti-D plasma from paid donors?

e) Was the fact that Anti-D (which represented 10% of SNBTS products) was produced using plasma from paid donors known to the public?

A68.

a) My understanding from reading the documents referenced is that the Scottish Executive were aware that negotiations were ongoing in relation to the purchase of Life Resources, but that they had no interest in the purchase, which was being undertaken purely to address the needs of England and Wales.

b) I have no recollection of having any discussions with counterparts in England about the purchase.

c) My view on the use of products from paid donations was that it was justified when stocks were low, and there was no other way of meeting NHS/patient needs. SNBTS applied rigorous quality and safety criteria to such products in terms of donor testing and the viral inactivation processes used in manufacture.

d) I have no recollection of how the decision was made to source Anti-D from paid donors.

e) I can't be absolutely sure, but suspect that the public were not aware that Anti-D was made from plasma from paid donors.

<u>Section 6: HIV and Blood Transition/Tissue Transfer scheme</u>

69. On 25 March 1992 GW Tucker wrote to Professor JG Collee and Dr JA McDonald to invite them to become members of a Panel being set in up to facilitate the HIV and Blood Transition/Tissue Transfer: Scheme for Ex-Gratia Payments ("the Scheme") (SCGV0000238_072, SCGV0000238_073). Mr Tucker wrote to the Panel members on 22 April 1992 on their acceptance of the roles and to Mr DB McIntosh of SNBTS

SCGV0000238_018, DHSC0002701_009, SBTS0003033_002). In this correspondence, Mr Tucker provided your name as a contact should any queries arise. On 1 April 1992 David Hogg wrote to David Burrage enclosing a proposed Public Notice regarding the Scheme and a document setting out the proposed process of the scheme(MACK0000044). Within the process document, you are named along with Mr Henderson as the person responsible for agreement to payment. On 9 April 1992 Mr Tucker set out the final arrangements for the proposed Scottish Scheme, copying you in (SCGV0000239_024).

a) **Please provide an overview of how the scheme worked, with reference to the budget, key decision makers and method for assessing claims.**
b) **How were potential claimants notified of their ability to claim under the scheme?**
c) **What were the similarities and differences between the Scottish and English versions of the scheme?**
d) **Please explain what your role was within the scheme.**
e) **Did you have any input into devising how the scheme should work?**

A69.

a) I'm afraid I have no clear recollection of the setting up or administration of the scheme, but SCGV0000239_024 (a submission from Mr Tucker) seems to provide detail on these points. The Panel mentioned in the submission was established to consider difficult cases where there was uncertainty or doubt about any aspect of the claim.

b) The policy team would have led on this aspect. I believe the Solicitors' Office liaised with those who had submitted legal claims, while the policy team would have made MPs and others who may have been in contact with people who were infected with HIV through transfusion or tissue transplant aware of the scheme. SCGV0000239_024 suggests that the CMO also wrote out to the clinical community to raise awareness of the scheme.

c) I did not have any recollection of differences. However,having looked at SCGV0000239_024, the differences appear to have been regarded as minor, as it refers to them being due to differences in Scots law and being mainly presentational.

d) I was one of the points of contact (along with Richard Henderson) for any queries on the working of the scheme.

e) Not that I recall.

70. On 21 April 1992, Dr R Kendell wrote to the Directors of Public Health and Chief administrative Medical Officers in Scotland regarding the Scheme, enclosing a copy of

the finalised version and providing contact details for applications. Dr Kendell stated "*We understand that SNBTS has already tried to inform consultants of any transfused donations that might have been at risk of transmitting HIV...I appreciate the need to ensure that the medical confidentiality of patients is maintained and that there may be some instances where it is not considered to be in the best interests of the patient to be aware* 26 *of the details of a particular medical condition at this time...Any medical enquiries relating to this matter should be addressed to Dr A Keel...*"

a) To your knowledge, what efforts did SNBTS make to try to inform consultants of any transfused donations that might have been at risk of transmitting HIV?
b) Did the Scottish Home and Health Department take any additional steps to publicise the scheme?
c) What was the policy within the Scottish Home and Health Department in respect of making patients aware of HIV from contaminated blood product?
d) Did you have any concerns that potential claimants would be unable to make use of the scheme if their treating consultant had decided not to inform them of their medical condition?

A70.

a) In April 1992 I would have been in post for only two months. I have no recollection of the efforts made by SNBTS to try to inform consultants of any transfused donations that might have been at risk of transmitting HIV. It sounds as if these would have pre-dated my joining SHHD.

b) Again, I have no recollection of SHHD taking any additional steps to publicise the Scheme. Policy colleagues involved at the time would be better placed to answer this question.

c) I believe the policy would have been to make every effort to make patients aware of the risk of HIV from contaminated blood products, but I have no recollection of how that policy was implemented.

d) I have no recollection of having any concerns about consultants deciding not to inform patients.

Section 7: Financial support for patients infected with HCV

71. On 28 July 1998 you were copied into a letter from Andy Nichol to Mr Galbraith, regarding hepatitis C compensation, advising that the DH would not be offering compensation to individuals infected through NHS treatment and were recommending that "*a similar position be adopted in Scotland*" (SCGV0000167_181). Rachel Sunderland responded on behalf of Mr Galbraith on 29 July 1998 to agree with the recommendation (SCGV0000167_178).

a) The 28 July letter suggests that Scotland, Wales and Northern Ireland were required to adopt a consistent line on the issue of financial assistance. Is this a culture you encountered? Is it an approach which you agreed with at that time?
b) Were you asked to advise on this issue in 1998 and if so, what advice did you provide?
c) Did you agree with the view that the circumstances in which recipients of blood products contracted HIV and HCV could be differentiated? If so, did you agree this justified a differing approach to financial assistance?

A71.

a) The four UK countries had always agreed that this was a UK-wide issue, which revolved around whether there had been any clinical negligence involved in the transmission of HCV by blood or blood products. The UK government view, which was shared by the devolved administrations, was that there had been no such negligence on the part of the NHS and that haemophilia patients had received the best available treatment at the time. I agreed with this view.

b) I have no recollection of providing advice on this matter, but I may well have done so.

c) I agreed with the view that the circumstances surrounding the infection of patients through blood transfusion with HIV were very different from those relating to transmission of HCV. At that point, a diagnosis of HIV infection was a death sentence, as well as being associated with considerable social stigma. Neither of these factors applied to HCV infection.

72. The matter was reconsidered by the Minister for Health and Community Care following renewed campaign by the Haemophilia Society after devolution: see a letter from David Bell (Health Care Policy Division) to the Minister which you were copied into, dated 15 July 1999 (SCGV0000176_118). Mr Bell invited the Minister to endorse the decision of the previous Minister and concluded that "*further examination would only*

***draw the same conclusions previously reached*". Did you have any input into this discussion once the new Minister was in place?**

A72. I'm afraid I have no recollection of input to this submission, which was in essence a restatement of the extant position in Scotland (to which I would have previously contributed) for the purpose of briefing the new Minister.

73. In an email dated 24 March 2000 (SCGV0000240_121), Christine Dora set out comments on the 'HCV Litigation Submission' (which was attached to S0000353_014 and is at DHSC0032274_074). A further comment was provided by Thea Teale (SCGV0000240_074) with a handwritten note signed by you.

a) Were you involved in any of the discussions that contributed to Christine Dora's comments?
b) Your handwritten note might be read to suggest that you considered that those with haemophilia who had contracted HCV should not be provided with any compensation. If that is a correct reading of your note, please explain why that was your view.

A73.

a) I am confident that Ms Dora would have sought my views on the draft DH submission.

b) As explained at **A71. a)** above, I believed that there had been no clinical negligence on the part of the NHS in the treatment of haemophilia patients, and therefore that there was no case for compensation. The litigation referred to in the DH submission related to an entirely different matter, i.e. the introduction of HCV testing in 1991 and the possible liability of the NHS under the CPA legislation introduced in 1988.

74. Were you involved in providing any further advice in relation to the settlement of Hepatitis C litigation claims in Scotland? If so, please explain your involvement and any advice you gave.

A74. I have no specific recollection of providing additional advice in relation to the settlement of HCV litigation claims in Scotland. Any additional advice would, as always, have been channelled through policy colleagues.

75. On 25 April 2000 you were copied into an email sent by Christine Dora, regarding advice given to Minister for Health and Community Care Susan Deacon and enclosing a Draft Report on the Treatment of Blood Products in the mid-1980s (SCGV0000171_031, SCGV0000171_077). In response to the circulation of the report, John Aldridge commented that the Minister should be "*pointed very firmly in the*

***direction of not agreeing to compensation or special priority treatment*" for hepatitis C sufferers who may have been infected by NHS treatment. In response, Christine Dora expressed the view that she hoped compensation would not be pursued (DHSC0032292_045). She commented that the Macfarlane Trust had set an uncomfortable precedent. Francis Gibb said in response; "*beware of going down a path which could have serious repercussions for the future, we could open the floodgates if we are not careful*".**

a) Were these views widely held amongst the Scottish Executive and the Health and Community Care Department around this time?
b) What were your views at this time on the advisability of Ministers establishing a scheme for compensation for patients infected with HCV?
c) Did you give advice to Ministers around this time on whether a compensation scheme for patients infected with HCV was desirable or feasible?
d) What did you understand was meant by Francis Gibb when he warned against opening the floodgates? Was this a view you shared?

A76

a) These views were widely held in SE and the health department around this time, because of the risk of setting a precedent to compensate patients where the there was no evidence of NHS negligence.

b) I agreed that the establishment of a scheme for compensation of HCV infected patients would set a dangerous precedent. There may well have been other possible categories of patients who might, on the face of it, have been eligible for such schemes, and there seemed no reason to treat HCV infected patients differently.

c) My advice to Ministers would have been along the lines outlined above, and have been channelled through policy colleagues.

d) My understanding is that Mr Gibb was also keen to avoid a precedent being set. I shared his view.

76. On 15 June 2000 you received an email from Thea Teale, expressing concern about the Department of Health's backstop position of offering a sliding scale of compensation to anyone infected with HCV by transfusion, that there may be people waiting in the wings to put forward claims (SCGV0000240_074). A handwritten note on the email, which appears to be signed by you and dated 19/6 reads: "*I totally agree with Thea's reservations below. If we go down this route we will a) have an unknown number of (as yet) non litigants who might be eligible for 'compensation' because of the* [???]

testing issue – although 'infected' long before this was developed b) we will have absolutely no grounds for not compensating haemophiliacs"

a) Did you pass your views on to the CMO or Ministers in the form of advice?

b) Did you think a financial assistance scheme for haemophiliacs should be in place at all? If so, what form of alternative scheme were you advocating?

c) What was the basis of your reluctance to compensate haemophiliacs who had been infected?

A76

a) I would have passed my views to CMO, probably verbally, and channelled advice to Ministers through my policy colleagues.

b) As discussed above, my view was that a compensation scheme for haemophiliacs would be inappropriate. I do not believe I was advocating an alternative form of scheme.

c) The basis of my reluctance to compensate haemophiliacs is laid out in my answers to questions 71a), 73 and 75 above.

The internal investigation

77. In a brief to the Minister for Health and Community Care on 15 July 1999, copied to you, (SCGV0000176_118), it was recommended, in relation to the Haemophilia Society's *"continuing campaign for haemophiliacs infected with Hepatitis C as a result of NHS treatment using blood or blood products"*, that: *"In light of the fact that the Department of Health have rigorously examined this issue twice in recent years and that the Haemophilia Society have not produced fresh evidence to support their claim for financial assistance, we advise that a further examination of this issue would only draw the same conclusions previously reached".*

a) Did you contribute to this recommendation?

b) What were your views of the recommendation?

A77.

a) I have no specific recollection of this submission, but I would almost certainly have contributed to it in draft form.

b) I agreed with the recommendation.

78. Why was an investigation subsequently commissioned? What changed between the recommendation to "adopt a consistent line" throughout the UK's Health departments

by not investigating HCV infections by blood/blood products (SCGV0000176_118), and the decision to begin an (internal) inquiry? SCGV0000176_101 may also be of assistance.

A78. Having read the referenced documents, I believe that the decision to begin an internal inquiry at that point, was made because of increasing pressure from the Haemophilia Society, though the Scottish Parliament, including the Health and Community Care Committee. The Department wished to document the steps taken by SNBTS to provide HCV safe factor concentrates in the mid-1980s and the provision of information to patients by Haemophilia Directors, in a transparent and open manner.

79. What is your understanding of why an internal investigation was commissioned, rather than a public inquiry? What consideration, if any, was given to the Haemophilia Society's concerns that a departmental inquiry could mean that officials were investigating matters that they were once involved in themselves. (WITN2287024 SCGV0000170_232 and SCGV0000170_011) may also be of assistance.

A79. The Minister was very keen to establish the facts surrounding the Haemophilia Society's allegations. She listened to their concerns relating to an internal inquiry, but stated her belief that a public inquiry would not be the best way to proceed.

80. Please consider the note of a meeting held on 1 September 1999 to discuss the information required to assist the investigation of circumstances surrounding the safety of SNBTS blood products from hepatitis C (PRSE0000978). You attended along with Michael Palmer, Sandra Falconer and Professors Ludlam and Lowe.

a) What was the purpose of this meeting?
b) What information did Professor Lowe provide about the Haemophilia Society's central claim?
c) What information did Dr Palmer provide about the Haemophilia Society's central claim?
d) What observations did you make about the differences between the BPL and SNBTS approaches?
e) What action did you take to prepare information for the investigation?(LOTH0000011_007 may assist)?

A80.

a) The purpose of the meeting was to clarify the information required to brief the Minister on 9 September 1999, in advance of her meeting with the Haemophilia Society on 14 September.

b) I'm not clear from the note of the meeting that Professor Lowe was in a position to comment on the Haemophilia Society's central claim, which was that the SNBTS had been negligent in not producing an HCV inactivated FVIII product earlier. He did however, confirm that he had not used commercial product during the period in question. Both he and Professor Ludlam confirmed that they always informed patients of the results of HCV tests.

c) Mr Palmer confirmed that the Haemophilia Society were likely to focus on the period between September 1985 and June 1987.

d) I observed that BPL and the PFC had taken different approaches to solving the technical problem of coagulation factor virus inactivation in the early/mid 1980s, for perfectly justifiable reasons. At that point, plasma production companies across the world were trying to develop such manufacturing processes, essentially working in the dark. Many different approaches were taken in an effort to hit on a solution, e.g. wet/dry heat application, different temperatures and different periods of heating. In the event, the PFC was ahead of BPL with an HIV-safe product developed by 1985 (one year after the virus was identified). BPL was ahead of the PFC in developing an HCV-safe product in 1985 (although this was not proven until 1988). However, this product was not produced in sufficient quantities to make England self-sufficient. By 1987, through PFC endeavours, Scotland was self-sufficient in the HCV-safe product Z8.

e) Following the meeting with Professors Lowe and Ludlam, I wrote to Dr Brian Colvin at the UKHCDO Register in Oxford asking if he would be able to supply details of the number of Scottish patients treated for the first time between 1 September 1985 and 30 June 1987, together with the type of product used.

81. In SCGV0000170_152, an email dated 23 September 1999, it is noted that the First Minister, Donald Dewar, was *"a little concerned about the possible financial implications and fears that an open mind could be taken to mean an open cheque book".* A handwritten note has been added that *"Ms Deacon's office advises that this is very much a PR exercise and there is unlikely to be any compensation paid".*

a) Do you know who added this handwritten note?

b) Were you aware at the time that the internal investigation was regarded as *"very much a PR exercise"?*

c) Did you provide advice or guidance on the possible financial implications, and if so, what was your advice/guidance?

A81.

a) I do not know who sent the handwritten note.

b) I was not aware of the internal investigation being regarded as a PR exercise. I certainly viewed it as being extremely useful in documenting the facts, particularly around the very complex technical protein fractionation challenges that BPL and the PFC were facing at the time.

c) I shared the view of the First Minister and others about the potential financial implications of a compensation scheme, which could have resulted in significant opportunity costs for the NHS, i.e. money spent on the scheme would not then be available to spend on direct patient care.

82. Michael Palmer of the Health Care Policy Division circulated some recommendations ahead of the meeting with the Haemophilia Society that was scheduled to take place on 14 September 1999 (SCGV0000170_164). On page 1, at paragraph 4a) he emphasised that *"the Department is at arm's length from SNBTS and is engaged in an impartial and objective analysis of the events and circumstances surrounding this issue"*. A handwritten note at the top of page 1 reads: *"Whilst I see the point you are making at x, this is open to misinterpretation. The Minister should settle on the inquiry being impartial and objective".*

a) What was your understanding of why Michael Palmer thought it was important to emphasise that the Department was "at arm's length" from the SNBTS?
b) Do you recall there being concern about the maintenance of impartiality and objectivity of the investigation? If so, why was there such concern?
c) Did you consider the investigation to be impartial and objective?

A82.

a) My understanding is that he wished to reinforce the impartial and objective approach that was being taken by the Department to the internal inquiry. SNBTS clearly had a strong interest on the outcome, and their views were to be sought. However, the views of haemophilia

patients and Haemophilia Directors were also being taken into account. This was definitely not a case of SNBTS being allowed to "mark its own homework".

b) My recollection is that Bill Wright of the Haemophilia Society expressed concern about the impartiality of the inquiry. The longstanding aim of the Society was to achieve the establishment of a Public Inquiry.

c) I consider the investigation to have been impartial and objective.

83. Please set out your involvement in the internal investigation commissioned by Ms Deacon. In particular:

a) Who decided the scope and content of the internal investigation?

b) Why was the scope limited to patients with haemophilia?

c) What was your role within the investigation?

d) Did you have any involvement in determining the interim conclusions of the investigation? PRSE0000978, SCGV0000171_077,SCGV0000170_015, SCGV0000170_078, ARCH0003312_031, SCGV0000171_068, SCGV0000171_069, SCGV0000043_047, MACK0001929_029, PRSE0001249 and SCGV0000172_110 may also be of assistance.

A83.

a) The scope and content were based on the specific allegations made by the Haemophilia Society.

b) As stated above, the scope was limited to the allegations made by the Haemophilia Society in relation to haemophilia patients only.

c) My role within the investigation would have included:

(i) information gathering on the numbers of patients affected during the "window period" of the inquiry, through the Scottish Haemophilia Directors and the UKHCDO Register in Oxford, which I recall required a certain amount of "chasing" on my part.
(ii) commenting on the draft report once available.

d) I have no recollection of being involved in determining the interim conclusions of the investigation, which was being led by Ms Dora. However, we would undoubtedly have had conversations about the report as it was developing.

84. In March 2000, documents from Professor Cash appear to have been considered by the Department for the purposes of the investigation. Christine Dora, in an email to you on 28 March 2000, states that *"as far as I can make out, "we" (in Scotland) were only getting around to seriously thinking about ALT testing of donations in March 1988 – after the period in question. I suppose we could try to emphasise about how unreliable it was – but that in itself is a big dollop of hindsight"* (SCGV0000171_052). She also notes a letter from David McIntosh to Professor Cash suggesting that civil servants and government *"had not got it together on a start date for testing donations for HCV"* and she was concerned not to *"be accused of having suppressed this letter"*. Please explain:

- **a) Whether you read the papers provided by Professor Cash;**
- **b) Why this understanding of the position in relation to ALT testing was not included in the final report;**
- **c) Whether you provided advice in relation to the sequence of events;**
- **d) If you provided any such advice, what the advice was and what you based your advice on;**
- **e) Your recollection of the contents of the letter between Mr McIntosh and Professor Cash;**
- **f) What advice you gave, and/or recall others giving, in relation to the letter from Mr McIntosh and whether it should be included in the investigation report.**

A84.

a) I would definitely have read the papers provided by Professor Cash, but regret that I have absolutely no recollection of their content.

b) The issue of ALT testing was not in any way directly related to the allegations which prompted the inquiry, i.e. that SNBTS were negligent in not providing HCV-safe FVIII at an earlier date than they did. ALT is a blood test which is by no means specific for HCV (or even hepatitis in general). The introduction of HCV testing in 1991 completely superseded any perceived utility in using ALT as a surrogate marker for HCV. The matter of ALT testing was therefore not included in the report, as it was not relevant to the scope of the inquiry. I would have pointed this out to policy colleagues.

c) I am not sure whether the sequence of events referred to relates to ALT testing or HCV testing? Either way, I would have provided any medical input required by my policy colleagues.

d) I have no recollection of what specific advice I provided in this context.

e) Again, I have no recollection of the contents of the letter between Mr McIntosh and Professor Cash.

f) Again, I'm afraid I have no recollection of what advice was given by me or others in relation to Mr McIntosh's letter.

85. Please explain:
a) who identified Professor Greaves as someone that the Department considered was suitable to assist with the investigation;
b) why he was chosen to assist;
c) what involvement he had had previously with matters of the Department;
d) whether he was in fact an independent expert, in light of the quotation marks used in relation to him at SCGV0000174_031;
e) what his role in the investigation was and how that interrelated with your role (SCGV0000174_031 p.7 may be of assistance).

A85.

a) My recollection is that I identified Professor Greaves.

b) Professor Greaves was an eminent expert in the field of bleeding and clotting disorders and was extremely well placed to judge the accuracy of the points made in the report, and its conclusions.

c) I think that he was one of the CMO's specialty advisers at that point. These were a group of senior consultants appointed to provide objective, expert advice to the CMO (and health department) in relation to their speciality.

d) I do not know why quotation marks were used. Professor Greaves was absolutely independent of the department. He did not work for SNBTS, nor was he a Haemophilia Director.

e) My recollection is that Professor Greaves had no role in the investigation as such. He was asked to review the draft report and provide comments. He believed the report to be an

accurate representation of the considerable clinical and technical problems surrounding the development of safe and effective factor concentrates in the mid-80s. I shared his views. I have no recollection of having any conversations with Professor Greaves in advance of the draft report being produced, at which point we were both involved in checking that the report was scientifically accurate.

86. When you provided comments on the first draft of the report (SCGV0000171_053), you noted that *"as far as financial help is concerned you will need no reminding that DH [Department of Health] are very nervous about this. Mike McGovern made a point of bringing the issue up with me during a recent unrelated telephone conversation ...".* What do you recall of the conversation with Dr McGovern on this issue? Did this influence, in any way, your recommendation to make the conclusions of the internal investigation report *"more definite"*?

A86. I have no clear recollection of the conversation with Dr McGovern, other than what appears in my minute. The conversation had absolutely no influence on my recommendation to make the conclusions of the report "more definite". The latter stemmed solely from a desire to draw out the clear scientific facts which had been uncovered by the investigation.

87. On page 3, at paragraph 10 of SCGV0000171_077, a submission from Christine Dora to Ministers, copied to you, it is stated that *"publishing this draft ought to be kept as low-key as possible*". What was the reasoning behind this? Did you agree with it?

A87. I assume Ms Dora wanted to keep publication of the report low key because it was to be published as a draft to allow comments from those with a principal interest in it, including the Haemophilia Society. I agreed with this approach.

88. In preparation for a meeting between the Minister and the Haemophilia Society to discuss the findings of the report, it was suggested, in an email copied to you, that an eminent scientist should be identified to attend (SCGV0000172_069). Subsequently, Kate Cunningham stated that there had been difficulty in finding an eminent scientist and asked "[w]ill no one support our findings?" (SCGV0000172_059).

a) Why was it difficult to find an eminent scientist?
b) Which scientists were approached?
c) Did scientists who were approached to attend the meeting not support the report's findings?

A88.

a) I'm afraid that I have no clear recollection on the issue of finding an eminent scientist to support the report's findings.

b) I do not recall which , if any, scientists were approached.

c) Again, I have no precise recollection of these events. However, we know that Professor Greaves, an extremely eminent scientist, supported the report's conclusions.

89. At a meeting (attended by you) on 30 August 1999 to discuss the investigation (see page 2, at paragraph 8 of SBTS0000379_040), it was noted that Professor Franklin advised that some of the SNBTS files had been destroyed but he was aware that Professor Cash had retained some records and would therefore approach him for them.

a) Did Professor Franklin inform you which documents had been destroyed?
b) If so, what were the nature of these documents?
c) What if any steps were taken to ascertain when and why they had been destroyed?

A89.

a) Professor Franklin did not specify which documents had been destroyed.

b) See above.

c) Professor Franklin and Mr McIntosh agreed to find out when and why they had been destroyed.

A89. In your draft statement, you state that *'Professor Franklin and Mr McIntosh agreed to find out when and why they had been destroyed.'* Do you recall the outcome of this?

I'm afraid have no recollection of the outcome.

90. In a briefing to Ministers on 4 September 2000, copied to you (see page 10, at paragraph 6 of SCGV0000172_049), it is stated that some files had been destroyed and this was *"presumably during routine procedures for the reviewand disposal of files"*.

a) Was a log kept of the files that were destroyed?
b) Do you know which files were destroyed and when?
c) Do you know why it was presumed that the files were destroyed during routine procedures for review and disposal? Did anyone confirm that that was the reason why they were destroyed?

A90.

a) and **b)** I have no knowledge of whether a log was kept of the departmental files that had been destroyed, nor which were destroyed, nor the timing of that destruction. The control of files was a matter for administrative colleagues, not professional staff.

c) I believe it would have been assumed the files had been destroyed as part of the Scottish Office's filing review system, under which files were routinely culled. Policy colleagues working at the time may have more detailed knowledge of these processes

91. The report was published on 24 October 2000 (SCGV0000173_031). Not long before, it had been expected to be published at the end of September 2000 (SCGV0000095_050). Why was there a delay until 24 October?

A91. My recollection is that the report was delayed due to difficulties in obtaining complete data from UKHCDO and the Scottish Haemophilia Directors on the numbers of patients who had been treated for the first time in the "window period" being investigated, i.e. 1 September 1985 and 30 June 1987.

92. Did you have any involvement in determining the final conclusions in the report of the Investigation? Please see SCGV0000172_049.

A92. I certainly commented on the draft report, but I cannot remember precisely what I contributed in terms of the final conclusions.

93. What actions, if any, were taken as a result of the internal report?

A93. The report was shared with the Haemophilia Society as well as SNBTS. As anticipated, the Society was not satisfied with its conclusions and continued to press for a full inquiry.

94. Did you make contributions to the 'line to take' (set out in a memo dated 7 December 2000, copied to you, at SCGV0000173_031) which was in response to the Haemophilia Society's request for an urgent meeting following publication of the internal investigation report? If so, what were your contributions? Did you agree this was the right way to respond, and if so, why?

A94. I have no specific recollection of contributing to the "line to take", but in all events I'm confident it would have been shared with me. In the absence of any further specific issues or evidence being provided by the Society, the Minister decided that there would be no point in holding a further meeting. The Society had agreed to the scope of the investigation at the outset and the Report had concluded that no blame was attributable to SNBTS. Under the circumstances, it seemed to me that there would be nothing really to be gained for anyone by having another meeting with the Society at that point.

95. At a meeting attended by you on 24 November 2000 (see page 1, at paragraph 1 of SCGV0000095_035), it was agreed that *"SNBTS should ensure it had a definitive archive of the whole issue"* of HCV infected haemophiliacs. Was it your understanding that such an archive did not already exist? Did it surprise you that SNBTS did not already have a definitive archive on the issue of HCV infection in haemophiliacs?

A95. My interpretation of this statement is that SNBTS intended to pull together all of the information they held on HCV infected haemophiliacs into one document, so that it was readily accessible.

96. On 26 January 2001 Christine Dora circulated a memo regarding the HCCC and Hepatitis C (SCGV0000174_076). It sets out the Haemophilia Society's unhappiness with the quality of Susan Deacon's report and the request for a meeting with her. What advice did you give about whether she should meet with the Society and what were your reasons for giving that advice? The 26 January memo also refers to interest groups and political pressure on the Minister to change her stance on compensation

and that she will be receiving advice on the same. Did you advise the Minister on this issue and, if so, what was your advice?

A96. My answer to Q 94 above covers my advice on the question of a further meeting with the Haemophilia Society. I have no specific recollection of providing advice on the matter of the Minister's stance on compensation at that time.

97. On 16 February 2001 you received an email from Christine Dora stating that Lord Hunt had agreed to meet Lord Morris, President of the Haemophilia Society, to revisit the issue of compensation for hepatitis C positive haemophiliacs SCGV0000174_068). A handwritten note on the email, which appears to be written by you, states: "*This gives me enormous concern. Please arrange for urgent contact to be made with Phillip Hunt's office (either at PS or ministerial level) emphasising that we have withstood enormous pressure on this issue – not least after discussions directly with him- any movement from the previous position, without discussion with other administrations, would, in my view, be quite unacceptable. Happy to have conversation directly if nec.*"

a) Why did you view this matter as one which needed to be treated with urgency?
b) What did you think the consequence of one of the four administrations deciding to give financial assistance to hepatitis positive haemophiliacs would be?
c) Did you advise the Minister for Health and Community Care in these terms and if so, did she accept your advice?

A97.

a) The subject of the meeting between Lord Hunt and Lord Morris was to revisit the matter of compensation for haemophiliacs infected with HCV, to which Lord Hunt was apparently sympathetic. The meeting was imminent (scheduled for the following day) and therefore the matter was urgent.

b) The consequence would have been enormous pressure on the other administrations to follow suit.

c) I have no clear recollection of providing advice to the Minister, but I'm confident I would have drawn her attention to the risks inherent in the forthcoming meeting, in terms of

potentially undermining Scotland's clearly defined position on compensation for haemophiliacs.

98. On 21 February 2001 the private secretary to the Minister for Community Care forwarded a set of emails between her and Sandra Falconer (SCGV0000174_066). Do you know why the Minister expressed relief that Lord Hunt had made it clear the government had decided against compensating haemophiliacs with HCV?

A98. The Minister would have been relieved that Lord Hunt had held the "UK line" on the matter of compensation for haemophiliacs with HCV.

99. The outcome of the Burton court case was discussed in a meeting which you attended on 15 May 2001 (SCGV0000243_161). How did the outcome of the case affect the Scottish Executive's approach to pending litigation, and the issue of compensation for hepatitis positive people infected by the NHS more widely? Did your own view evolve when you were told about this judgement?

A99. In the light of the Burton judgement, the Scottish Executive, myself included, accepted the inevitability of having to reconsider the issue of compensation for haemophiliacs with HCV. However, I still adhered to the view that there was no evidence that the NHS had been negligent in this area.

100. On 3 October 2001, you wrote a memo to Mrs Falconer regarding the recommendations of the Health and Community Care Committee(SCGV0000247_094). Please explain:

a) Why you "*were expecting the Committee to recommend compensation for those who have contracted Hep C through blood transfusion and fall outside the terms of the Burton judgement*";
b) What the recommended protocol was that is referred to in paragraph 5 and what the response of the Executive was to this recommendation;
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c) Why you considered "*the allegation [...] that the Departmental report did not consider the non-use of the ALT test*" to be "*inaccurate and irritating*".

A100.

a) My recollection, when supporting the Minister in giving evidence to the Committee in the course of their inquiry, is that the majority of Committee members favoured a much broader approach to compensation, rather than restricting it to those who fell within the terms of the Burton judgement.

b) The protocol recommended by the HCCC required the Executive to consult the Committee on the terms and membership of any future internal inquiries. This was rejected by the Executive who pointed to the existing protocol which worked quite satisfactorily if properly implemented.

c) I suspect I was irritated by the comment on ALT testing and its omission from the report of the internal inquiry, because the latter's remit (which had been agreed with the Haemophilia Society) was focussed on the so-called "window period" and did not cover testing of any type.

101. In a briefing from November 2001, copied to you, (SCGV0000247_013 paragraph 14), it was suggested that the Committee recommendations which proposed *"financial and practical support for all people who had contracted HCV from NHS Scotland blood"*, were to be rejected but that an expert group could be set up to consider the generic principle of offering support. Why was this course taken?

A101. The recommendation to establish a scheme of financial and practical support for all people who had contracted HCV from transfusion was rejected because it was considered inequitable. There were potentially other groups of patients who would feel they too would benefit from such a scheme, but would be excluded. The Executive instead suggested the establishment of an expert group to look at the generic principle of offering such support and determining whether this would be right, practicable, and what universal criteria might be applied.

102. To the extent not already addressed above, please set out your involvement with the decision to commission the internal investigation, the carrying out of the investigation, and the response to the investigation.

A102. I believe that I have fully covered all the salient points in terms of my involvement in the decision to commission the internal investigation, its implementation and the response to its findings, in the evidence provided earlier in this section.

Outcome of the Health and Community Care Committee report

103. In September 2001 the Health and Community Care Committee ("HCCC") produced a report recommending the Scottish Executive set up a mechanism for providing financial and other practical support to Hepatitis C sufferers who contracted the virus as a result of blood transfusions in Scotland or blood products from SNBTS (HSOC0009371). On 3 October 2001 you wrote to Mrs Falconer about the outcome of the HCCC report (SCGV0000247_094). What concerns did you have about the implementation of the recommendations, be they practical or financial? Was the HCCC report fair and accurate in your view, and if not, why not?

A103. In terms of the HCCC report, I thought that the Committee had done its best in trying to assess the complex evidence surrounding the transmission of HCV by blood/blood products. However, I felt that its principal recommendation to establish a compensation scheme for all patients infected with HCV through blood transfusion was potentially unfair to other patient groups who felt that they had been harmed by NHS treatment. The Committee also seemed to me to underestimate the complexities inherent in assessing levels of compensation "based on need, with regard to the physical or psychological loss individually suffered". This was an issue that, more widely, had been given much thought over the years, but with no clear emerging solution. My main concern around the financial impact of such a scheme was that its costs had not been fully estimated, and any money spent on it would, by definition, not be available for direct patient care, or indeed further risk reduction measures in the field of blood transfusion. I had similar concerns over the practical difficulties that would be involved in the provision of information on all risks of blood transfusion. The Committee also did not appreciate that the CSBS' remit did not cover the oversight of an investigation into the adequacy of advice to patients on risks relating to transfusion.

104. On 12 November 2001 a parliamentary question was asked of the Secretary of State for Health regarding the Scottish Executive's Health and Community Care Committee's recommendations to give financial assistance. The response from Mr Hutton was that "*the devolved Administration in Scotland is considering these recommendations. We currently have no plans to compensate haemophiliacs who became infected with hepatitis C through*

National Health Service blood products" (DHSC0020742_071). On 13 December 2001 the Deputy Minister for Health and Community Care, through his private secretary, emailed to ask you and others for examples of people who had suffered harm from 'other causes' but were not entitled to compensation (SCGV0000248_108). Emails on a similar issue were sent to you from Bob Stock on 7 January 2002 (SCGV0000248_043) and 27 March 2002 (SCGV0000249_062). Did you provide the Deputy Minister with any advice on this point, and if so please explain that advice? What were your own views on the validity of the comparisons made with other medical conditions?

A104. I was not actually on the copy recipient list of the Deputy Minister's email of 13 December 2001, but I assume Mr Stock shared it with me, and that I supplied him with at least some of the suggestions that he offered to Mr Henry. I thought these were valid comparators with the HCV/blood transfusion group.

105. Please consider this chain of emails regarding the estimated costs for the proposed Scottish HCV Compensation Scheme ("the HCV Scheme"): SCGV0000248_108. It appears that the emails with Bob Stock and others were exchanged in anticipation of the Expert Group meeting led by Lord Ross on 28 August 2002. Why did you hope that the cost estimate for the scheme composed by Chris Naldrett would give the Expert Group pause for thought? What did you think should happen instead of the existing compensation proposal?

A105. The costs estimated by Mr Naldrett were very significant and I was again concerned about their impact, in a finite NHS funding envelope, on the availability of funding for direct patient care and health prevention measures. I regretted that the Burton judgement had forced a move away from the previous principal that no compensation was due where there was no negligence proven on the part of the NHS.

The outcome of the Lord Ross report

106. You may wish to refer to the Ross report (HSOC0003349) and (HSOC0020367) when preparing a response to the following questions. 106. On 30 January 2003 Bob Stock circulated the Scottish Executive Proposal for Ex Gratia Payment Scheme [Hepatitis C from blood] (SCGV0000251_018). The document communicated that a scheme had been costed and agreed by the First Minister on the basis of a £20,000 lump sum to all those living with Hepatitis C and a further £25,000 to those who have cirrhosis, liver

failure or cancer. Malcolm Chisholm wrote to Lord Ross to inform him of this outcomeand that he would not be directly following his recommendations (HSOC0020367).

a) So far as you were aware, what was the consultation or decision-making process by which Malcolm Chisholm decided to deviate from the Ross Report recommendations?
b) What did you understand to be the rationale for this decision?
c) Did you advise or discuss the issue with Malcolm Chisholm, his deputy, or his private secretary? If so, what advice did you give or what did you discuss?

A106.

a) As far as can I recall this was a cabinet decision. I assume it would have been based on discussions of estimates provided by finance colleagues, in which I was not involved.

b) I understood the rationale to be one of affordability.

c) I have no recollection of discussing affordability with Mr Chisholm, his deputy or his PS.

107. What input did you have into the criteria to be applied under the HCV Scheme to trigger financial support? What were your own views on the appropriate trigger? It may assist you to consider DHSC0046315_010 and SCGV0000252_023.

A107. The papers indicate that I was involved in discussions with clinical colleagues to try to determine the trigger for the Stage 2 payment. Definitive diagnosis of more advanced liver disease and/or cirrhosis requires liver biopsy, which is an invasive procedure with an associated (although low) mortality rate. It is particularly hazardous for patients with bleeding disorders such as haemophilia. My recollection is that following discussions with Professor Peter Hayes, who was the CMO specialty adviser in this area, he was unable to offer an alternative, non-invasive test. I also had discussions with Dr Hugh Nicholls in DH, who were beginning to realise the implications of the Ross Report for England. My view was that we could not subject all potential claimants to liver biopsy, and that any claim would have to be settled on a balance of probability basis, informed by evidence provided by the claimant's clinicians(s).

108. Once Malcolm Chisholm had announced the revised version of the scheme, were discussions ongoing about the feasibility of compensating the dependents of deceased persons? What was your view on this issue and what advice did you give? It may assist to consider SCGV0000256_028.

A108. As Mr Stock's email of 3 December 2003 indicates, a major consideration in designing the scheme was one of affordability. Including relatives of deceased persons in the scheme would clearly have made it less affordable. I have no recollection of offering any advice on this point.

Section 8: Irish HCV Compensation Tribunal ("Irish Tribunal")

109. In the record of a telephone conversation with you in April 2000 (SCGV0000194_048), it was confirmed that you *"could not see any reason why we should not agree to SNBTS participating in the Irish Tribunal"*. Subsequently, it appears that Lynda Towers expressed concerns about SNBTS participation in the Irish Tribunal (SCGV0000194_043). What was your understanding of her concerns? Did you agree with them? What was your own view of whether SNBTS staff should give evidence at the Irish Tribunal (SCGV0000194_010 may be of assistance)?

A109. My initial advice to agree with the request for SNBTS to give evidence to the Irish Tribunal was based on my view that, in general, a spirit of openness and cooperation is the best approach in such circumstances. However, Mrs Towers highlighted possible risks to the government in going down this route, and I absolutely agreed that the request merited further reflection in light of the risks identified by her.

110. On pages 2 and 3 of a memorandum circulated by Sandra Falconer on 4 May 2000 (SCGV0000194_030), including to you, three options were set out for how the SNBTS could respond to the invitation of two members of staff to appear as expert witnesses at the Irish Tribunal. It was recommended at paragraph 10 to take Option 2 which was to decline participation in the Irish Tribunal.

a) Whose handwriting can be seen on the document?
b) Did you make contributions to the discussion of these three options?
c) If so, what was your contribution and or view of what should take place?

A110.

a) I don't recognise the hand but presume that the annotation came from the Minister.

b) I have no recollection of contributing to discussions of the options, but I'm sure that I would have been involved in developing them with policy and legal colleagues.

c) My recollection is that I still came down on the side of SNBTS giving evidence to the Tribunal.

111. In an email dated May 2000 (copied to you) (SCGV0000194_034), a fourth option was suggested which was that the SNBTS gave evidence in affidavit form. A hand written note on page 1 states you confirmed you were content.

a) Is the note correct?
b) What was meant by *"the areas we would prefer them to avoid"*?
c) Why was evidence by affidavit not pursued (SCGV0000095_197 may be of assistance)?

A111.

a) I cannot see the note referred to on the referenced document, but I recall I was content.

b) It was agreed that it would be unhelpful to the Scottish Executive if SNBTS were challenged in the Tribunal on their position, or if the evidence given were different from that which might appear in the forthcoming internal investigation report. In addition, there was a risk that the pending UK litigation in this area might be brought up in the Tribunal.

c) Evidence by affidavit was not pursued on the basis of advice given to SNBTS by the Central Legal Office. I have no recollection of the grounds for that advice.

112. At a meeting in September 2000, at which you were present (SCGV0000095_050) it was stated that the Irish Tribunal expert witness request *"would be reviewed when the [internal investigation] report was published"*. Why was it considered necessary to postpone the decision to assist with the Irish Tribunal until after the report was published?

A112. I have no strong recollection of the reasons for postponing a decision on participation in the Tribunal until after the publication of the report of the internal investigation. It may have been to ensure that the evidence uncovered by the latter and the conclusions drawn matched SNBTS' memory of events.

Section 9: Professor Cash documents

113. On the 24 September 1999, you wrote in a memorandum that it had "emerged that Professor John Cash [...] took with him some files which may be relevant, which he has "gifted" to the Royal College of Physicians in Edinburgh" (SCGV0000170_150). You state that you had "tried without success to persuade him that it would be much more convenient to allow [...] access to the files in another location" but "Professor Cash is extremely resistant to the idea". You asked Lynda Towers for her "advice on the question of ownership".

a) What was contained in these files?
b) Did you ascertain why Professor Cash was not willing to share these files?
c) What advice did Lynda Towers provide with regard to the ownership of these documents?
d)Were the documents subsequently obtained?

A113.

a) I don't know what specifically the files contained, but clearly, I thought they might be relevant to the ongoing internal investigation

b) No, I did not ascertain why Professor Cash was not willing to share them. However, SCGV0000240_028 states that they were photocopied and held in St Andrews House, although I don't recall reading them. I suspect that they did not add to the sum total of knowledge emerging in the course of the internal inquiry.

c) I infer from the documents that Mrs Towers advised they belonged to the Secretary of State

d) See answer at b) above.

114. In an email (copied to you) dated 21 July 2000 SCGV0000240_028, SandraFalconer mentioned that you held incomplete copies of Advisory Committee on the Virological Safety of Blood ("ACVSB") minutes.

a) What was missing from them to make them incomplete?
b) Where had you obtained these documents? Were these from Professor Cash?
c)Do you know if copies of the documents were kept or destroyed?

A114.

a) I don't recall what was missing from the ACVSB files

b) I was a member of the Committee and received papers. These were not always filed systematically in my office. The papers were definitely not from Professor Cash.

c) I don't recall what happened to my copies of the ACVSB files. The latter was a DH committee, so the expectation would have been that DH would retain copies of all of the papers.

115. In the second paragraph of SCGV0000240_028, Sandra Falconer stated that Professor Cash's documents were held by your secretary and she had asked for the documents to be kept "in the meantime".

a) What were the reasons for retaining the documents?
b) How long did you/your secretary keep the documents for?
c) What was eventually decided in relation to retaining these documents, and who made the final decision?

A115.

a) I suspect that I advised keeping copies of Professor Cash's papers in case there was a need to revisit them during the internal investigation or thereafter.

b) I have no recollection of how long the papers were retained.

c) Again, I have no recollection of what was eventually decided in relation to these papers.

116. In an email dated 15 November 2000 SCGV0000173_044 you stated that Professor Cash had told you that he had "rescued" the documents he had in his possession "from a potential bonfire at CSA when they were about to be destroyed by a previous SNBTS manager".

a) Did Professor Cash ever disclose to you his understanding as to why the documents were going to be destroyed?
b) Did Professor Cash tell you the name of the previous SNBTS manager? If so, who was it?

A116.

a) No, Professor Cash did not clearly explain his understanding of why the documents were going to be destroyed.

b) He told me it was David McIntosh

117. In SCGV0000173_044 you expressed that you were "very doubtful" that Professor Cash got many of the papers from the Department of Health (England). What were the reasons for your strong doubts, and where did you think Professor Cash got the papers from?

A117. I was doubtful that Professor Cash had obtained the papers from DH, because the ACTTD was not a DH committee. It had been set up by Dr Harold Gunson, the National Medical Director of the NBA, principally to advise the blood transfusion service(s) on transfusion transmitted infections. Professor Cash was a member and he would have received the papers directly from the NBA secretariat.

Section 10: Lack of inquiry

118. In a briefing document to the Minister for Health and Community Care (SCGV0000044_024) lines to take were prepared for a meeting with Scottish Haemophilia Groups Forum. Did you make contributions to this briefing, and if so, what were they? Did you agree with what was said to be the views of ministers previously, namely that it was not in the public interest to hold a public inquiry?

A118. I have no clear recollection of my involvement in developing this briefing document, but I'm confident policy colleagues would have invited my views. I agreed with what was said about previous Ministers' views on holding a public inquiry, namely that, unless new evidence were to emerge it would not be in the public interest to hold such an inquiry.

119. In a subsequent briefing to the Minister dated 22 August 2005, copied to you, (SCGV0000263_020) it was stated that there were documents that contained "some sensitive issues, particularly relating to the introduction of testing which do not reflect well on the Government of the 1980s as there are arguments presented on the grounds of cost [...] despite pleas from SNBTS [Scottish National Blood Transfusion Service] to introduce tests as a moral obligation to patient safety". It was stated that these would "provide the Society with just cause to call anew for a public inquiry".

a) Did you have sight of these documents? If so, could you provide further detail as to what was contained within these documents, specifically what arguments were presented?
b) When were you aware of these documents?
c) At the time, did you think the documents should or should not have been disclosed?
d)Do you know whether or not the documents were eventually disclosed?

A119.

a) I have no recollection of having seen these documents.

b) I can't be absolutely sure when I became aware of the documents. It may have been when I read the briefing paper.

c) I have no clear recollection of forming an opinion on whether the documents should be disclosed or not, nor whether they were eventually disclosed. Policy colleagues, in conjunction with legal advisors, were responsible for developing advice on this kind of issue.

d) Again, I have no clear recollection of forming an opinion on whether the documents should be disclosed or not, nor whether they were eventually disclosed. As above, policy colleagues, in conjunction with legal advisors, were responsible for developing advice on this kind of issue.

120. On page 3, paragraph 8 of SCGV0000263_020 it is noted that approximately 60% of the content of the files were being held back and it is noted that "embarrassment and eventual claims for compensation could result from the release of this documentation". What was the content of those documents and why might they result in embarrassment and eventual claims for compensation? Did you agree with the view of the author that there was no justification under FOI for holding back what was being proposed to be released?

A120. As stated above, I have no recollection of reading the documents. However, I infer from pages 2 and 3 of the briefing that the potential embarrassment being referred to may relate to the non-introduction of ALT testing in the UK in the mid-80s. As noted earlier in this statement, ALT is an extremely non-specific test which may be elevated in hepatitis (of any type), but also in numerous other situations, e.g. alcohol abuse, obesity, extreme exercise etc. For this reason, it had not been introduced in the 80s. However, apparently some SNBTS directors were keen to see the test deployed and wrote to The Lancet on the matter. Policy colleagues were concerned that this might be construed as "new" evidence by the Haemophilia Society in their efforts to secure a public inquiry. In my view the decision to release the documents under FOI would have been a matter for policy colleagues and legal advisers.

121. On page 4, at paragraph 12 of SCGV0000263_020 it was stated that "one possible solution might be to encourage the Committee to commission its own inquiry rather than a full public inquiry". Did you participate in discussions about whether to commission an inquiry in this way? If so, what were the contents of those discussions and the reasoning for and against commissioning such an inquiry?

A121. Unfortunately, I have no recollection of participating in discussions on this issue.

122. A Department of Health briefing dated 26 May 2006 (DHSC0041159_205) stated (at paragraph 7) that you had been consulted regarding Scotland's view on holding a public inquiry or not and that "[a]dvice from SE officials to Scottish Ministers continues to be very strongly against holding a public inquiry".

a) What was your view at the time on whether a public inquiry should be held or not?
b) Did you provide advice to the Scottish Executive ("SE") on this matter, and if so, what did you advise?

c)Why were SE officials opposed to a public inquiry?

A122.

a) My view was that, in the absence of any new evidence, a public inquiry would not be appropriate.

b) My advice to SE on this matter would, as always, have been discussed with and channelled to Ministers through policy colleagues.

c) SE officials were opposed to a public inquiry principally on the grounds that no new evidence had emerged since the internal departmental investigation's report was published in 2000.

Section 11: Better Blood

123. A memo was sent from Mike McGovern (Health Services Directorate) to a number of recipients including you, regarding the Better Blood Transfusion note of meeting with UK CMO on 21 June 2001 (DHNI0000013_052). What improvements were planned in respect of organisation openness with patients?

A123. One of the aims of the planned conference in October 2001 was to promote a more "full and open relationship" between patients/public and the BTS. Blood transfusion should not be described as risk free and informed consent should be introduced. The intention was to involve patients in the conference, including a key-note speaker.

124. Please consider a letter from Ian Gordon to Colleagues in the Scottish Health Department dated 19 May 2003 summarising the Better Blood Transfusion Programme (SCGV0000098_179) and a newsletter about the Programme from December 2003 (SCGV0000098_124).

a) What were the aims of the Programme?
b) What was your role?
c) How effective was the programme in your view?

A124.

a) One of the principal aims of the Better Blood Transfusion Programme was to identify variation (which was considerable) in clinical use of blood/blood components, and reduce inappropriate use of the latter. Others included reviewing blood ordering and administration; efficient management of blood components; and clinical effectiveness and use of evidence based practice. The Scottish Programme appointed a very energetic and effective Project Manager and 18 Transfusion Practitioners (mainly nurses) to lead teams in hospitals. Amongst other things, they provided education and training to blood prescribers. Usage data was fed back regularly to clinicians – a very effective way of highlighting variation between hospitals, or even within clinical units.

b) I was on the Steering Group for the Programme, so responsible for its governance and progress. I also acted as an "ambassador" for the Programme, using my clinical networks throughout the NHS to promote its aims, particularly through Medical Directors.

c) I believe it was very successful. I can't recall the precise figures, but even within the first year there was evidence of a significant reduction in blood wastage and inappropriate usage

125. Please add any further comment that you wish to provide about matters of relevance to the Inquiry's Terms of Reference.

A125. I have no further comments that I wish to add.

Statement of Truth

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

Signed GRO-C

Dated _13th July 2022_____

Table of exhibits:

Date	Notes/ Description	Exhibit number

13/05/1992	Memo from A. Keel, Scottish Executive Health Department, to Dr. Sowler, Scottish Executive Health Department, cc'd Dr. McIntyre and Dr. Thomson, Re: Meeting with Scottish National Blood Transfusion Service staff on 12 May 1992 issues raised regarding potential demand for Anti-D immunoglobulin and HCV testing of Blood Donations	SCGV0000057_057
24/12/1992	Letter from G W Tucker, NHS Management Executive 3 to PS/Minister of State, re: Scottish National Blood Transfusion Service: Pharmaceutical Products Produced from Non-HCV Tested Plasma Cc; PS/Chief Executive, Mr Anderson, CMO, CNO, Solicitor, Mr Henderson, Solicitor's Office, Dr Keel	SCGV0000121_074
18/08/1992	Memo from A. Keel to CMO, re: HCV Testing of Donor Blood; HCV Testing of Plasma for Fractionation; Anti-D Immunoglobulin.	SCGV0000163_006
21/07/2000	Email between Falconer Sandra and Tower Lynda, re: HCV Litigation - England	SCGV0000240_028
09/04/1992	Memo from G. W. Tucker to Private secretary/Chief Executive. Re: scheme for payments to HIV infected recipients of blood and tissue	SCGV0000239_024
10/05/1995	Letter from Dr A. Keel, The Scottish of Office of Home and Health Department, to Dr. Ian J. Kerr, re: Hepatitis C Lookback	SBTS0003833_421