Witness Name: Gloria Hooper
Statement No.: WITN7005001
Exhibits: WITN7005002-WITN7005046
Dated: 14/06/2022

INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF GLORIA HOOPER

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Section 0: Opening Comments

I, GLORIA DOROTHY HOOPER, will say as follows: -

0.1. My name is Gloria Dorothy Hooper. I was born on GRO-C 1939. My address is known to the Inquiry.

0.2. I am providing this statement in response to a request from the Infected Blood Inquiry under Rule 9 of the Inquiry Rules 2006, dated 30 March 2022. I have been asked by the Inquiry to provide a witness statement regarding my involvement in the issues set out in the Inquiry's Terms of Reference during my period as Parliamentary Under Secretary of State for the Department of Health (**DH**, or **the Department**) from 17 October 1989 until 9 April 1992.

Opening comments

0.3. I wish to make the following comments before I respond to the Inquiry's questions.

0.4. The infection of men, women and children with HIV and other blood borne diseases through blood and blood products was a tragedy. I am deeply sympathetic to all those who have suffered as a result. I offer my sincere condolences to all who have suffered, and I recognise the importance of this Inquiry for the infected and the affected.

0.5. In preparing this statement, I have reviewed copies of documents supplied by the Inquiry and some further records from DH. My independent recollection of these matters is really very limited indeed, as the events that I have been asked about took place over 30 years ago – and furthermore, at the age now of 83, my recollection of past events is generally not as good as it used to be. On some of the issues raised, I have no recollection of the specifics at all and I am completely reliant on the documents. Whilst the documents help to some extent, it is unlikely that the documentary record itself is complete. It was my practice to initial / mark documents in some way to record that I had seen a document. Without seeing the original documents copied to my office, and given the passage of time, I cannot be sure that I saw all of the documents referred to in this statement, even when copied to my Private Office. I am unable to recall all of the issues which would have been discussed in meetings and less formal conversations, unless a minute of the meeting is available.

0.6. I have endeavoured to answer the Inquiry's questions as fully as I am able against these limitations. If required, I will revise my statement in light of any further material which is brought to my attention.

0.7. I hope this statement will contribute to the Inquiry process and to an understanding of events, if read in conjunction with documents and information provided by others also involved at the time.

Structure of the statement and exhibits

0.8. A table of contents is included at the outset, for ease of navigation. I have adopted the same section numbering that is used by the Inquiry in the Rule 9 request dated 30 March 2022.

0.9. Where a document has been drawn to my attention by the Inquiry in the Rule 9 request or is already available on the Inquiry's database, I have included the document ID number in the body of this statement. All other documents that I refer to are exhibited.

0.10. To avoid confusion, I have referred to ministers or others by the titles that they were known by at the time of the issues discussed in this statement.

Section 1:Introduction

1.1. Prior to entering the House of Lords in 1985, I practised as a solicitor. I became a partner at Taylor & Humbert in 1974, where I practised until 1979 / 1980. I was elected a member of the European Parliament between 17 July 1979 and 16 July 1984.

Political Career

1.2. Outlined below are the details of my political career to date:

Table 1 – Employment History

1979-1984	Member for Liverpool of the European Parliament (MEP)
1985	Created a Life Peer
1985-1987	Government Whip and Baroness-in-Waiting to the Queen
1987-1988	Parliamentary Under Secretary of State (Lords), Department of Education and Science
1988 - 1989	Parliamentary Under Secretary of State, Department of Energy
1989 – 1992	Parliamentary Under Secretary of State for Health (Lords)
1993 - 2018	Deputy Speaker, House of Lords

Role as Parliamentary Under Secretary of State for Health

1.3. To the best of my recollection, I succeeded Lord Trafford as Parliamentary Under Secretary of State for the Department on or around 17 October 1989. Lord Trafford had briefly been the Minister of State for Health (Lords) but sadly died on 16 September 1989. I was asked to take up the position of Parliamentary Under Secretary after this.

1.4. At the time of my appointment, my main focus was on the Health Reform Bill, which later became the National Health Service and Community Care Act 1990 (in his memoir "Kind of Blue", Mr Kenneth Clarke – as he then was – referred to me as being appointed to manage the passage of this controversial piece of legislation through the House). In addition, I have been reminded that my specific departmental responsibilities included: dentistry; drug, alcohol and smoking addiction; health education; and links with voluntary organisations (for example, Guide Dogs for the Blind). I was also involved in international matters and attended EU Council of Ministers meetings in Brussels on behalf of the Department, particularly in relation to health warnings and restrictions on the sale of tobacco products.

1.5. The statement which I gave to the BSE Inquiry refers to a press release on 17 October 1989 **[WITN005046]**. The press release indicated that I was responsible for the following matters, which included blood products:

> *"NHS Services for Children, services for elderly people, disablement services (including younger physically disabled), prevention and health promotion, including nutrition and smoking, drug and alcohol abuse, dental services, ambulance services, blood products, the private health sector, section 64 grants, vaccine damage, inner cities, research."*

1.6. There is also reference to a Cabinet Office List of Ministerial Responsibilities which suggests that I was also responsible for pharmaceuticals, abortion and family planning issues and other areas. In my statement to the BSE Inquiry, I note that I am not sure whether the press release or list of responsibilities was more accurate. However, I did not recall having much involvement with pharmaceuticals, or any involvement in abortion and family planning.

1.7. The extent of my involvement with issues relating to blood products is dealt with in this statement, below.

1.8. I am not and have not been a member of any committees, associations, parties, societies groups or organisations relevant to the Inquiry's Terms of Reference.

1.9. Between 5 December 1994 and 27 December 2000, I was a non-executive Director of SmithKline Beecham plc, a pharmaceutical company.

1.10. I provided a written witness statement to the BSE Inquiry which was announced in Parliament on 22 December 1997 and set up on 12 January 1998. I was not asked to give oral evidence to that inquiry.

Section 2: Decision-making structures

Q6: Responsibilities as Parliamentary Under Secretary of State for Health

6.1. The Inquiry has asked me to describe, in general terms, what responsibility I had in the Department for matters relating to blood and blood products.

6.2. The main focus at the time of my appointment as Parliamentary Under Secretary in DH was on the Health Reform Bill (which later became the National Health Service and Community Care Act 1990). I had already gained significant experience in taking major Bills through the House of Lords. I was previously Parliamentary Under Secretary of State for the Department of Education and Science, and then in the Department of Energy. During the first period, I had taken the Education Reform Act 1988 through the House of Lords. After that, I moved to the Department of Energy, where I was responsible for the passage of the Electricity Privatisation Bill 1990 through the House of Lords.

6.3. There was only one minister for each government department in the House of Lords, supported by government whips who responded to debates when the minister was not available. In my role, I was therefore required to deal with legislation, answer Parliamentary Questions and debates on all health topics, not only on my specific departmental responsibilities. I believe that my predecessor, Lord Trafford, was appointed in large part because of his medical background and qualifications. It was in this context (i.e. speaking to Health matters across the board) that I most recall involvement in blood-related matters. However, the documents that I have been shown remind me that I did have further involvement, most particularly in relation to the structure or organisation of the blood services and also in respect of the introduction of screening of blood for the Hepatitis C virus. The documents suggest that I was not responsible for, or involved in, matters relating to the AIDS pandemic; this topic was handled by the Ministers of State, Mr David Mellor and then Mrs Virginia Bottomley (now Baroness Bottomley).

6.4. Other than as explained in paragraph 8.1 below, I have no recollection of the civil servants with whom I dealt and by whom I was briefed. Before I took office, I believe that my knowledge and understanding of these issues would have largely come from reports within the press regarding those who had been infected by blood or blood related products. After I took office, if there were matters which specifically needed to be brought to my attention, this would come through my Private Office. If my Private Office was the main recipient of the submission (i.e. I was the minister expected to make the decision), then I would have undoubtedly seen the submission.

Structure and organisation of the Department

6.5. To assist the Inquiry, I set out below a brief summary of how ministerial responsibilities were organised within DH.

a) The Secretary of State: The Secretary of State had overall responsibility for the Department's policies, as well as the wider responsibilities that came with Cabinet membership. The Secretary of State would delegate more routine matters to the Minister of State. When I began my role as Parliamentary Under Secretary of State, Mr Kenneth (now Lord) Clarke was the Secretary of State for Health until 2 November 1990. Mr Clarke was then succeeded by Mr William (now Lord) Waldegrave.

b) Minister of State: The Minister of State also had specific areas of responsibility, usually for higher profile areas. Mrs Virginia Bottomley (now Baroness Bottomley) took over the post of Minister of State from Mr David Mellor on 27 October 1989. More routine matters could be delegated further to the Parliamentary Under Secretaries of State.

c) Lord Trafford was appointed Minister of State (Lords) on 25 July 1989, but he sadly died on 16 September 1989.

d) Parliamentary Under Secretaries of State: Parliamentary Under Secretaries of State were assigned their own areas of responsibility, documented in a list of ministerial responsibilities. In summary, they were responsible for replying to correspondence, answering most Parliamentary Questions and for speaking in routine debates. Each department had an Under Secretary of State in the Commons and the

Lords. At the time, Mr Roger (now Lord) Freeman was the Under Secretary in the House of Commons, before being succeeded by Mr Stephen Dorrell. As noted above, I took over from Lord Trafford as Parliamentary Under Secretary of State for Health in the House of Lords on or around 17 October 1989.

e) Permanent Secretary: The Permanent Secretary was responsible for overall operational management of the Department (i.e. structure, personnel and resourcing). The Permanent Secretary was also responsible for liaising with the Cabinet Office. At the time, Sir Christopher France was the Permanent Secretary. Mr Strachan Heppell was one of his very able Deputies (Grade 2), the head of the Personal and Social Services Group.

f) The Chief Medical Officer (**CMO**): The CMO fulfilled a fundamental role in advising ministers on public health. The CMO was the medical advisor to the Department, and to the government as a whole. There were a number of health issues that the CMO and his team were responsible for advising ministers on, which often involved complex and difficult subjects. Sir Kenneth Calman succeeded Sir Donald Acheson as the CMO in September 1991.

g) Private Office: I had a Private Office of around five staff. My Principal Private Secretary (who is generally referred to as PS(L) / PS in the government's internal documents) was responsible for keeping me informed on a number of key issues, as well as liaising with the Secretary of State and the Minister of State. Assistant Private Secretaries took responsibility for subjects which were not covered by my principal Private Secretary. I also had a diary secretary who arranged my appointments.

Q7: Communication

7.1. The Inquiry has asked me to describe how information and issues would be brought to my attention. As I was the only Health Minister in the House of Lords, I had to respond on all health issues, including those which were not my direct responsibility. Junior health ministers were expected to keep abreast of all issues affecting DH while having their own portfolios of responsibility. My Private Office was often copied into documents and submissions which sought the decision of other ministers.

7.2. My Private Office would organise my written submissions, correspondence and other documents by putting these in a red box for me to take home. I had trust in my Private Office staff, and they endeavoured to ensure that we, as Ministers, received the relevant information. I had full confidence that my Private Office staff would ensure that the Minister of State and other key departments were suitably informed of the significant issues with which DH was concerned.

7.3. Miss Burnett became my Private Secretary towards the end of my tenure. When Miss Burnett took over this position from Mrs Delfgou, she requested a note from the Branch and Section Heads on 2 October 1991 **[WITN7005002]**. Although I was not aware of a specific formal criterion for determining whether a matter was of sufficient importance to be brought to my attention, Miss Burnett's note somewhat indicates how ministers / officials would have communicated with me at that time. The majority of my communications relating to blood products would have come from Mrs Delfgou, Mrs Baldock or Miss Burnett.

7.4. I endeavoured to see most of the documents that came into my office. It is, nevertheless, likely that my Private Secretaries would have exercised their discretion as to whether I needed to see a document, particularly at a busy time or if I was abroad. So I may not have seen documents which I was merely copied into. When I began my tenure in DH, there was a vast amount of correspondence relating to the Health Reform Bill, for which I was also responsible. This was a major piece of legislation which I devoted much of my time to.

7.5. During my time in DH, informal ministerial meetings were held regularly (usually two or three times per week). The purpose of these meetings was to ensure that ministers and senior officials kept in touch. On average, two meetings per week would be attended by all of the health ministers and senior officials (such as the CMO, Permanent Secretary and the Chief Executive of the NHS) to discuss the issues of the week. One meeting was usually set aside to discuss political issues, which was attended by the ministers, party whips and advisors only. These meetings were informal in nature and as far as I am aware, minutes were not kept.

Q8: Responsible Civil Servants

8.1. My independent recollection of the senior civil servants with whom I principally dealt in DH (or from whom I received advice) in relation to blood or blood products is limited. However, I do recall that Mr Heppell was a senior official in the Department. Mr Heppell was the Grade 2 Head of the Health and Personal Social Services Group. From the documents, it is clear that Mr Heppell was a key advisor on issues relating to blood products. I thought that Mr Heppell was highly experienced and effective in his role.

Q9, Q10: Relationship with relevant bodies in Scotland, Wales and Northern Ireland

9.1. The Inquiry has asked, first, about my interactions with the Territorial Departments in Wales, Northern Ireland and Scotland in relation to blood, blood products, the licensing and regulation of pharmaceutical companies, and related issues of blood borne viruses. I do not now specifically recall dealings with the Territorial Departments in these areas. I have, however, addressed these in the subsequent sections of my statement where they arise in the documents.

9.2. I was referred to the following documents by the Inquiry in relation to this issue:

a) **[DHSC0002883_012]**, which is a memorandum from Mr Burrage to Mr Dobson and Ms Baxter dated 1 May 1991; and

b) **[DHSC0002883_013]**, which is the briefing accompanying the memorandum.

9.3. However, I do not think that this memorandum was sent to my office. Whilst it is addressed to PS(L), as far as I can remember Ms Baxter was Stephen

Dorrell's Private Secretary; he was the Parliamentary Under Secretary from 4 May 1990 – 14 April 1992. This also makes sense of the reference in the Note to Harriet Harman MP – she was obviously in the Commons. That said, the Note is an example of how briefings were given by officials to ministers, to handle questions in debates.

10.1. I was further asked whether I interacted with any other health-related bodies in Wales, Scotland and Northern Ireland on these topics. Generally speaking, I cannot now remember any interactions. There may have been discussion at conferences, or similar.

Section 3: Safety of Blood and Blood Products

Q11: Information on Taking Office

11.1. I have been asked about the advice or information that was given to me when I first took office, in relation to the safety of blood and blood products or the Blood Transfusion Service and how it was organised. I am not able to remember what information or briefings were provided to me and no relevant documents have been shown to me.

11.2. The Inquiry has referred me to a number of documents: **[DHSC0002374_030]**, **[DHSC0002374_031]** and **[DHSC0002374_032]**. These relate to haemophiliacs who had died of HIV and the testing of blood for HIV antibodies, but they appear to be correspondence in August and early September 1989 addressed to the Private Office for the Minister of State for Health (i.e., MS(L), not PS(L)), who at the time was Lord Trafford, who was in post until his sudden death on 16 September 1989. Whilst I succeeded him, it is impossible to say whether this material was drawn to my attention when I took office, or not.

11.3. From recollection now, my knowledge and understanding of these issues before taking office had largely come from reports within the press regarding those who had been infected by blood or blood related products.

Q12: Understanding when in office

12.1. I have been asked how my understanding changed when in office.

12.2. After that point, if there were matters which needed to be brought to my attention, information would generally come through my Private Office or (possibly – although I cannot remember examples – through the general ministerial discussions I have outlined above).

12.3. In addition, I have tried to set out below my involvement in particular areas concerning blood policy in response to the specific questions asked by the Inquiry, although I am essentially dependent on the documents provided.

Q13, Q14: Knowledge of Risk and Regulation of Blood Products

13.1. I have been asked about my knowledge of the risks associated with blood and blood products. In general, I cannot now recall specific involvement in the way in which risks associated with the use of blood and blood products were assessed and decided upon. However, I have set out more details of my involvement with the topic of Hepatitis C screening of blood at Section 5 below.

14.1. I cannot now recall my knowledge of the way in which blood products were regulated and licensed.

14.2. I have been referred by the Inquiry, in relation to the issue of how blood products were regulated and licensed for use, to: **[BPLL0011217_019]**, **[BPLL0011220_002]** and **[BPLL0010892]** and **[BPLL0011214]**. These documents contain an extract from Hansard with a Parliamentary answer given by me on 7 December 1989 to a question by Lord Winstanley about clinical trials upon stocks of Factor VIII and Factor IX, referring back to a question asked in 1986. The remaining documentation is correspondence between officials at DH and Dr Lane at the Central Blood Laboratories Authority (the **CBLA**) about concerns that my answer ought to be clarified. I can see that I wrote to Lord Winstanley on 31 January 1990 in order to make a clarification **[BPLL0010892]**. Whilst I was not copied into the correspondence between officials, I would have been made aware of the omission through my Private Office, leading to the letter which I wrote to Lord Winstanley. This would have been drafted on advice from officials.

14.3. The documents referred to above do not relate directly to how blood products were regulated and licensed for use – they are about clinical trials. However, the process does show the effort that went in to ensuring accurate information was given to Parliament and that the record was corrected when necessary.

14.4. Generally, it was important to keep abreast of all issues affecting DH. Whilst I had my own areas of responsibility, I would be required to answer Parliamentary Questions on all health topics. I would be briefed by my advisers and would respond to questions based upon the information I was given.

Q15: Establishment of a National Blood Authority

15.1. I have been asked by the Inquiry about the establishment of a National Blood Authority (the **NBA**).

15.2. I can see from documents provided that that I was involved in DH's oversight of the CBLA. Specifically, in relation to the Inquiry's question, I can see that issues relating to the structure and organisation of the CBLA and the National Blood Transfusion Service (the **NBTS**) were raised, from c. early 1991 onwards. The issue of the structure of the NBTS was, apparently, considered in a report commissioned by the National Directorate if of the NBTS, from Ernst & Young. The report was delivered, I have been reminded in May 1991.

15.3. I have been referred to documents relating to the Accountability Review Meeting which took place on 10 July 1991 **[DHSC0002434_016]**. This memo, which was part of the briefing for that meeting, refers to proposals from Ernst & Young for a National Blood Authority, *"which would be a contracting body which would obtain blood from the RTCs for supply to hospitals and would contract with BPL to have plasma fractionated into blood products."*

15.4. I have then been referred to a submission from Mr Dobson to my Private Office and the Private Office of the Secretary of State dated 12 July 1991 **[DHSC0004245_017]**, which followed that review meeting. The submission set out proposals from the CBLA and the National Directorate of the NBTS to:

a) set up a National Blood Authority to improve the quality standards and efficiency and cost-effectiveness within the NHS;

b) to 'decouple' the CBLA's manufacturing arm, the Bio Products Laboratory (**BPL**), to allow it to operate in a more commercial basis; and to pave the way for

c) a possible privatisation of BPL (although this was regarded as more sensitive and potentially difficult).

15.5. The submission set out how concerns were raised following a DH study in 1987 that the way in which Regional Transfusion Centres (**RTCs**) were run meant that there were inefficiencies within and between the RTCs. These were attributed to a lack of reliable management information system and the lack of cooperation and coordination between the RTCs and the CBLA. The response to these concerns was to set up the National Directorate of the NBTS in 1988 **[DHSC0002534_034]**.

15.6. In his submission of 12 July 1991, Mr Dobson wrote that the National Directorate had had some successes, but at this time (i.e. 1991) its officers now considered that they were *"nearing the limit of what can be achieved within the present voluntary structure"*. It was recognised that the National Directorate was unable to address all of the problems with management within the NBTS and so had commissioned a report from Ernst and Young to explore the role of a central body within the NBTS and the organisational options.

15.7. The drive for reform appears then to have come from consideration of the Ernst and Young report prepared for the NBTS itself. However, it also seems from my subsequent note to the Secretary of State on 16 July 1991 **[DHSC0004245_004]** that there had also been issues to sort out with the CBLA in the interim; I referred to completing the Annual Review of the CBLA "which is now running more smoothly".

15.8. I can see from the documentation now provided that I then worked to action the proposals in order to take the initial steps towards establishing a National Blood Authority. I commented on the proposals in the submission of 12 July in my note to the Secretary of State, Mr Waldegrave, dated 16 July 1991 **[DHSC0004245_004]**. He responded on 17 July **[DHSC0004245_003]** to say he was happy with the proposal to establish a National Blood Authority but did not wish to see reforms regarding CBLA/BPL go any further (see Q16).

15.9. On 26 July 1991, I was then sent a further submission from Mr Dobson, asking for further guidance in the light of the Secretary of State's decision **[DHSC0014938_067]**. This set out proposals on the management of BPL, in particular. This was followed on 12 August 1991 with proposals to consult on the changes suggested **[DHSC0004369_031]**. It seems from the submission of 14 November 1991 from Mr Canavan **[DHSC0006858_081]** that a consultation document was issued in September 1991. It seems that although there was basic support for the idea of a National Blood Authority, there were concerns about the details. Further work to achieve a consensus was recommended. It is apparent from the documents, including the letter from Mr Wing, the CBLA Chair, dated 21 November 1991, that the proposals took some time to be developed in a way that commanded acceptance **[DHSC0002435_003]**. The same complexities are evident in my note to the Secretary of State on 21 January 1992 **[DHSC0004082_085]**.

15.10. I understand that the NBA was eventually created in 1993.

15.11. I have been asked why a body with national authority had not been brought into existence prior to 12 July 1991, despite the suggestion in the submission that the NBTS was a "*national service in name only*" (see para 4 of the submission). As I have noted, the submission explained that a DH study had identified concerns in 1987, and a National Directorate had been set up in 1988 to address those concerns.

15.12. The response to the 1987 study pre-dated my time in office and I am unable to comment on why the decision was taken to set up a National Directorate, as opposed to setting up a body with national authority, or why a body with national authority was not set up, prior to my time in office. However, presumably once the National Directorate had been set up in 1988, there would have been a desire to let that development 'bed in' and see what could be achieved.

15.13. In this regard, I have been referred to the witness statement of Mr Roger Moore **[WITN6919001]** who, relevantly, was the Deputy National Director of the National Directorate at the NBTS between 1989 and 1992. Mr Moore's statement provides an overview of the tasks in hand at the National Directorate during that period (see paragraphs 6.3 – 6.10 of his statement); it is apparent not only that there was an extremely busy 'agenda', but also that the Directorate was effective in bringing the RTCs together so that the RTCs "*were better prepared for the unified management structure that was to come later with the establishment of the NBA*" (see para 7.8, also Q77 at p45 and Q149 at p74). Although I cannot recall the extent of my involvement with the National Directorate and its work, neither this statement nor documents now shown to me suggest that there was any real pressure to move to a more unitised structure, prior to the discussions of 1991 and the commissioning of a report from Ernst and Young by the NBTS.

15.14. I have been asked if I have or had any views on whether it would have been preferable for a national body to be created at an earlier stage. I cannot recall what my views were at the time as to whether a national body should have been created at an earlier stage. I also find it difficult to comment now on whether it would have been preferable for a national body to have been created earlier. I was not involved in the initial decision to set up the National Directorate at the time these issues were first identified and the Directorate was set up, so I do not know why that was the route which was taken. However, I presume, based on my own experience, that my colleagues would have taken advice on the matter and have sought to address any issues in the most appropriate way possible based on the information available at the time. Similarly, I sought to act on the information made available to me when the proposals for the reform of the National Directorate were developed.

Q16 Reform of the Bio Products Laboratory

16.1. I have further been asked to consider the proposals for the reform of BPL. I have been referred to various documents, starting in March 1991. It will be apparent that there is an overlap with the topic of the reform of the NBTS considered above, and that the submission of 12 July 1991 (considered above) addressed both topics.

16.2. I understand that the issue of reform of the CBLA and BPL was considered by Touche Ross, in a study commissioned by the CBLA itself. The documents show that I was supplied a copy of the Touche Ross report **[NHBT0002310]**, although I cannot remember this now; a copy was supplied by Mr Wing on 22 January 1991 **[NHBT0000065_031]**. I comment on the report in the context of Mr Canavan's submission of 5 March 1991, at paragraphs 16.3 and 16.4 below.

16.3. It seems that on 5 March 1991, I was sent a submission from Mr Canavan **[DHSC0002534_034]** which noted that the CBLA had asked Touche Ross to carry out a review of the future strategy and options for the organisation. The submission summarised the main issues arising, noting that I would be discussing them when I visited Elstree (the site of BPL) on 11 March. The submission canvassed the arguments for a separation of the functions of the

CBLA and the production and manufacture of blood products at BPL. Mr Canavan included comments on the Touche Ross report, which officials regarded as '*rather disappointing*' **[DHSC0002534_034]**.

16.4. It seems that these issues were scheduled to be discussed at the Accountability Review meeting with the CBLA on 10 July 1991 **[DHSC0004369_010]**. I had a discussion with members with the CBLA about their concerns over the need to make BPL more commercially viable. The Chairman of the CBLA, Mr Wing, expressed concerns that a change in European regulation meant that BPL would need to compete with European fractionators as well as commercial fractionates, and at the same time serve the NHS. It was noted that the market for plasma products was growing and that clinicians in the UK were free to buy commercial products. The minutes record me as saying "that the second report from Touche Ross had provided the basis for the decision on the BPL / CBLA decoupling". As far as I am aware, this is a reference to the report referred to at paragraph 16.2; I have been shown only one report and do not recall another. I asked for the views of the CBLA on the individual options presented. The recommendation in the short-term was that BPL should operate as separate division with the CBLA from October 1991. However, it appears that no decisions were made at this meeting, and I said I would take proposals to ministers.

16.5. I was subsequently sent the submission of 12 July 1991 **[DHSC0004245_017]** which I have already referred to. Recommendations were made in relation to making BPL more commercially viable and freeing BPL up to exploit new products and markets. The advice given was that by making BPL more commercialised and allowing the most efficient use of the plant at Elstree, this would benefit the NHS as the whole by leading to lower prices for CBLA products and, through competition, for commercially supplied products. This in turn would free up resources to be used elsewhere, thus providing a benefit to the NHS. It was envisaged that this would lead to more consistent quality and lower prices for the NHS. The recommendation to ministers was therefore to go down the route of 'decoupling' BPL to enable the pursuit of commercial enterprises, such as marketing products outside the UK under its own label.

16.6. I expressed support for the proposals to the Secretary of State in a memo dated 16 July 1991 **[DHSC0004245_004]**. It is clear, however, that I acknowledged the risks of any move towards 'privatising' BPL, as this would be politically controversial and I am not clear now how far along that road I expected changes to go; the first stage was to 'decouple' BPL and the CBLA to give BPL greater freedoms, with privatisation a later possibility.

16.7. However, the suggestion to decouple BPL so that the BPL plant could be used to full capacity, including the option of eventual privatisation, was not supported by the Secretary of State, albeit he offered to speak with me further about this **[DHSC0004245_003]**.

16.8. In light of the views of the Secretary of State, further guidance was sought on whether BPL could be given more freedom to pursue commercial interests without going down the route of privatisation. In a submission to my Private Office dated 26 July 1991, officials advised that BPL could become a distinct operating unit within the CBLA and that it should be encouraged to fractionate volunteer plasma from non-UK sources and market the products under its own label outside of the UK. This appears to be in response to a question from me as to whether constraints on BPL could be loosened in order to maximise the use of the Elstree plant, without decoupling BPL from the CBLA/NBA. In his submission, Mr Dobson recommended that BPL be given additional freedoms to improve its commercial viability **[DHSC0014938_067]**.

16.9. The key reasons for the decision not to 'decouple' BPL appear to include concerns about the potential criticisms relating to a privatised BPL making profits from freely-donated plasma and concern that the move would be viewed as evidence of 'selling off' the NHS, which was particularly controversial (see **[WITN7005003]**).

16.10. I informed the CBLA on 5 August 1991 that no changes should be made which might suggest BPL was being prepared for a change in status. The desire for additional freedoms was discussed, including the suggestion of marketing products derived from non-UK donors under its own label. I informed Mr Wing that these moves could attract the same criticisms as uncoupling BPL and thus they should concentrate on making use of BPL's existing freedoms

[DHSC0004369_018]. I wrote to Mr Wing, chairman of the CBLA on 2 September 1991 confirming the discussions we had had and the decisions made **[DHSC0020713_110]**, **[NHBT0000067_028]**.

16.11. It is apparent that Mr Wing continued to favour the 'decoupling' option: see his letter to me dated 12 March 1992 **[DHSC0002939_010]**. He stressed the problems that would occur if BPL was not given the freedoms sought. However, I reiterated that BPL should continue to build on their recent achievements and concentrate on working within existing freedoms **[WITN7005004]**. It appears that the decision was taken that no further action should be taken before the election, but I had suggested that the Accountability Review in the summer of 1992 would provide an opportunity to reconsider the position **[WITN7005003]**.

16.12. I then left office on 14 April 1992 and therefore was not involved in any further discussions on this matter.

16.13. I have been asked a series of questions about these proposals, and my thinking at the time. I should say that it is now virtually impossible for me to recreate my thinking at the time, unless revealed by the documents I have seen. I have done my best to work out the answer from those sources, but I am limited by the lack of memory.

Commercial Operations outside of the UK.

16.14. First, I have been asked if I agreed that BPL should be encouraged to fractionate volunteer plasma from non-UK sources and market the resulting products under its own label outside of the UK. I can see that this proposal formed a part of the scheme put forward in the submission of 12 July 1991 (see paragraphs 10 and 11), although it is important to note that UK plasma from UK volunteer donations was to be separately managed, with the CBLA retaining ownership and ensuring their use for NHS patients. The context was said to be an *"increasingly competitive market for blood products and the likely appearance of synthetic substitutes for some products within 5 – 10 years."* A gradual process of "decoupling" was recommended, as a response.

16.15. I can see that I reacted favourably to the general proposal of giving increased freedom to BPL in my note to the Secretary of State on 17 July. I wrote that it *"offers clear benefits to patients [but] could be politically controversial".*

Pursuit of 'commercial interests'

16.16. Second, I have been asked why BPL needed to "pursue commercial interests, as opposed to solely producing blood products for the CBLA".

16.17. As to that, BPL was operating in a competitive market (see paragraph 10 of the submission of 12 July). It was constrained, as well as supported, by its public funding: see the statement in the submission that *"It was also difficult for BPL to move into new production areas (e.g. synthetic products) because of the demands that this would make on the NHS for R & D and other funding."* BPL did not have a guaranteed NHS market; clinicians were able to buy commercial products as an alternative to the BPL product. It is also apparent that the scheme for pursuing wider commercial interests was aimed at using BPL's full capacity (see paragraphs 15 and 17).

Political Controversy

16.18. I have then been asked why decoupling BPL from the CBLA could be politically controversial. This emerges from the submission and my Note to the Secretary of State (as well as his reaction); it was potentially linked to the privatisation of BPL (see paragraphs 14 and 17 of the submission of 12 July, which set out the difficulties in detail).

Benefits to Patients

16.19. The Inquiry asks what "clear benefits to patients" were envisaged by decoupling. I would refer back to the detailed arguments presented in the submission of 12 July 1991, which - as far as I can now tell from the papers - I appear to have accepted when I wrote to Mr Waldegrave.

Views of the CBLA

16.20. I have been asked whether I was aware that the CBLA / BPL felt strongly that they were "receiving two contradictory sets of signals from the Department of Health, one requiring them to act commercially and maximise the financial return from the plant, the other imposing ethical and political constraints" which hindered them from doing so; and what were my views on this.

16.21. Over 30 years later, I cannot remember what I knew or was aware of at the time. I can see that this is a view set out in the submission and I would have had no reason to doubt that this was indeed the CBLA's view. The proposals set out in Mr Dobson's submission were intended to deal with any such 'mixed messages', by dividing the functions of the CBLA / NBTS from those of BPL. It is apparent from his letter of 12 March 1992 that Mr Wing felt strongly about the proposals.

Public Trust

16.22. I have been asked if I was concerned that privatising BPL would have damaging implications in terms of public trust, particularly by those frequently requiring blood products. I cannot remember what I thought about this at the time, although I was certainly aware that it would be politically controversial – and Mr Waldegrave decided that the option should not be pursued.

16.23. I cannot recall now how far my support for the privatisation option extended, given that the first step would have been to decouple BPL. Privatisation was a further step that may have followed further down the road. In any event, it is plain that this option was not supported by the Secretary of State and so privatisation proceeded no further whilst I was in office.

Mixed Source Plasma

16.24. I have been referred to **[DHSC0002534_034]** and asked if it was being suggested that products manufactured using mixed plasma sourced from both the NBTS and Europe would be marketed to the NHS. This document is a submission sent to my Private Office by Mr Canavan dated 5 March 1991. The page referred to (p6) contains comments by department officials on proposals set out in the Touche Ross report, at para 5.1.2 of that report **[NHBT0002310].** Looking at that report now, it is apparent that at p24 the report noted the potential to source plasma from European countries provided, that it was from non-paid (voluntary) donors. Then at p30, there is mention of evaluating European supplies (again, from voluntary donors) for quality and price. It was said that "*If further NHS sales can be secured this should be achieved through purchase of NHS plasma or plasma from Europe*". These comments or proposals are not detailed, but they appear to envisage some use of mixed NBTS / European plasma. But the officials (i.e. Mr Canavan in his submission of 5 March 1991) reacted by suggesting that, if so, there might need to be separate NHS and non-NHS product lines, for products from mixed NBTS/European plasma – i.e. preserving UK supplies separately.

16.25. However, the submission of 12 July 1991 referred to (i) "*The EC move to promote community self-sufficiency in blood products made from freely donated plasma…";* but (ii) proposed only to allowing offers *"for commercial partners to buy an interest in BPL in order to open up new markets for products not involving UK plasma*" (see paragraphs 18 and 19 of the submission). So it seems that the context was a proposal for European co-operation involving freely donated blood but it was not suggested that this should be pursued as part of the BPL 'decoupling'.

NHS Financing

16.26. I have been asked about what actions I took to address the issue of financing within the NHS "resulting in persistent problems such as a failure to make prompt payment for blood products." This question appears to relate to comments I made at the Accountability Review of 10 July 1991 (see para 11 of **[DHSC0004369_010]**. I said that that financing in the NHS was high profile and that persistent problems such as failure to make prompt payment for blood products would need to be fed back into the Management Executive.

16.27. This was in response to the Chairman of CBLA, Mr Wing, saying that since 1 April 1991 (i.e. the date of the introduction of the NHS 'internal market'), when there had been a change in the way payments were made, hospitals, districts etc. had been slow in paying BPL invoices. He, however, expressed hope that there would be an improvement following a recent meeting with finance managers. My comment therefore appears to say that should these problems continue, the Management Executive will need to be informed. It was early days.

Q17: NBTS and self-sufficiency

17.1. Finally, I have been asked how the NBA performed in its role in ensuring the UK became self-sufficient in blood. Whilst I was involved in the initial proposal and decision to set up a National Blood Authority, the NBA was not in fact established until 1 April 1993. I left office as the Parliamentary Under Secretary of State for Health on 14 April 1992 and therefore do not feel in a position to comment on how well the NBA performed with regards to ensuring the UK became self-sufficient in blood.

17.2. With regards to the NBTS and its National Directorate which I was in office, I find it difficult to recall what I knew about this topic in 1989 – 1992 or to have a view now. I refer again to the Witness Statement of Mr Moore, at Q33, where he says that from 1988 – 1993, the National Directorate was able to co-ordinate plasma supplies so that sufficient plasma was always available to meet BPL's capacity. Shortages of plasma are not, as far as I can see, a feature of the documents referred to me.

Section 4: Financial support and litigation

Q18: Payment increase to the Macfarlane Trust, 1989

18.1. The Inquiry has asked whether I had any involvement in the decision to increase the payment to the Macfarlane Trust by £19m in 1989, and has referred me to a number of documents. I do not specifically recall the circumstances leading to that decision. At that time, I believe that Mr Clarke and Mrs Bottomley had overall responsibility for the decisions relating to payments to the Macfarlane Trust.

18.2. The Inquiry has referred me to a number of letters exchanged with the Haemophilia Society, which were sent either before or very early on in my tenure:

a) Letter from the Haemophilia Society (Mr Watters) to Lord Ennals in August 1989 **[DHSC0046945_039]**; this updated Lord Ennals on the High Court litigation proceeding and the Society's perspective on the moral responsibility owed by government, but predates my tenure;

b) Letter from Lord Ennals to Lord Trafford dated 1 September 1989, which passed on the letter from Mr Watters; **[DHSC0046945_040]**;

c) Letter from the Haemophilia Society to Mr Norman Lamont (Chief Secretary to the Treasury) dated 23 October 1989 **[HMTR0000001_004]**. This is not a letter I would have seen but outlines the Haemophilia Society's campaign;

d) My letter to Lord Ennals dated 30 October 1989 **[DHSC0046945_038]**, in which I responded to his letter of 1 September to Lord Trafford.

18.3. I have been reminded that on 16 November 1987, the then Minister of State for Health, Mr Tony Newton announced the unprecedented action the government was taking in establishing the Macfarlane Trust and providing £10m by way of an ex-gratia payment **[LDOW0000241]**. It was said that in doing so, the special circumstances of haemophiliacs were recognised. Mr Newton stressed that the payment was not compensation, as compensation was a matter that should be determined by the courts.

18.4. I can see that I replied to Lord Ennals, in place of Lord Trafford, on 30 October 1989 (see (d) above) almost immediately after I took office. I set out what I understood to be the government's position, that the fund had recognised the "special circumstances" of those infected with HIV. This was consistent with a letter that had already been written by Lord Trafford to Mr Watters of the Haemophilia Society on 21 August 1989, in response to its letter to the Secretary of State **[DHSC0003989_067]**.

18.5. The Inquiry has also referred me to the following submissions:

a) A detailed submission from Mr Dobson dated 26 October 1989 sent to the Private Office of the Minister of State for Health (MS(H)), and copied to my Private Office **[DHSC0002536_078]** and **[WITN5292079]**. This advised that, at that time, the government should not signal any readiness to provide additional funding, "beyond the steps already in hand to allow greater flexibility to the Trust (and a veiled promise to consider topping up when needed);

b) A note from Mr Heppell to the Secretary of State's Private Secretary (Mr McKeon) dated 7 November 1989, copied to my Private Secretary **[DHSC0004415_156]**. This was a note in preparation for a discussion with the Secretary of State that appears to have been initiated by the Minister of State for Health, i.e. Mrs Bottomley. It outlined various proposals to adequately respond to the situation of haemophiliacs with AIDS / HIV and sufficiently meet the aspirations of the Haemophilia Society;

c) A Note from Mr Heppell to Mrs Bottomley's Private Office, dated 10 November 1989, again copied to my Private Office **[DHSC0004415_155]**, which reported on Mr Heppell's meeting with the Haemophilia Society on 9 November 1989. It was suggested that a sum of £120m was required to bring the litigation to an end; Mr Heppell doubted that these sorts of figures would be contemplated by government.

d) Letter from me to The Reverend Tanner, Chair of the Haemophilia Society, dated 13 December 1989 **[HSOC0003582]**, informing the Society of the additional £19m to be paid.

18.6. I have been asked what involvement I had in the decision making that culminated in the letter of 13 December, referred to above.

18.7. Review of these submissions suggests – and I think that this is correct, as far as I can remember – that I did not have any substantive involvement in the discussions about whether or not the money available to the Macfarlane Trust should be supplemented, in late 1989. I was not involved in the discussions referred to in Mr Dobson's note, about "steps in hand" to increase flexibility for the Trust. It seems that the Ministers of State for Health (i.e Mr Mellor and then Mrs Bottomley) were leading on this, and that the Secretary of State for Health Mr Clarke, was involved as well. I have been shown a copy of the Second Statement of Mr Clarke **[WITN0758001]**, **[WITN0758012, paragraphs 25.1 – 36.8]**; from this, I can also see that the Prime Minister was involved in the discussions. But again, it does not seem that I was.

18.8. It is likely that the submissions that are listed above, or any other key documents sent to my Private Office, would have been passed to me by my Private Office, to ensure that I was updated of the current position; however, I simply cannot remember this happening now. My place on the copy list suggests that the information was being sent as a courtesy, rather than because I was playing a particularly active role.

18.9. On 23 November 1989, Mr Clarke announced an additional payment of £19m to the MacFarlane Trust in a Written Answer to a Parliamentary Question from Mr Key MP **[HMTR0000001_023]**.

18.10. I have been referred again to the letter that I sent to The Reverend Tanner of the Haemophilia Society on 13 December 1989 **[HSOC0003582]**, which stated:

> *"Our exceptional measures in setting-up the Macfarlane Trust in March 1988 with the initial £10 million ex gratia payment was a tangible expression of our deep concern that their special needs should be met. This was not intended as compensation and does not deter haemophiliacs from pursuing compensation through the Courts, as some are now doing. We said at the time of the original announcement in*

> *November 1987 that the sum would be kept open to review. The Trust has already been able to give significant and valuable help to a large number of infected haemophiliacs and their families. However the true nature and extent of the needs of the infected haemophiliacs have become much clearer now that the Trust is in operation and has been able to examine individual cases in detail. In fulfilment of our 1987 commitment, we now considered it right to reassess the total sum we had made available to the Trust."*

18.11. In that letter, I outlined that the government had the following objectives in making the new allocation:

a) To enable the Trust (if the Trustees saw fit) to make individual payments of £20,000 this year to each person with haemophilia who was infected with AIDS as a result of treatment with blood products in the UK, or to the family of such a person who has died; and

b) To enable the Trust to continue their help to families in particular need on a more generous scale. I wrote *"We accept the need to ensure that the fund has adequate resources both to meet its existing commitment and to give more generous help to families in particular need. We will be discussing further with the Trust how these objectives should be met."*

18.12. I have been asked for my views on the policy. I do not now recall having a specific view on the decision to increase the sums paid to the Macfarlane Trust. I had understood from Mr Newton's announcement that the sums made available to the Macfarlane Trust would be kept under review, and it seems that they had. I had the greatest sympathy for all of those who were infected and their families, and I expect that I was pleased that more money had been found.

18.13. The Inquiry has asked whether I was optimistic that the proposals contained in my letter would be sufficient to persuade the Haemophilia Society to recommend not proceeding with legal action to its members. Unfortunately, I do not recall having a specific view on this issue, perhaps because I was not involved in the negotiations or the thinking behind them. I would have thought that those more involved in the decision and also in the management of the litigation would be better able to comment.

18.14. The Inquiry has asked me if I was briefed on how long the additional £19m was intended to last.

18.15. A memo dated 21 November 1989 was sent by Mr Heppell to Mr McKeon **[DHSC0046959_097]** and copied to my Private Office. The memo attaches a draft answer to the following question: *"To ask the Secretary of State for Health whether he will make a statement on the financial support available for haemophiliacs who have been infected with HIV"*.

The draft response states:

> *"...The Government is therefore proposing to make an additional ex gratia payment to the Trust of £20 million. The House will appreciate that as before this is not a compensation, but a recognition of the particular circumstances of the families concerned. This new allocation will be spread over the next 3 financial years..." [emphasis added]*

18.16. I do not recall being briefed on how long the £19m (in fact subsequently increased to £24m - see Lord Clarke's Statement) provided to the Macfarlane Trust was intended to last. From the draft response above, I would have expected that the increased funding, of £20,000 per family, would be made available over the next 3 years, with any additional funding to be reviewed thereafter. But if there were 1,200 affected victims, then paying each one £20,000 would have implied a total payment of £24m, exhausting the additional funds that were eventually made available much more quickly. My own letter to the Society on 13 December 1989 made it clear that there would be a separate discussion on supplementing the 'discretionary' or hardship funds.

18.17. I have not been provided with any documents that would assist me to remember what, if any, process of discussion followed that letter. I can see from Lord Clarke's statement that time was taken up in setting up a new Trust (Macfarlane No. 2) as it was discovered that the original Trust could not properly make 'lump sum' payments that were not directly linked to hardship. I also note that by around November 1990, discussions had started on the subject of settling the HIV litigation, and that this eventually led to a further payment of £42m into the Macfarlane Trust. It is possible – although I cannot remember the details or having any involvement – that these developments 'overtook' any discussion of additional payments to the Trust. But I would need to be referred to officials' correspondence to find out more.

18.18. I have also noted that in Mr Waldegrave's letter to the Chief Secretary to the Treasury on 2 December 1991 (see Q27 below), when he discussed using the

Macfarlane Trust to support non-haemophiliacs infected with AIDS, he said that this option would "bring forward the time when the Macfarlane Trust will need topping up." It seems, therefore, that there was a general acceptance that the Trust would need 'topping up' when it exhausted its funds.

18.19. Other than being able to confirm that I was aware of the fact that ministers / officials had indicated that the sums provided would be reviewed as necessary, I do not consider that I can meaningfully comment on how often the Department reviewed the sums provided to the Trust, as I was not directly involved in the decisions in this area. I do not specifically recall being asked for my view on this topic; I think that the documents show that others led discussions of this matter.

Q19: The HIV Haemophilia Litigation

19.1. I have been asked whether I had any knowledge of or involvement in the HIV haemophilia litigation before my tenure began in October 1989 (not July as the Inquiry suggests, see the comments on Lord Trafford). Although it is likely that I read about the litigation in the media, I do not recall having any detailed knowledge of it.

Q20: Events from November 1989 onwards

20.1. The Inquiry has referred me to a number of briefings which my Private Office was copied into, leading up to my contribution to the Parliamentary Question (PQ) in the House of Lords on 27 November 1989 **[DHSC0002948_007]**.

20.2. I have been referred to Mr Heppell's memos dated 7, 10 and 21 November 1989, which I referred to in paragraph 18.5 above. When read with Mr Dobson's memo dated 26 October 1989 **[DHSC0002536_078]** and Mrs Farr's memo dated 16 November 1989 (copied to my Private Office) **[DHSC0002536_061]**, these documents show the range of sums suggested by the Haemophilia Society to settle the litigation, and a high-level summary of the risks posed to the government in continuing with the litigation. Initially, the sum of £120m was proposed by the Haemophilia Society to bring the litigation to an end. The

Haemophilia Society then (see note of 16 November) indicated that it would be prepared to accept payment of £86m to recommend settlement of the claim.

20.3. However, my placement on the copy list confirms my recollection that I was being kept informed, rather than asked to contribute to substantive decision-making.

20.4. In similar fashion, I was informed about the meeting between a Parliamentary delegation, Mrs Thatcher and Mrs Bottomley which took place on 22 November 1989 **[DHSC0002536_031]**. The record of this is in a letter from Mr Gray to Mrs Bottomley's Private Secretary.

20.5. The Prime Minister (Mrs Margaret Thatcher) is recorded to have stated:

> *"... the Government recognised the need to provide additional assistance. [The Prime Minister] could not, however, accept the case for action on anything like the scale being suggested by some of the pressure groups, not least because there could be no question of the Government accepting legal liability in the run up to the prospective court hearings. There was also a major problem in ring-fencing any assistance given to the haemophiliacs. The position was they had been given the best treatment available on the then current medical advice, and without it many of the haemophiliacs would have died. She could therefore not accept that blame rested on the NHS; were that principle to be accepted it could be extended throughout the range of the NHS activities and indeed also to drug licencing."*

20.6. The following day, Mr Heppell provided the Secretary of State's Private Office with a draft press release and a copy of the notes prepared for the Minister of Health's use at the meeting on 22 November 1989 **[DHSC0002536_034]**. My Private Office was copied into Mr Heppell's memo. The next day and as noted in paragraph 18.9 above, Mr Clarke announced an additional payment of £19m to the Macfarlane Trust in a Written Answer to Mr Key's Question **[HMTR0000001_023]**.

20.7. These are all matters addressed under the heading of Q18, the additional support to the Macfarlane Trust of November 1989.

20.8. I have been asked if I was in personally involved in any of the decisions taken on the management of the HIV litigation at this time. I do not have any recollection of being personally involved in any of the decisions taken on the government's position in the HIV haemophilia litigation at this stage. I believe that the key decisions in this area were taken by the Minister of State and the Secretary of State, together with (at times) the Prime Minister. I followed the issues to the extent that I was required to debate them in the House of Lords and respond appropriately to correspondence (see, for example, my response to the Haemophilia Society on 13 December 1989 as noted in paragraph 18.10 above).

20.9. I presented the government's agreed position in the House of Lords on 27 November 1989 **[DHSC0002948_007]**. I have been asked by the Inquiry whether I had a fixed position on the litigation and whether this was in accordance with the government's official position. I do not recall disagreeing with the government's position at that time.

Q21: My involvement in the Haemophilia Litigation - 1990

21.1. The Inquiry has then asked me to explain who I understood to be responsible for making decisions on the conduct of the HIV haemophilia litigation, and ultimately its settlement, from 1990 onwards.

21.2. I have been referred to a number of documents, which discuss the issue of limitation in the context of the litigation. Other than being asked for my view on the limitation point (explained further below) and responding to questions in the Lords, I do not recall being involved in decision-making in this area. I suspect that the key decisions in this area would again have been made by the Secretary of State and Minister of State for Health, based on advice that they would have received both from officials and the legal team.

21.3. I have set out summaries of the documents to which I have been referred below, to remind both myself and any readers of events. But they confirm the limited extent of my involvement, as set out above.

Q21: Comments on the Limitation Defence

22.1. On 9 May 1990, Mr Stephen Dorrell, the Parliamentary Under Secretary of State for Health, spoke in the House of Commons on this issue

[DHSC0000290]. Mr Dorrell presented what I believe would have been the government's agreed position at that time:

> *"I should stress that… the £34 million total provided to the two Macfarlane Trusts represents ex-gratia payments. They are not intended as compensation because in this country in successive Governments, there has never been a scheme of no-fault compensation for those damaged by medical treatment…The system remains that those seeking compensation should pursue the matter through litigation… A number of haemophiliacs with the AIDS virus… are doing just that. I am sure that the House will understand that it would not be appropriate for me to comment on issues that are before the courts."*

22.2. I have been referred to a submission dated 30 May 1990, whereby Mr Canavan sought the wider views of ministers on the handling of the litigation **[DHSC0038699_023]**. The submission was addressed to Mrs Bottomley's Private Office but copied to other ministers. Mr Canavan sought *"Ministers' views on whether the Department, Medicines Licensing Authority and the Committee on Safety of Medicines should plead the defence that the haemophiliacs action for damages is out of time."* He proposed a number of options following counsel's advice. Mr Canavan's view was that we should not plead limitation at all (option ii).

22.3. I agreed with Mr Canavan's reasoning and was content to follow his advice. It did not seem that there were many practical benefits of pleading the limitation defence when the Court could well be minded to grant an extension in these exceptional set of circumstances. I understood that there was a risk that pleading the limitation could be seen as a delaying tactic. Equally, if the Department was successful on limitation, then there could have been criticism that justice was denied and the case was won on a technicality. I understood Mr Canavan's point of view.

22.4. In light of these considerations, my Private Secretary indicated to Mr Canavan on 6 June 1990 that I felt strongly that we should not plead the limitation defence at all **[DHSC0046957_044]**.

22.5. I am aware that there were differing views on whether limitation should be pleaded, and Mrs Bottomley was in favour of counsel's preferred option of reserving the government's position (option iii). I understand that she deferred to the Secretary of State on this issue based on his legal expertise, as shown in her response of 19 June 1990 **[DHSC0046957_043]**, **[DHSC0046957_044]**, **[DHSC0046957_045]**. On 25 June 1990, Mr Clarke agreed with the approach of reserving the government's position on limitation **[DHSC0046957_026]** commenting that: *"...we should certainly not abandon the limitation point"*. I understood and respected my colleagues' views; clearly, there were advantages and disadvantages in each possible course of action, as the submission showed.

22.6. I have been asked whether I recall being consulted about, or offering an opinion on any other aspects of the litigation at that time, but I do not and I have not been shown documents that suggest that I was involved in this way. I do not recall discussing these matters with any other ministers (although the litigation could have been discussed in the general ministerial meetings held).

Q23: Changes following Mr Justice Ognall's comments

23.1. The Inquiry has referred me to a number of documents relating to the litigation strategy following Mr Justice Ognall's comments at the interlocutory hearing in the litigation on 25 June 1990 **[DHSC0046964_024].** Mr Justice Ognall expressed the view, in strong terms, that the government should consider settlement of the proceedings, as the Plaintiffs were in a *"unique position"*. He also commented on the public's expectation of the government to take a position which was not solely confined to legal principles, and that this was not an attractive principle. Mr Justice Ognall's remarks were well-known across the Department, and evidently led to much discussion amongst ministers.

23.2. On 20 July 1990, a memo was sent from the CMO to the Minister of State and the Secretary of State **[HSOC0017025_004]**. The CMO referred to HIV infection in haemophiliacs as a *"unique catastrophe"*. The CMO indicated that he hoped that the government could find some way to make an ex-gratia payment to infected haemophiliacs.

23.3. On 24 July 1990, Mr Heppell circulated a note to the CMO, Mrs Bottomley's Private Secretary and Mr Clarke's Private Secretary regarding the litigation. He attached further information and a note from Mr Dobson (see

[DHSC0046964_003], **[DHSC0004360_147]**, **[DHSC0046962_186]** and **[DHSC0046964_024]**). Mr Heppell's note and its accompanying submission from Mr Dobson were also copied to my Private Office, amongst other recipients.

23.4. The CMO, the Secretary of State and Minister of State were being briefed on the options for reconsideration of their position in light of the comments made by Mr Justice Ognall. The note explored in detail the government's current position in the legal action at that time, and the reasons for maintaining this. It alluded to the unprecedented nature of Mr Justice Ognall's statement and the *"high costs, political as well as financial, if the current policy goes wrong"*. Despite counsel's view that the government had a good chance of a successful outcome for the majority of these cases, Mr Dobson's recommendation was that the Department would *"do well to make a further 'political' gesture to avoid the embarrassment of a legal wrangle likely to continue through the whole of 1991"*. Ministers were being asked to judge whether the *"political costs of maintaining the present line outweigh the risks of setting an expensive precedent if some further easement is offered"*.

23.5. Mr Heppell thought the choice boiled down to either resisting the action firmly, coupled with being ready to provide further ex-gratia help through the Macfarlane Trust; or settling out of Court. He favoured the former course of action (including noting that further payments under the Trust would be very welcome).

23.6. I can see that Mrs Bottomley sent a similar response: she commented that the government should maintain its present position in a memo sent by her Private Office on 27 July 1990 **[DHSC0046964_008]**. Mrs Bottomley stated: *"Once we move towards conceding on cases like these it will have inevitable long-term implications for the Department"*. The Secretary of State agreed with her view, which is shown in a memo dated 31 July 1990 **[DHSC0046964_007]**. Mr Clarke commented that he was *"in favour of sticking to our legal defence and continuing to fight the action. He does not think that it is necessary at this stage to send a minute to the Prime Minister and he considers that the decision should be communicated to the Judge and the Plaintiff's solicitors in strict confidence"*.

23.7. I have been asked for my own views at that time on the litigation strategy and Mr Justice Ognall's remarks. I do not now remember what I thought at the time and I have not seen any documents that might assist. From the documents I have seen I do not believe I provided a view; this matter being dealt with by ministers more senior than me.

23.8. I have similarly been asked for my reaction to the CMO's observations was at the time **[HSOC0017025_004]** (see paragraph 23.2 above). Similar to the position outlined above, I have not seen any documents that assist me in understanding my opinion at the time, and I cannot now recall my reaction to the CMO's observations.

23.9. In his note (see above paragraph 23.3), Mr Dobson referred to some *"modest additional help for the haemophiliacs through the Macfarlane Trust, as already agreed in principle, subject to negotiations with the Treasury."* I have been asked about this, but have no independent recollection of when, why and by whom this would have been agreed, or what the intention was. It may be that Mr Dobson was referring to the fact that sums under the Macfarlane Trust were under review and subject to discussions between the Secretary of State and Treasury, but officials such as Mr Dobson or ministers directly involved would be better placed to comment.

23.10. The Inquiry has reminded me that on 18 September 1990, Mr Dobson provided a further submission to the Secretary of State (in light of an upcoming hearing on 2 October 1990). Mr Dobson proposed that the government should take its next steps quickly **[DHSC0020866_091]**.

23.11. On 3 October 1990, Mr Heppell wrote to the Treasury Solicitor's Department and confirmed that the government's position on behalf of the Secretary of State for Health **[DHSC0046936_091]**. Mr Heppell's response to Mr Justice Ognall's letter seems to be consistent with what I would have thought at that time. As far as I can now recall, I accepted the Department's strategy at that time.

Q24: Settlement of HIV haemophilia litigation

24.1. I have been asked about my role in the discussions and decisions that led to the settlement of the litigation. I do not recall playing a role in this.

24.2. As far as I can see, the documents are consistent with this.

24.3. I believe that the settlement strategy changed when Mr Waldegrave began his tenure as Secretary of State for Health. On 11 December 1990 Ms Harriet Harman asked the following Written Question **[WITN7005005]**:

> *"To ask the Secretary of State for Health what representations he has received from organisations and individuals in respect of an out-of-court settlement for people who have contracted HIV through national health service infected blood or blood products."*

24.4. Mr Waldegrave responded as follows:

> *"The Government have carefully considered these proposals and agree that they will provide a fair and proper way of ending this litigation and of making financial provision for all affected haemophiliacs and their dependants, whether or not they have joined in the litigation. We believe that our case is legally strong and that the plaintiffs would not succeed in proving negligence on the part of the Department of Health. None the less the Government have always recognised the very special and tragic circumstances of the haemophiliacs infected by HIV and of their families. We recognise too the harrowing effect legal action would have on them. The Government have therefore agreed in principle to meet the steering committee's proposals. In outline the compromise would result in the Government providing to the Macfarlane Trust, in addition to the £34 million already paid, a further sum of about £42 million for distribution to all HIV haemophiliacs and their families according to their respective circumstances. Furthermore, the Government have agreed that payments from the Macfarlane Trust will not affect entitlement to social security and other statutory benefits. The plaintiffs' reasonable legal costs would also be paid by the Government."*

24.5. I have been referred to a submission and briefing materials sent to the Secretary of State, but copied to my Private Office on 23 November 1990 sent by Mr Dobson **[DHSC0003654_115]**. It seems that the purpose of the material was to ensure that the new Secretary of State, Mr Waldegrave, was briefed before a meeting with the Treasury. I have been asked if I consider that I was adequately briefed and consulted about the settlement.

24.6. I consider I was properly informed and that senior colleagues were taking the matter forward.

Q25: Terms of the Final Settlement

25.1. On 3 May 1991, Mr Waldegrave made the following announcement **[WITN7005006]**:

> *"I am pleased to be able to announce that a formal offer conveying the detailed terms of settlement has now been made to the plaintiffs' representatives. The new trust, which will administer the payments, the Macfarlane (Special Payments) (No 2) Trust, is being set up today.*
>
> *Payments can begin as soon as acceptances have been received from individual plaintiffs and the settlement has been approved by Mr Justice Ognall. This should be within a few days.*
>
> *Full details of the payments to be made under the settlement will be given once those details have been announced in open Court."*

25.2. A final announcement followed by Mr Waldegrave in the Commons on 10 June 1991 **[HSOC0001457]**:

> *"I welcome the announcement today in court of the conclusion of this litigation and the acceptance of the terms of a settlement by the overwhelming majority of those in England and Wales who were pursuing action… While maintaining its denial of any negligence, the Government have provided £42 million to cover the cost of the payments. This is in addition to the £24 million made available in 1990 to provide a sum of £20,000 for each HIV-infected haemophiliac. We are also committed to ensuring that the original Macfarlane Trust set up in March 1988 with a Government grant of £10 million will continue to be able to give additional help where there is special need. These payments are in recognition of the very special and tragic circumstances of the haemophiliacs infected by HIV and provide a substantial measure of financial security for them and their families."*

25.3. The Inquiry has asked me about the reason why it was stipulated that those who accepted the settlement could not go on to sue for being infected by Hepatitis C. I have been referred to the discussion at paragraph 11(a) of Minutes of the Sixth Meeting of the UK Regional Haemophilia Centre Directors Committee held on 16 September 1991 **[HCDO0000441]**.

25.4. I do not recall who was involved in that particular decision, or being involved myself.

HIV Infection Following Blood Transfusion

Q26: Briefings received

26.1. The Inquiry has asked me a series of questions about the position of non-haemophiliacs who contracted AIDS as a result of blood transfusions administered before blood was screened for HIV/AIDS from, I understand, about October 1985 onwards. I have been asked to recollect my involvement in the issue of financial support for this group of infected individuals.

26.2. I can see that I had become involved in the subject of transfusions by March 1990, when I started to respond to questions raised by MPs, as set out further below.

26.3. I have been asked whether I can remember any specific briefings on this topic. The details of any briefings that have been located by my advisors are set out below.

26.4. First, I can see that Mr Freeman MP responded to a debate on this issue in the House of Commons on 6 March 1990 **[BNOR0000359]** stating:

> *"...to an extent, haemophiliacs suffered a double tragedy. They had a disadvantage – there is no denying that – before the accidents occurred. The establishment of the first and second Macfarlane Trusts acknowledged the tragedy of this group. Both, of course, were ex gratia payments: they were not compensation payments in the strictest sense of the term. They were not in lieu of the legal right to sue... The argument for a no-fault compensation with a preserved right to sue – I understand that some days ago in a Committee in the House the Member for Ladywood argued the case for no-fault compensation with the right to sue – would have the benefit of some automatic payment to relieve financial pressures. I strongly believe that that system... would leave to a low, complicated and bureaucratic tariff, which would prove an impediment or discouragement to suit."*

26.5. My Private Office was then copied into a memo sent to the Secretary of State's Office on 16 March 1990 **[DHSC0002861_002]**. Mr Canavan noted that:

> *"The pressure to give special help to people who have contracted HIV through blood transfusions has been renewed following the announcement of the £20,000 lump sum payments for haemophiliacs. This is a repeat of what happened in 1987 after the first payment for haemophiliacs was announced.*

> *The 'Sunday Times' is now mounting a campaign and writing to MPs....*
>
> *It has always been considered important to ring fence the arrangements for haemophiliacs to prevent their use as a precedent for others injured through medical treatment and the draft reflects the arguments that have been used."*

26.6. The submission attached a draft reply for him to consider. A letter was duly sent by Mr Clarke on 19 March 1990 and a copy was sent to my Private Office, amongst others **[WITN7005007].**

26.7. I have now been made aware of the fact that Mr Canavan sent a briefing to the Private Office of the Minister of State for Health on 28 March 1990, summarising what arrangements other countries had made to compensate those who had received HIV infected blood **[DHSC0002848_005]** and **[DHSC0046951_068]**. However, it does not appear that my Private Office was copied into that memo at the time.

26.8. Focussing on the briefings I received, it is apparent that on 28 February 1990, Mr Andrew Neil (editor at the Sunday Times) wrote to Mr Burt MP **[WITN7005008]** expressing gratitude for his support on the Sunday Times campaign to compensate haemophiliacs who had been infected with HIV, but raising now the topic of non-haemophiliacs who had acquired AIDS through blood transfusion (this is the campaign referred to by Mr Canavan in his briefing to Mr Clarke). Mr Burt wrote to Mr Freeman (the Parliamentary Under Secretary in the Commons) on 8 March 1990 **[WITN7005009]** forwarding the Sunday Times letter and supporting its argument.

26.9. It appears that I replied on behalf of the Department on 26 March 1990 **[WITN7005010].** My letter expressed the same views as those of the Secretary of State, but in less detail. (I have also been referred to a similar letter from me to Mr Robert Banks, MP dated 12 March 1990 – **[DHSC0002861_011]**).

26.10. Mr Burt appears to have responded with a telephone inquiry to my Private Office, although it is not possible to be sure of the exact chronology. It seems that I responded by asking for a more detailed brief on the issue of blood transfusion recipients who are infected with HIV / AIDS.

26.11. Thus, on 28 March 1990, Miss Elaine Webb sent a note to Mr Canavan and Miss Edwards of my Private Office to assist with a response to a telephone inquiry from Mr Alastair Burt. The briefing (see **[WITN7005011]**, **[DHSC0042272_152]**, **[WITN7005010]**, **[BNOR0000359]** and **[WITN7005012]**) gave further details and stated:

> *"**It is considered important to ring fence the arrangements for haemophiliacs to avoid wider repercussions**. It would be difficult to maintain a distinction between blood transfusion cases and the recipients of skin grafts, organ transplants who have been infected with HIV, people with other transfusion transmitted diseases or people who have suffered catastrophic side effects from other medical treatment…There has never been under successive Governments a general system of "no fault" compensation for medical accidents, and by identifying this group it would be difficult in log to resist giving compensation to any group of patients who are harmed as an unintended by-product of NHS treatment." (emphasis in original).*

26.12. In terms of briefings, I also received briefings ahead of my debates and questions in the Houses of Lords on 1 May 1991 and 7 June 1991 **[WITN7005013]**, **[DHSC0002871_008]**, **[WITN7005014]**, **[WITN7005015]**, **[WITN7005016]**, **[WITN7005017]** and **[WITN7005018]**.

26.13. At the time, I accepted the advice from officials, as is shown in the correspondence that I sent out in relation to this issue, including the letter to Mr Robert Banks MP **[DHSC0002861_011]** in response to his letter to Mr Freeman dated 22 January 1990, the reply I had sent to Mr Burt MP on 26 March 1990 **[WITN7005010]** or a letter to Mr Rowe MP, sent around 9 July 1990 **[DHSC0002858_003]**.

26.14. I appreciated that my responses would have been disappointing. But at the time, I did not consider that the financial arrangements in place for haemophiliacs could be extended to those who had been infected via blood transfusion. I believe that my response was consistent with: a) what the government's general policy was; b) the advice from officials; and c) the approach that other ministers were taking (whether in the Commons debate – Mr Freeman – or in correspondence, such as Mr Clarke's letter of 19 March 1990).

26.15. It was a difficult decision for ministers to make, but I accepted the judgement that haemophiliacs who had contracted HIV infection through blood products formed an exceptional case. It was known that haemophiliacs already suffered from a serious hereditary disorder before contracting HIV. Ministers involved in this issue were concerned that further inequities could be created through extending support, with criticism attracted from others who had suffered a medical accident or unintended side effect. I believe that my responses conveyed what the government's agreed policy was at that time.

Subsequent documents - 1991

26.16. I returned to the issue in the House of Lords when Lord Kilmarnock (the Chairman of the all-party parliamentary group on AIDS) initiated a wide-ranging debate on AIDS in the House of Lords on 5 February 1991 **[DHSC0003548_092]**. I provided the Lords with updates on the many issues raised during that debate. At the end of the debate, Lord Kilmarnock asked that consideration should be given to those who have contracted HIV through transfusion and invited the government to look at this point again.

26.17. It seems that by this stage, the announcement of the proposed settlement for haemophiliacs with HIV (December 1990) meant that the position of those who had contracted HIV via NHS treatment but through other mechanisms came under additional scrutiny. But initially, the Departmental policy did not shift. Thus, I can see that on 7 March 1991, Mr Waldegrave responded to Mr Robin Cook MP on the issue of extending payments to people other than haemophiliacs infected with HIV. In that letter, he stated that the government's view remained that people infected with HIV as a result of blood or component transfusion were no different in principle from other groups of patients harmed in consequence of NHS treatment **[WITN7005019]**.

26.18. It is difficult for me to now recall when I first became aware that Mr Waldegrave was considering a change of position. I have been referred to a note from Mr Dobson to the Secretary of State's Private Secretary dated 23 April 1991 **[DHSC0003560_051]**. However, this was not copied to my Private Office. The memo states:

> *"...The Secretary of State asked for a note on our present position on compensation for people infected with HIV through blood transfusion...The government has always justified its special provision for HIV infected haemophiliacs on the grounds that they are a uniquely*

> *unfortunate group - in particular, because the tragedy of infection with the HIV virus was superimposed on a severe hereditary disability. In contrast, it is difficult to draw any logical distinction between the HIV-infected blood transfusion cases and other victims of medical accidents."*

26.19. It appears that following receipt of further advice, the Secretary of State agreed to "hold the line" on these cases on 25 April 1991 **[DHSC0002433_058]**. This minute was widely copied, including to my Private Office. I understood this to mean maintaining the government's position that those who were infected or affected by HIV / AIDS through transfused blood could not receive similar financial assistance to haemophiliacs.

26.20. I have also been referred to a memo from Mr Burrage to Mr Dobson and Ms Baxter, said to be the PS(L)'s Private Secretary, dated 1 May 1991 **[DHSC0002883_012]**. I have already explained (see paragraph 9.3 above) that I think that this was a document sent to Mr Dorrell, not me.

26.21. I did, however, speak in the House of Lords about the government's policy towards HIV / AIDS sufferers who had received infected blood from NHS transfusions on 1 May 1991 **[DHSC0003643_015]**. I conveyed the government's policy at that time during the debate:

> *"... the general policy is that the Government do not accept that there is a case for no-fault compensation for medical accidents. These blood transfusion cases fall into the general medical accident category for which compensation must be sought through the courts. An exception, for the reasons on which I have at some length elaborated, was made in the case of haemophiliacs because they have very exceptional circumstances."*

26.22. On 23 May 1991, I sent letters to Lord Kilmarnock and Lord Molloy **[WITN7005020]** and **[WITN7005021]** and referred to our exchanges during Questions. I thought it necessary to clarify the following statement:

> *"These blood transfusion cases fall into the general medical accident category for which compensation must be sought through the courts".*

26.23. In each letter, I remarked:

> *"This does not mean that everyone harmed through an accident would succeed in a claim for compensation through the courts. It would only be where the harm was caused through negligence rather than a genuine accident that a right to compensation arises and can be pursued through the courts. I am sure you will have recognised this to be the case but I thought I should write to remove the risk or any misunderstanding."*

26.24. I am aware that a letter dated 16 May 1991 was sent to the Secretary of State by Mr Ross of J Keith Park & Co Solicitors **[SCGV0000237_173]**. The Inquiry has referred me to Mrs Bottomley's letter of response, which was sent on 6 June 1991 **[DHSC0002879_002]** and a subsequent letter sent by Mr Ross on 7 June 1991 **[DHSC0002878_010].** The letter of 7 June 1991 was copied to my Private Office.

26.25. In relation to this second letter, I have been asked whether I had a view on Mr Ross's arguments for extension of the scheme, and specifically that non-haemophiliacs were more disadvantaged as they did not have access to the Macfarlane Trust for assistance. I find it difficult to say now what my thinking was at the time. I have no further comments on the exchange of correspondence, other than the fact that Mrs Bottomley's letter looked to be in line with what the government's policy was at that time, and did not take a view that was not already expressed in my previous correspondence on the issue.

26.26. However, I do not know whether I was fully aware of the further consideration of this issue which was ongoing, and was being driven by the Secretary of State. I can see that he asked for a further briefing on this topic on 31 July 1991 **[DHSC0002913_008]**, but I was not copied into this.

26.27. I addressed the issue in the Lords again on 7 June 1991 **[HSOC0001434]**. Lord Molloy asked the following question:

> *"Whether public support for giving compensation to those infected with the AIDS virus at NHS hospitals has persuaded them to reconsider their policy."*

26.28. I believe that my responses were also consistent with what the Minister of State for Health, Mr Dorrell conveyed in his meeting with Mr Patrick McCormack MP on 29 July 1991, and the government's overall line to take based on the advice **[WITN7005022]**.

26.29. The issue was raised again by way of a Question from Sir David Steel to Mr Waldegrave **[WITN7005023]** on 18 June 1991. Mr Waldegrave responded as follows:

> *"The Government have no plans to extend further the special financial help available for haemophiliacs."*

26.30. A copy of a Commons Early Day Motion with 69 signatory MP's was copied to my Private Office on 19 July 1991 **[DHSC0002434_007]**, accompanied with lines to take (see **[WITN7005024]** and **[DHSC0002434_008]**). It was sent to my office again on 17 October 1991 (**[WITN7005025]** and **[WITN7005026]**), and again on 13 December 1991 **[WITN7005027]**.

26.31. I understand that this House of Commons Early Day Motion was formed by a group of MPs who were proposing that financial assistance should be given to non-haemophiliacs infected with HIV by blood / tissue transfer. I have been asked what influence the Motion had on my thinking. I do not recall the Commons Early Day Motion having much influence on my thinking at that time, and would have largely been guided by the views of officials and advisors.

26.32. Finally, I have been asked about my personal views at the time. I recognised and understood that some felt strongly that the government should provide compensation to those who had been infected with HIV by transfused blood. I also had enormous sympathy for those concerned and their families in these circumstances. At the time, however, the financial arrangements made in respect of haemophiliacs had been regarded as exceptional in nature. I would have understood the difficulties of finding additional resources, when there were always good competing claims for the Department's budget, and I was not in a position to determine which of those claims should be met ahead of others.

Q27: Changes made to the financial support strategy

27.1. The Inquiry has referred me to a number of documents which show discussions between officials, debates between ministers and exchanges of correspondence in the lead up to a significant change in this policy, in late 1991 / early 1992.

27.2. On 14 October 1991, Mr Canavan sent an updating submission to my Private Secretary **[DHSC0002435_117]**. Mr Canavan updated me on subjects including the campaign led by The Observer, pending litigation on the topic and potential pressures relating to the preservation of blood donor anonymity, in that context. I was informed that the Secretary of State was considering matters, but officials did not consider that a change in the government's position was required at that stage.

27.3. This was a submission conveying updating information, but no response was expected from me.

27.4. I again set out the government's agreed position in my letter to Sir Michael McNair-Wilson MP dated 18 October 1991, in that it had no plans to extend financial assistance to recipients of blood transfusions **[DHSC0002900_006]**.

27.5. I have next been referred to Mr Heppell's letter to the Secretary of State's Private Secretary on 29 November 1991 **[DHSC0002537_262]**, **[WITN7005028]**. My Private Office was copied in. Mr Heppell attached a draft letter to the Chief Secretary for the Treasury (by now, Mr Mellor) *"along the lines [they] discussed"*. It is apparent that a move towards recognising the claims of this category of those infected was being contemplated by Mr Waldegrave. But, Mr Heppell advised:

> *"Secretary of State will want to reflect on the financial and policy aspects of the letter before he writes.*
>
> *3. On finances, the position is that we have already absorbed an extra £3 million for the haemophiliacs as a consequence of higher costs and numbers than expected. Nevertheless we can make some further contribution if that is what Secretary of State judges necessary to resolve the matter. There is inevitably some uncertainty about the final outturn this year but £6 million can be guaranteed if Secretary of State is prepared to accept that this will use up all his personal fund.*
>
> *4. We must also assume that Treasury would not entertain any further bids on the Reserve for additional cases.*
>
> *5. On policy, this extension of eligibility will leave us with a less secure ringfence than for haemophiliacs. We believe that two groups of people, those infected with hepatitis and those treated with human growth hormone, are currently preparing legal action against the Department.*
>
> *Both groups will be able to argue that like the HIV cases they were entitled to expect safe treatment. And the hepatitis cases will also be able to point to infection through blood. So we will be more vulnerable than we now are on the no-fault compensation issue."*

27.6. On 2 December 1991, Sir Christopher France minuted that he had seen Mr Heppell's minute, and advised *"long reflection before [the Government moves] further in to no-fault compensation for medical accidents. Is this really the most pressing marginal case for the deployment of money from the health programme?"* **[DHSC0002931_005]**.

27.7. It was clear that the Secretary of State had reached a different view. On 2 December 1991, Mr Waldegrave wrote to Mr Mellor at the Treasury following a discussion after a Cabinet meeting, about non-haemophiliac patients infected by HIV (i.e. blood transfusion, transplant or tissue transfer) **[DHSC0002921_009]**. The handwritten names at the top of the letter suggest that my Private Office was provided with a copy of the letter. Mr Waldegrave set out his view that: *"[the government] should move now to resolve the matter by recognising the needs of these people and their families-in the same way as we have recognised those of haemophiliacs."*

27.8. In his letter, Mr Waldegrave provided two options, either:

a) giving the same financial payment given to the haemophiliacs following the out of court settlement in the litigation; or

b) giving the same financial assistance provided to haemophiliacs earlier (i.e. if the Government could arrange access to the original Macfarlane Trust).

It is apparent that Mr Waldegrave favoured the second option.

27.9. The government had not moved towards accepting that change, at this point. In a letter from Mr John Major, the Prime Minister, to Mr John Marshall MP dated 2 December 1991 **[WITN7005029]**, the Prime Minister responded as follows:

> *"We made clear when we made the settlement in the case of haemophiliacs that they were a very special case. The Government has acted accordingly. I have every sympathy with the plight of those non-haemophiliacs who have been infected with HIV as a result of blood transfusions. But, as you know, the House has very recently decided, on a free vote, that it did not support the principle of no fault compensation for medical accidents... the cogent arguments which led the House to reject the principle of no fault compensation apply, I believe, also in this case."*

27.10. On 4 December 1991, the Parliamentary Branch provided ministers with an updated list of proposers for the Early Day Motion, which was copied to my Private Office. The number of proposers had now increased to 249 **[DHSC0003577_061]**.

27.11. On 5 December 1991, the Secretary of State made a request for ministers' views on Mr Heppell's minute of 29 November 1991 **[DHSC0002537_063]**. I provided my response on that day **[DHSC0002537_062]**. My response outlined my view on the issue:

> *"In regard to Strachan Heppell's minute of 29 November, I think we should hold the line however difficult this may be. I am not aware of a sudden pressure via correspondence or otherwise."*

27.12. Whilst the Prime Minister appeared to be aligned with this view on the basis of his letter of 2 December 1991, it was clear that other ministers had different views, albeit that there was a sense of caution or reservations expressed. On 10 December 1991, the Minister of State for Health conveyed her support for seeking a further extension of financial support **[DHSC0002938_004]**. Mr Dorrell was also in favour of extending the financial support to those in receipt of transfusions **[DHSC0002537_242]**. I was thanked by the Secretary of State for my note on 12 December 1991, but was referred to the Early Day Motion **[DHSC0002537_056]**, which he noted *"seems to have got the ball rolling again"*; I think this was a comment on my view that there had been no *"sudden pressure"*. I have already commented on what my thoughts were at the time on the Commons Early Day Motion at paragraph 26.31 above.

27.13. Sir Michael McNair-Wilson MP spoke in the Commons Adjournment (Christmas Debate) on 12 December 1991 **[DHSC0002437_065],** making the case in favour of compensating non-haemophiliacs infected with HIV. The extract from Hansard was copied to my Private Office on 13 December 1991 **[DHSC0002436_070].**

27.14. Sir Michael made the following observations on my letter of 18 October 1991, and DH's policy overall:

> *"So the Minister seems to acknowledge that those people have been seriously harmed through a medical accident derived from their treatment at the hands of the NHS, but the Minister goes on to say that it was nobody's fault—and anyway, that the haemophiliacs got compensation because they were haemophiliacs, not simply because they had been given contaminated factor 8. It is almost the identical defence originally submitted by the Department of Health when it first refused to pay compensation to haemophiliacs."*

> *"I find the Department's argument that haemophiliacs are a very special case a very difficult one to follow. All these people are human beings. They have been given this dreadful virus, not because they asked for it, but because of something that happened within the Department. The same faith in the NHS that persuaded the haemophiliac to accept factor 8 from the NHS persuaded the 50 to accept blood transfusions from the NHS."*

27.15. I understood the scale and the tragedy of the situation. I had the greatest of sympathy with Sir Michael's position. I realised the difficulties there could be in the government maintaining this stance and sincerely regret that I was not in position to do more. I think every minister involved wanted to do more to help the plight of those who had suffered, however they had been infected. But at that time and based on the advice received, it was not the government's agreed policy to extend financial payments to those who had received transfusions.

27.16. Thereafter, I commented on / responded to letters relating to HIV infected transfusion recipients (see for example, Mr Bruce's letter of 16 December 1991 **[WITN7005030]** and the Haemophilia Society's letter of 12 December 1991 **[WITN7005031]** which were consistent with the government's policy. On 18 December 1991, my Private Secretary sent a memo to Mr Canavan and requested his advice on a response to Sir Michael **[DHSC0041438_047]**. In light of the EDM, the statements made in the debates and the public feeling, it was clear that I thought that further advice was required.

27.17. On 20 December 1991, the issue was debated in the House of Commons **[DHSC0002932_010]**. Mrs Bottomley responded on behalf of the government to Mr Gavin Strang MP:

> *"The Government have not been persuaded… that blood transfusion and tissue recipients constitute a special case. We shall, of course, consider the views which have been expressed by the hon. Gentleman. We have great sympathy for these tragic cases and for their families."*

27.18. On 9 January 1992, I received a response to my request for advice **[DHSC0002431_040]**. I was informed that Sir Michael had also written to Secretary of State. I was advised that a draft reply had been prepared for the Secretary of State and that my reply of 18 October 1991 had set out the government's position:

> *"PS(L)'s reply of 18 October set out the Government's position. There were no new points raised in the debate on the motion for the Christmas*

> *adjournment, and our advice is that there is nothing in what was said that would need a response from Ministers. If the draft which we have prepared for Secretary of State to send to Sir Michael McNair-Wilson is accepted, there would appear to be no need for a letter to go from PS(L)."*

27.19. On 13 January 1992, Mr Mellor gave his view on the subject to Mr Waldegrave **[DHSC0002537_219]**, **[HMTR0000003_051]**. Mr Mellor indicated in his letter that he recognised why Mr Waldegrave wanted to provide compensation for non-haemophiliacs infected with HIV, and that he sympathised. I also sympathised, and respected Mr Waldegrave's desire to go further. Mr Mellor expressed serious reservations about whether it would be possible to ring fence any such compensation, and alluded to the range of other groups who have also suffered as a result of treatment under the NHS, where there is no question of negligence. Mr Mellor went on to state:

> *"By compensating those acquiring HIV from blood transfusion, we will be taking a further long stride towards no-fault compensation in general. Virginia Bottomley put forward a good defence of our current position in the adjournment debate called by Gavin Strang on 20 December. It would be difficult to reverse our position so soon after that clear statement."*

27.20. On 17 January 1992, Mr Kendall sent a submission to Mr Waldegrave's Private Office **[DHSC0002929_007]** and **[WITN7005032]**. My Private Office was copied in. The submission outlines the available options for the funding of payments to blood / tissue recipients who had contracted HIV. It was received in the Minister of State's office on that day, and the handwritten note on it conveys: *"I am sure SoS will want to discuss this. It will be difficult to find the money".* It was clear that the Secretary of State wanted to progress providing financial assistance for infected non-haemophiliacs further.

27.21. I debated the issue in the House of Lords on 30 January 1992 **[DHSC0003523_037]**. Lord Tordoff asked the government whether it would reconsider its position in relation to the compensation of non-haemophiliacs infected with AIDS through blood transfusions. I provided the following response:

> *"My Lords, any case where a patient suffers a medical accident is, of course, a great tragedy. However, both your Lordships' House another place and the Royal Commission have indicated that the Government should not go down the path of no-fault compensation which the noble*

> *Lord advocates. It must be remembered that we offer first rate services for everyone suffering from HIV and AIDS. Some £200 million has been earmarked this year especially for that area to spend on those suffering from HIV and AIDS. We took the view that haemophiliacs were a special case… we consider that the haemophiliacs are a special case because the health, social and financial problems caused by the haemophiliacs' lifelong condition were exacerbated by the onset of HIV. It was that combination of circumstances that persuaded us to make a concession in that case."* [emphasis added]

27.22. This reflected the government's position at the time, but the number of debates and questions in both the House of Commons and the House of Lords is perhaps indicative of the political pressures at the time.

27.23. On 31 January 1992, Mr Canavan provided a briefing for the Secretary of State's meeting with Sir Michael McNair Wilson and Mr Strang MP **[WITN7005033]** and **[WITN7005034]**. Whilst it does not appear that my Private Office was copied into that briefing, it provides a background of the government's continuing policy at that time. I believe that this was still being affirmed in Mr Waldegrave's subsequent letter to Sir Michael on 31 January 1992 **[WITN7005035]**. In that letter, Mr Waldegrave expressed concern about the cost of extending financial payments to non-haemophiliacs, stating:

> *"The cost would be further inflated if other groups were to regard special provision for the blood transfusion and tissue transfer cases as a precedent. We are concerned that we do not move in piecemeal fashion towards a scheme of no fault compensation. In her letter, Baroness Hooper explained our reasons for rejecting a general scheme of no fault compensation for medical accidents. It was forcefully put to us, and it has been widely accepted that haemophiliacs are a special case. We have acted accordingly."*

27.24. I have been asked what discussions I had with Mr Waldegrave at the time. I cannot now recall what discussions I had with him, if any and it seems unlikely I would have had any one-to-one discussions with him about this issue.

27.25. I have been asked if my position changed. I had the deepest of sympathies for those infected with HIV via transfusion / tissue transfer, as well as haemophiliacs. To the extent I could, I endeavoured to make the right decisions based on the advice of those best placed to provide it. Ministers involved often had difficult decisions to make and did not always agree on the best course of action to take in making those decisions. There were many competing interests which needed to be considered and balanced against the inevitable limitations of the DH budget. Although I indicated that we should continue to "*hold the line, however difficult this may be*", I would have respected the motivations and decisions of other ministers who took a different view to the one that I had reached.

Q28: Announcement of financial support: February 1992

28.1. It is clear that the position was being revisited by the time of a meeting with the Prime Minister and a group of senior conservative MPs, including Sir Terence Higgins and Sir Michael McNair-Wilson on 5 February 1992 **[CABO0000044_023]**. It appears from the documents that I have been shown that, whilst the Prime Minister expressed personal sympathy for those affected, he was concerned about taking a step towards no-fault compensation. From this note of the meeting and Mr Scofield's submission of 6 February 1992 **[DHSC0002585_017]**, it is clear that the Prime Minister wanted to revisit the decision with the Secretary of State and the Chief Secretary. Mr Scofield understood that the Secretary of State wished to intervene by sending a robust personal note to the Prime Minister seeking his intervention with the Treasury **[CABO0000044_024]**.

28.2. It is clear that by 12 February 1992, the Prime Minister was set to announce that financial assistance would be offered to those who had been infected with HIV transfused blood (see Mr Scofield's briefing of that day **[DHSC0020274]**, **[DHSC0002582_007]** and **[DHSC0044287_011]** which my Private Office was copied into).

28.3. I have been asked if I was surprised that the government changed its policy, but it did not surprise me, given the sympathies of all concerned that I have referred to.

28.4. On 14 February 1992, Mr Mellor indicated his agreement to extend payment to non-haemophiliacs infected with HIV on the basis of Mr Waldegrave's assurance that there would be no further extension and the agreement could be 'ring-fenced' **[WITN7005036]**. The money was to be found without additional Treasury resources.

28.5. On 17 February 1992, Mr Waldegrave announced that the special assistance which was being provided to haemophiliacs was being extended to those who acquired the infection through blood transfusion or tissue transfer, in his response to a Parliamentary Question from Sir Michael McNair-Wilson **[DHSC0002578_001]**. I understand that officials discussed the line to take and a briefing for No 10 shortly thereafter, although it does not appear that my Private Office was copied **[WITN7005037]**, **[DHSC0002578_001]** and **[WITN7005038]**.

28.6. I conveyed Mr Waldegrave's announcement in a letter to Lord Waddington on 19 February 1992 **[WITN7005039]**. In my letter, I enclosed a copy of the press release. I explained that the extension of payments to transfusion recipients was a further recognition of very special circumstances, and that the matter had been considered very carefully with colleagues.

28.7. Mr Scofield provided a further submission on 20 February 1992 seeking agreement on the outline of the proposed compensation scheme **[NHBT0015117_001]** and an accompanying annex after **[DHSC0002642_004]**, as the financial support had been announced. My Private Office was copied into the submission, along with others.

28.8. The Secretary of State's approval of the recommendation in Mr Scofield's submission was given on 2 March 1992 **[DHSC0002653_004]**.

28.9. I have been asked a series of questions about this submission.

28.10. I do not recall being consulted by Mr Scofield, or by anyone else, regarding details of the compensation scheme or how it was to operate.

28.11. I have no recollection of any conversations with the Secretary of State concerning the proposals either.

28.12. I have been asked if I had reservations. The proposals represented an obvious change in policy. However, it was for the Secretary of State to determine the overall direction of the policy as he saw fit and on the basis of the advice / submissions that he had received. It was clear that the Prime Minister was now involved in this decision too, together with the Secretary of State. I do not recall being consulted further about how this scheme was to operate or being involved in any further discussions, but I was content to follow the advice provided and respected the decisions made by ministers.

28.13. The Inquiry has referred me to paragraph 5.2 (p17) of the annex to Mr Scofield's submission, and the requirement that anyone accepting a payment under the scheme would *"be required to give an undertaking not to pursue legal action against the Government or Health Authorities over matters of policy or broad operational concerns"* (though actions against Health Authorities for medical negligence could be pursued). I have no recollection of any discussions concerning the need for this undertaking or involvement in this issue.

28.14. I have also been referred to paragraph 4 of the minute, which concerns including non-haemophiliacs infected with HIV through fractionated blood products administered in (e.g. surgery). I was aware that it had been possible for a patient to become infected with HIV upon receipt of blood products (prior to effective heat-treatment of such products), and this was alluded to in Mr Dobson's minute of 31 January 1992, but I do not recall being aware of this sub-group of claimants specifically. It seems that it was thought to be a very small group.

Q29: General Election, 1992

29.1. I have been asked if I had any further involvement before the General Election that took place on 9 April 1992. I responded to a letter sent to Mrs Bottomley from Mrs Angela Rumbold MP (who had received a letter from her constituent) on 18 March 1992 **[DHSC0014966_096]**. The purpose of this letter was for me to convey the change in policy.

29.2. I note that a press release was issued on 27 April 1992 **[NHBT0015110]**.

29.3. Other than as set out above, I had no other involvement in the establishment of the scheme. The General Election took place on 9 April 1992. I am not aware of any influence the impending General Election had on the decision to establish the scheme, or the steps taken to set it up. Overall, it is preferred to have policies finalised before agreed upon and finalised before a General Election.

Section 5: Hepatitis C Virus screening and Look Back exercises

Q30: Implementation of surrogate / screening tests for Hepatitis C

30.1. I have been asked to provide a chronological account of the involvement and knowledge I personally had of decisions on whether, and if so, how and when to implement surrogate or screening tests for all blood donations for Hepatitis C.

30.2. The Inquiry has asked me to set out what information or advice I received in relation to the case for screening, the financial implications and any cost-benefit studies or analysis. I have addressed this below, in chronological form.

Information, advice and briefings provided

30.3. I have also been asked to set out the identities of the individuals who advised me in relation to the same. I regret that I have no independent recollection of the individuals that advised me, and rely heavily on the documents in that respect. I can see, looking at papers, that the 'underlying' source of advice was a scientific committee made up of independent experts, the Advisory Committee on the Virological Safety of Blood (the **ACVSB**), and chaired by Dr Metters (**DCMO**). However, materials from these medical advisors would have been provided to me via submissions from civil servants to my Private Office.

30.4. Broadly speaking, I do not recall receiving advice / information from anyone else other than, through this route, the DCMO (Dr Metters) and the members of the ACVSB.

Surrogate Tests for Hepatitis C

30.5. I have been asked what information or submissions I received addressing whether 'surrogate' tests for Hepatitis C should be introduced.

30.6. The first ministerial submission on the subject of testing to which I have been referred is a minute from Miss Reenay dated 15 February 1990 **[NHBT0000189_055]** which was sent to Dr Metters and my Private Office. This did not mention surrogate testing. I cannot remember receiving any advice on this topic and have not been provided with any documents that suggest that I was. It seems that this was an issue that was not raised at a ministerial level (or, at least, not with me).

Screening Tests

30.7. In relation to screening tests, I have been referred to documents which show the conclusions reached by the ACVSB and its subsequent recommendations.

30.8. The Inquiry has provided me copies of the minutes of the fourth - eighth meetings of the ACVSB **[NHBT0005043]**, **[PRSE0001477]**, **[NHBT0000072_098]**, **[PRSE0000976]** and **[NHBT0000073_018].** However, I have been asked for my personal recollections. I would not have seen copies of these minutes at the time.

30.9. The first ministerial submission to which I have been referred is a minute from Miss Reenay dated 15 February 1990 **[NHBT0000189_055]** which was sent to Dr Metters and my Private Office. The minute has a handwritten note at the top of it, which appears to be from Dr Metters. The note states:

> *"Mrs Baldock,*
> *The clear advice from ACVSB is that, as yet, there is not enough scientific data about the test marketed by Ortho for the committee to recommend that it be introduced".*

30.10. Looking at this, I do not consider that any action was expected from me at that point. It appears that the memo purely served as an update and the views in it were firmly expressed.

30.11. The Inquiry has then referred me to a letter from Mr Canavan dated 26 April 1990 **[DHSC0002497_061], [DHSC0002497_062]**, which attaches a draft note for me to consider **[DHSC0002497_063]**, discussing the possibilities of authorising funding. From the documents, it appears that some consideration was given to how the screening should be costed although the advisors did not appear to be in a position to provide finalised proposals at that point. Dr Pickles made the following comments:

> *"Do we need to tell minister the likely cost before the working party reports to the ACVSB so as to be sure that funding is available before ACVSB gives its view!"*

30.12. As this is a draft note, however, I would not have seen it.

QA31: Submission of 1 May 1990

31.1. The submission that was sent to me, I think, must have been that of 1 May 1990, when Mr Canavan advised me and Dr Metters of the developments in the screening of blood donations in Hepatitis C **[NHBT0000061_130]**. The note stated:

> *"In France, Belgium, Luxembourg and Finland, screening has recently been introduced for all donations and in Italy the screening is voluntary. However at its meeting on 24 April, our Committee reaffirmed its view that the introduction of routine screening would not yet be justified. The new tests developed in the USA have not been approved by the FDA [Food and Drugs Administration] and there are still unresolved difficulties concerning the tests. The Committee has advised that a pilot study should be carried out to learn more about the significance of a positive reaction to the test and the extent to which it predicts infectivity which could be transmitted in blood. A working party has been set up to draw up a protocol for the study and this will be considered at the ACVSB's next meeting on 24 July".*

31.2. Mr Canavan promised a further report after the next ACVSB meeting. Again, I was not asked for any particular input.

31.3. I have been asked for my views on this submission, and the judgment that *"the introduction of routine screening would not yet be justified"*; and referred to the minutes of the ACVSB meeting of 24 April 1990 **[NHBT0000072_098]**.

31.4. I have explained that I would not have seen these ACVSB minutes at the time, and do not think that they can now help me on what I thought about the submission then.

31.5. I understood from the submission that it did not deem the introduction of routine screening to be justified in the UK yet. It is clear from the note that consideration was given by the ACVSB to what other European countries were doing, but that the fact that some had introduced it was not regarded as enough. I am unable to speak to the importance of the fact that the new tests had not been approved by the FDA on the decisions made by Committee. It was one of the factors mentioned, but so too was the fact that there were "unresolved difficulties" with the test – the two appeared to be consistent. A pilot study was being proposed.

31.6. I have been asked whether I "scrutinised" this advice. I believe I would have considered the submission carefully, but I would have trusted the advice given by the ACVSB, which I understood to have consisted of some of the best medical experts in their field. At the time, I did not think that I needed to raise questions about that advice when there appeared to be a consensus, the basis for their reasoning seemed to be reasonable and they were best placed to advise us on the best course of action for the UK to take at any given time. Furthermore, they did not appear to be "standing still" – a pilot study was proposed and was being pursued.

31.7. I do not think that any action was expected of me as a result of this submission.

31.8. On 10 May 1990, I was informed by Mr Canavan that it had been agreed that NBTS was going to start testing all blood donations for HIV1 and HIV2 from 1 June 1990 **[DHSC0006351_050]**. His comments in respect of publicity about this development also mentioned the topic of Hepatitis C screening:

> *"We do not consider it would be appropriate to issue a press statement or to inspire a PQ to specifically draw public attention to this. It may well have an adverse effect by provoking questions and unnecessary enquiries about the progression of plans to introduce HCV testing, which as you know are underway but not yet complete."*

31.9. Again, I do not think that any action was expected of me as a result of this update.

31.10. On 11 May 1990, Dr Pickles provided an update to the Secretary of State's office on two stories in the press relating to hepatitis and blood products **[NHBT0000061_137]**. My Private Office was copied in. The update in relation to Hepatitis C was as follows:

> *"5. Some papers have linked this story to a Lancet article on hepatitis C (non-A non-B hepatitis). This shows, as expected, high rates of positivity with a recently developed test for hepatitis C in recipients of blood products. Before heat-treatment of blood products was instituted in 1985, transmission of non-A non-B hepatitis to haemophiliacs was commonplace and these findings reflect past infections. In the 4-5 years since heat-treated NHSBY Factor VIII has been issued from BPL, there is no recorded instance of transmission of this infection, or indeed of any other.*
>
> *6. But there remains the question of whether the NBTS should as an additional measure screen donations for hepatitis C to protect transfusion recipients. This is now being done in Belgium, Luxembourg, Finland and very recently in the USA. The Department's advisory committee on the Virological Safety of Blood, under Dr Metters, have been considering the available evidence, in particular on the significance of positive with this*

> *new test. The committee recommend further work on UK donors before a decision can be made."*

31.11. The ACVSB had its seventh meeting on 2 July 1990. I can see that at that meeting, the ACVSB decided, in principle, that the UK should introduce Hepatitis C testing on blood and plasma **[PRSE0000976]**.

31.12. From the documents provided, it does not appear that my Private Office was informed of this decision until 7 August 1990, by way of a submission from Mr Canavan to Mrs Baldock **[NHBT0000061_169]**. From the submission, it was my understanding that the ACVSB wished to carry out a further pilot study to evaluate which of the marketed tests (i.e. the Ortho and Abbott tests) would be most suitable to roll out across the RTCs with the results expected to be available by October 1990. The note states that a full submission setting out the case for screening, financial implications and the results of a cost benefit study would be provided "shortly". It was estimated that the screening of blood donations would cost an estimated £5 million - £6 million a year, however a full breakdown of how the screening would be funded had not been provided at that point.

31.13. On 17 August 1990, I responded to a letter from Mr Speed MP of 4 June 1990 **[NHBT0000061_176]**. Mr Speed had asked for information about hepatitis C screening. I apologised for the delay in responding and updated him of the current position, as had been outlined to me in the memo dated 7 August 1990.

31.14. I have been asked whether, at this point, I had been briefed on how long it would take to introduce any approved test. I cannot remember receiving any information in addition to that set out in the submission from Mr Canavan, or remember what I might have expected about how long it would take to 'roll out' such a test. I would have expected officials to be thinking about further steps needed, for further decision-making and implementation. I note that Dr Gunson, who was the National Director of the NBTS, was a member of the ACVSB.

31.15. I am aware that the ACVSB had their eighth meeting on 21 November 1990, and have been referred to a copy of the minutes **[NHBT0000073_018]**. I now note from these minutes that it appears that both screening tests could be deemed to be satisfactory for routine use within RTCs from an operational viewpoint, and the choice would be influenced by the equipment available in the RTC. It seemed that there was little to choose between the two kits. Further, several members confirmed of the ACVSB confirmed that better tests were about to be introduced. It was agreed to start screening "*as soon as practicable*" to enhance the safety of blood supply.

Submission of 21 December 1990

31.16. A submission was sent by Mr Canavan to the CMO and to my Private Office on 21 December 1990 entitled 'Hepatitis C Antibody Screening Test – Advisory Committee on the Virological Safety of Blood (ACVSB)' **[PRSE0004667]**. This set out the recommendation of the ACVSB that screening should be introduced 'as soon as possible' (strictly, the ACVSB minutes refer to 'practicable' but the two are being treated as meaning the same), but outlined the costs consequences for the NHS. The recommendation was that screening should be introduced, as a public health measure. The submission reported on developments in other countries and on the results of the pilot study. The costs were set out, together with a tentative and uncertain economic cost-benefit analysis. The costs to the RTCs were set out, but it was envisaged that they would be recouped from hospitals by higher blood handling charges under the new internal market system (see paragraph 11).

31.17. The submission noted that *"In view of the operational matters that need to be discussed and finalised, it is unlikely that routine screening could be introduced before 1 April 1991."* (para 15).

31.18. The concluding remarks of Mr Canavan's report dated 21 December 1990 state:

> *"...In view of the ACVSB's firm recommendation that routine screening should be introduced as a public health measure, the possible risk of litigation and the fact that other countries are routinely testing blood donations for the virus antibodies, any further delay in the introduction of HCV testing in the UK would be difficult to defend... We therefore recommend the introduction of routine screening for HCV antibodies. We ask if PS(L) is content that screening should be introduced and that preparations should be made to introduce it as soon as practicable".* [emphasis added]

31.19. On 31 December 1990, the CMO endorsed the recommendation, saying "*I agree, I consider that a difficult balance has been correctly struck in the circumstances.*" **[DHSC0002498_096]**.

31.20. By way of a letter from Mrs Delfgou to Mr Canavan dated 16 January 1991 **[NHBT0000191_013]**, I confirmed my agreement to introduce screening tests for Hepatitis C as soon as was practicable. I made the following comment: *"I don't see that we have any option"*.

31.21. I have been asked a number of questions about this history.

31.22. First, I have been asked for my comments on the fact that it took just under a couple of months for the Committee's recommendation of 21 November 1990 to be affirmed, by my decision of 16 January 1991.

31.23. I acknowledge there was a gap. However, I believe that the advisors would have worked very hard to ensure that ministers received advice without undue delay. The reality was that officials would have had to balance work on this matter with many other competing issues. I can see that at the time, blood policy related issues included the settlement of the HIV litigation, and more generally there was a lot of work being done to implement the NHS and Community Care Act 1990, which had received Royal Assent in the summer and was due for implementation by April 1991.

31.24. I also would have wanted to have the view of the CMO before taking any action; this was received at the end of December.

31.25. I have further been asked why, when I approved the case for introducing testing, I said that "*I don't believe we have any option*". I believe I said this acknowledging that although there might be doubts (see for example the rather uncertain economic analysis), there was no alternative.

Subsequent Progress - 1991

31.26. I have been asked further questions about the progress towards the implementation of testing, after my decision of 16 January 1991.

31.27. I have been asked, first, whether I was kept informed about the length of time that it took to introduce the test. When I sent the submission of 21 December 1990, I was told that *"it is unlikely that routine screening could be introduced before 1 April 1991"*.

31.28. I have now been shown a letter sent by Dr Gunson on 3 April 1991 **[WITN7005040]**, which updated Regional Transfusion Directors about implementation. From this, it seems that that an implementation date of 1 July 1991 had initially been set, but that Dr Gunson was informing colleagues of a new need to evaluate 'second-generation' tests and, as a result, setting a new implementation date of 1 September 1991. This is the date that, I understand, was eventually met.

31.29. It is more difficult to reconstruct what I knew about this at the time.

31.30. From the documents available to me, it seems that I had been asked to consider the issue of blood handling charges on 28 January 1991 **[WITN7005041]**, by a submission sent to me by Mr Canavan. At the time, handling charges were levied on blood supplied to the private sector only. However, it was planned to extend these charges to NHS hospitals, as part of the internal market reforms set out in the White Paper "Working for Patients". Mr Canavan proposed that regional funding should end, and that RTCs should determine their own operating costs. The money previously 'top sliced' for RTCs would be allocated to hospitals. RTCs would then be expected to recover their operating costs from the hospitals. A circular to that effect was proposed.

31.31. On 6 February 1991, my Private Secretary sent a note to Mr Canavan **[WITN7005042]**. It is clear that I had confirmed that regional handling charges should apply to both the NHS and private sectors (with the exception of MOD hospitals and hospices). The note also made clear that I thought the proposed circular should also refer to the 'pilot projects', i.e. the pilot projects for HCV screening. My Private Office asked to see a draft of that circular.

31.32. I can see that a draft of the circular was sent by Mr Rutherford to the National Director of the NBTS and others on 20 March 1991 **[WITN7005043]**. The letter dealt with blood handling charges and the screening of Hepatitis C. But at that time, it set out a proposed start date of 1 July 1991 for the screening of Hepatitis C.

31.33. I have already referred to Dr Gunson's letter of 3 April 1991, which suggested a revised start date of 1 September 1991.

31.34. I can see that on 11 April 1991, Mr Rutherford then provided the Territorial Offices with a copy of a draft document which was said to require my approval before it was issued **[SCGV0000136_135]** and **[SCGV0000136_136]**. The note explains that the second-generation tests were undergoing evaluation, and it was unlikely that routine testing could be introduced before 1 September 1991.

31.35. The finalised Circular was sent out in May 1991 **[WITN7005044]/ [NHBT0000192_001]** and referred to the proposed date of 1 September 1991. My advisors have not been able to establish whether which of these drafts, if any, were sent to me and whether I was provided with information about the changed in date. I cannot recall being made aware of any change in date.

31.36. I pause to comment that the circular, and Mr Canavan's submissions, show how it was intended that RTCs should be funded for the increased costs involved in screening; they would be able to charge them back to the providers to which blood was supplied. The increased costs of the testing thus fell on the NHS generally (and private sector organisations) to which the RTC funding had been transferred, rather than on the RTCs directly, as a consequence of the 1991 reforms.

31.37. I have further been asked to consider what information I had about the subsequent decision of Newcastle RTC to 'break ranks' and to start testing earlier.

31.38. I can see that on 30 April 1991, my Private Office was sent a note by Dr Rejman which informed me that Newcastle had unilaterally started to test donations *"despite agreement that screening would start simultaneously throughout the UK".* He said that Dr Gunson was seeking the justification for this action **[NHBT0000062_053]**. There was no mention of the proposed UK wide start date, or delays etc, and no request for any particular action.

31.39. However, it appears that officials decided that ministerial involvement in this development was not needed. I have now been shown copies of:

a) **[NHBT0000192_039]** which is discussed at 31.40 below.

b) Dr Metters' response dated 21 May 1991 to Dr Rejman and Mr Canavan, copied to Dr Pickles and Mr Dobson **[DHSC0004006_181]**, **[NHBT0000192_062]**.

c) Draft letter from Mr Malone-Lee to the Regional General Manager, Northern RHA **[DHSC0004006_175]**.

31.40. I would not have seen any of these documents at the time.

31.41. The first document is a letter from Professor Cash to Dr Gunson, copied to Sir Kenneth Calman (CMO) and Dr Metters (DCMO). In this, Professor Cash deplored the "unilateral actions" of Newcastle RTC. He noted that it had always been Scotland's view, both in the Scottish Office and throughout the SNBTS, that the introduction of microbiology donation screening tests would be subject to ministerial approval. In recent times, evidence that ministers wished to acquire a firmer grip on this activity came with the establishment of the Advisory Committee on the Virological Safety of Blood, he said. This development, in principle, was warmly welcomed in Scotland. Two happenings in the NBTS in past months indicated their interpretation to be flawed, he wrote: BPL demanding ALT donation testing and the HCV episode in Newcastle. *"It is difficult not to conclude, particularly having witnessed the passivity of the DoH on both occasions, that Ministers no longer wish to be involved in this exercise and that their current intention is to leave such matters to respective Health Authorities."* Should his conclusions be confirmed, he deplored this development.

31.42. In response, in the second letter of 21 May 1991, Dr Metters made observations to Dr Rejman and Mr Canavan, copied to Dr Pickles and Mr Dobson. He noted that he was not familiar with the issue of ALT testing and asked if had been put to ministers. He continued: *"we should take Ministers' minds on whether they wish, despite events in Newcastle, to maintain a policy that new screening tests will only be introduced on a uniform vesting date that will be decided centrally. Of course, when it comes to enforcement in the reformed NHS that could only be achieved through the ME [Management Executive]'s structures….. The dangers of a 'free for all', particularly the legal dangers are such that I suspect that Ministers will want to retain control. In which case a letter reminding all RTC Directors would be timely… centralisation would not be essential to reinstatement of the previous policy."*

31.43. There is a handwritten annotation on the minute, which I understand to be from Mr Dobson: - *"Mr Canavan – This is getting muddled! No harm in a letter to all directors, but I still think a letter targetted on the Newcastle director and his …*

[?] would be more effective. And I don't really see the need for M. Could we discuss this afternoon..."

31.44. Another annotation, signed by Mr Canavan and (probably) dated 28 May, continues the story:

"Dr Rejman – Mr Dobson spoke to Dr Metters and agreed that a reference to Ministers should be held in reserve. A draft letter to Northern RGM [Regional General Manager] will be going to Mr Malone-Lee shortly. If he is unwilling [to ... ??] then we must adopt the alternative at X."

31.45. The "alternative at X" was a reference to the alternative of a letter to all Directors. It seems, thus, that Mr Dobson's view was that there was no need for Ministerial involvement. This is consistent with the fact that I have not been shown any further documents (after Dr Rejman's note of 30 April 1991) discussing the situation in Newcastle or asking for Ministerial involvement. It is apparent from the correspondence between Professor Cash and officials that a great deal of importance was attached to a uniform start date by Professor Cash and officials.

31.46. I have next been referred to a letter from Mr Canavan sent to Mrs Delfgou of my Private Office dated 30 July 1991 **[NHBT0000192_125]**. A draft press release was attached to Mr Canavan's letter **[NHBT0000192_126]**. Mr Canavan asked me whether I wanted to issue a press release announcing the introduction of routine screening of blood donations for the presence of Hepatitis C. Mr Canavan recommended that a press release should be issued as a *"low key announcement"*. It appears that this was suggested by Mr Canavan due to publicity concerns.

31.47. I have been asked why it was thought that the announcement should be "low key". I find it very difficult to recall the reasons now. As far as I can see the reasons are set out in Mr Canavan's letter and I accepted his recommendation.

31.48. On 16 August 1991, the following press release was issued **[NHBT0000192_158]**:

> *"We are fully committed to ensuring that patients in our hospitals receive safe blood transfusions. To achieve this every blood donation already undergoes a series of tests before it is used. We are now satisfied that*

> *donations can also be screened for Hepatitis C using tests which have been developed recently. The introduction of this additional test will further improve the safety of our blood supply and we can counsel donors in appropriate cases about their own health."*

31.49. The Inquiry has referred me to a letter from Sir Robert McCrindle MP to Mrs Bottomley dated 16 October 1991, attaching a letter from his constituent dated 10 October 1991 (**[DHSC0014989_156]** and **[DHSC0002500_107],** respectively). The letter raises concerns about the cost of screening all blood donations for Hepatitis C. On 15 November 1991 I responded to Sir Robert **[DHSC0003565_079]**. My letter stated:

> *"The decision on whether and when to introduce any new screening test for blood donors is almost invariably a complex one and the Department has to strike a balance between the benefit to recipients, the amount of potential waste of good quality donations and the costs involved. The Department has various committees of internationally recognised experts to advise on the best way forward. On the basis of their advice, routine screening was not introduced immediately when the first unsatisfactory version of the screening tests were available, but only when better and additional tests made it appropriate to do so. The cost benefit of the screening was also considered in greater detail that could be given in the article enclosed with your letter, which drew together all the cost benefit factors. You will appreciate that in the health field the benefits derived from specific medical interventions cannot be assessed very easily and judgements have to be made on the best available evidence."* [emphasis added]

31.50. I believe that my response to Sir Robert accurately reflects what the government's position was in relation to the speed at which testing was introduced at the time. Ministers were advised by the ACVSB and Dr Metters on the course of action to be taken. The cost benefit analysis given in December 1990 (referred to in paragraph 31.12 above) showed the uncertainty of the economic analysis at that time. I accepted the advice of officials and medical advisors, and conveyed this in my response.

Q32: Reflections following the judgment of *Mr Justice Burton in A and others v The National Blood Authority*

32.1. I have been asked for my reflections, looking back now, on the length of time that it took to introduce the screening test and whether (i) more could have been done to introduce the screening test and (ii) if so, what, by whom and when? I am asked to do so in light of Mr Justice Burton's judgment in A and others v The National Blood Authority [2001] 3 All ER 289 **[PRSE0003333]**. I understand the speed at which testing was introduced was criticised in the litigation. Mr Justice Burton concluded that the public was entitled to expect screening to have been implemented sooner than it was, by 1 March 1990.

32.2. I respect the findings of Mr Justice Burton. Through my briefings, I was aware that several other countries commenced screening for Hepatitis C earlier than the UK did. But as far as I could see, the expert advisory committee, the ACVSB, gave careful consideration as to when it would be the right time to introduce routine screening for Hepatitis C, and to the steps needed to implement it appropriately. I do not think that I can now comment further on the judgments that were made, and which I agreed should be implemented when they were put to me.

Q33: Look-back exercises

32.3. I have been asked to consider whether I gave any consideration to instigating a 'look-back exercise' during my time as Parliamentary Under Secretary of State.

32.4. I have been advised that such an exercise would have been aimed at trying to identify those who had been infected by Hepatitis C prior to the introduction of screening of blood donations in September 1991.

32.5. I do not think that this was raised as a possibility with me at the time, and I suspect that I would have relied on officials and scientific advisors to do so.

32.6. I note that difficulties of the pilot study for the HIV look-back exercise were referred to in Mr Scofield's note to the Secretary of State dated 20 February 1992 **[NHBT0015117_001]**, which was copied to my Private Office. In that note (paragraph 11), Mr Scofield explained that there had been some resistance to tracing recipients, by consultants and local ethical communities. The subject involved a wide consideration of medical, ethical and legal issues. I cannot remember now whether I would have been aware of this, or whether it would have influenced any thoughts on a HCV lookback.

32.7. My understanding now is that the HCV lookback exercise started in 1995. I do not think that I can comment further on its timing.

Section 6: Adverse incidents

Q34: Adverse Incidents

34.1. I have been referred to a memorandum dated 11 May 1990 which was sent to the Secretary of State and copied to my Private Office **[NHBT0000061_137]**. The memo concerns a recall of products at the Bio Products Laboratory, and press reports of a recent paper about high rates of Hepatitis among recipients of blood products. The memo states:

> *"The Department considers that there is at present insufficient scientific information about this test. The matter of testing blood donations for hepatitis C is being kept under review. As far as processed blood products such as Factor VIII are concerned, it seems modern heat treatment methods as currently employed by the BPL successfully destroy this infection."*

34.2. The Inquiry has also referred me to a letter from Dr Pickles to my Private Office dated 24 May 1990 **[DHSC0002414_035]**, which states:

> *"As part of our enquiries into that episode, two more jaundice enquiries have been unearthed at NW Thames. Investigations and further tests are needed and at present there appears no justification for a product recall, although BPL have frozen the relevant stocks following the usual procedures."*

34.3. The sensitivities around timing are clear from Mr McKeon's (the Secretary of State's Private Secretary) note to Dr Pickles dated 15 May 1990 **[DHSC0002414_081]**. In that note, he referred to the very short notice period given to ministers of these issues. Mr McKeon asked Dr Pickles to impress upon BPL the need to inform DH and ministers via their contact officials in good time. Mr McKeon suggested that a system be put in place for flagging sensitive issues for ministers earlier.

34.4. On 18 May 1990, Mr Dobson responded on the topic of how the recall was handled **[DHSC0002414_062]**. In response to Mr McKeon's note, he stated:

> *"I have seen your minute of 15 May to Dr Pickles about the recent recall of blood products for possible contamination by hepatitis, and the failure of the Central Blood Laboratories Authority (CBLA) to give advance notice to the Department. We have been following up with various aspects of the episode both with CBLA and the National Blood Transfusion Service (NBTS). Ministers can be assured that the senior people in each case – Ron Wing, Chairman of CBLA, and Harold Gunson, Director of the NBTS – are fully aware of the difficulties which*

> *have been caused by the episode and are determined to see that mistakes are not repeated."*

34.5. I expect that these matters were brought to my attention as the minister with responsibility for blood products.

34.6. However, other than to forewarn me of these issues, I do not consider there was any other purpose for the memos. I do not think it was a prompt for me to decide or give my opinion on whether or not a recall was needed. It was important for ministers to be abreast of all issues (including media reports) for which they were responsible. In that context, I would have expected to receive some type of update on matters reported to the press or that would be reported to the press. I expected that these reports would have fed into the recommendations and subsequent decisions made by the advisors.

Section 7: Inquiries and Reviews

Q35 – 37

35.1. I have been asked what consideration I gave to calls for a public inquiry and what I understood to be the government's reasons for not establishing a public inquiry, when I was in office. I have also been asked what part the establishment and findings of inquiries in other countries played in the government's decision not to hold a full inquiry.

36.1. I have a very limited recollection of what was said about having a public inquiry at the time. My Private Office was copied into a submission on 26 October 1989 which set out various proposals on the approach to be taken to the HIV litigation, and I note that one suggestion was to establish a Commission of Enquiry (**[WITN5292079]**, at para 15). I have no real insight into why that proposal was not taken forward; as set out in Section 4 above, I was not greatly involved in the response to the HIV litigation or issues affecting the Macfarlane Trust.

37.1. I expect I would also have been aware that there were calls for a public inquiry from reports in the press which also appear to relate to calls by haemophiliacs infected by HIV (see **[WITN7005045]**). However, given that the documents I have seen reveal little about my involvement and I cannot recall my views at the time, I do not feel able to comment on the reasons why a public inquiry was not held at that time.

37.2. I cannot remember any discussion about inquiries and practice in other countries that time, and it was not something raised at the EU Council of Ministers meetings that I attended in Brussels.

Section 8: Other issues

Q38 – Involvement outside the Department of Health

38.1. I have been asked whether, after my time as Parliamentary Under Secretary of State for Health, I had any involvement in matters relevant to this Inquiry, whilst in Government.

38.2. I left the government in 1992 when I ceased being a minister in DH, and I cannot remember being involved in any relevant issues or policy-making after that.

Q39 – Q41: Reflections

39.1. I have further been asked to reflect, as of today, on the various issues of blood-related policy that I was involved in, from October 1989 – April 1992, and to say how well I think that the Department handled each at the time.

39.2. Time and careful consideration were given to these issues by ministers, by experts and by officials, each trying to find the right solution to the challenges raised above, and trying to balance various competing considerations at the time. I do not feel that I would wish to criticise any individual for the efforts made.

40.1. But looking back now, it occurs to me that one thing we did not, but could have done, was to invite those affected by this tragedy for meetings to hear more directly about their lived experiences and to improve our collective understanding. At that time, in the late 1980s and early 1990s, we did not have the same breadth and variety of sources that are now available, to inform ministers and policy-makers about patients' experiences – blogs, Twitter and social media generally have all now widened the ways in which these voices are heard. At the time, it seems that more limited contact and engagement with patients, and campaigners, was the norm.

41.1. If the Inquiry concludes that I should have done more at the time, I apologise to all those affected and am heartedly sorry for what they suffered.

Q42: Any other comments

42.1. I have been asked if I have any other comments to make on matters relevant to the Inquiry's work.

42.2. I trust my answers to the Inquiry's questions cover the ground as fully as possible, given the passage of time and quantity of papers involved. I also think that the role of government in the recent pandemic highlights the importance of expert advisors in these situations. I have nothing further to add, other than, once again, to express my condolences and sympathy to all those affected by this tragedy, and my hope that any mistakes that may have been made are never repeated.

Statement of Truth

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

Signed.......... GRO-C ....

Dated.......... 13·6·22 ....