FIRST WRITTEN STATEMENT OF VIRGINIA BOTTOMLEY Contents

Witness Name: Lady Virginia

Bottomley

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INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF VIRGINIA BOTTOMLEY

I, VIRGINIA BOTTOMLEY will say as follows,

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Section 0: OPENING STATEMENT

- 0.1. My name is Virginia Hilda Brunette Maxwell Bottomley. My date of birth and professional address are known to the Inquiry. I make this statement to assist the Inquiry and in response to a Rule 9 request dated 2 March 2022. I was:
 - (1) The Minister of State for Health from 28 October 1989 to 10 April 1992. The Secretary of State during this period was first Kenneth Clarke (until 2 November 1990) and then William Waldegrave.
 - (2) The Secretary of State for Health from 10 April 1992 until 5 July 1995. I was succeeded as Secretary of State by Stephen Dorrell.
- 0.2. Before appointment to the Department of Health, through friendships, I knew something of the circumstances created by infected blood products for people with haemophilia who had taken Factor VIII. A haemophiliac friend contracted HIV in the 1980s; we stayed with them shortly before I became a health minister. He tragically died in the 1990s.
- 0.3. In 1975 during a medical emergency, I received eight units of whole blood. GRO-c

 GRO-C also benefitted from donated blood during what became known as the risk period.
- 0.4. I do not recall individual constituents affected. My husband has given intensive support to a number of his constituents. He has also worked with Dame Diana Johnson MP in the present all-party group.
- 0.5. In preparation for this statement, I have reviewed copies of papers supplied by the Inquiry and others by the Department of Health. I kept neither papers nor records from my years as a minister. I did not write a journal or a diary. I have not subsequently published an account of my time as a Health Minister, having taken on a separate demanding career in senior executive search.
- 0.6. The Inquiry has provided me with copies of significant documents, and I have been provided with further documents from the Department of Health records

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all of which I understand have been disclosed to the Inquiry. My independent recollection of these matters is very limited and on some of the issues raised I have no recollection at all and am completely reliant on the documents. The documents help to some extent. The documentary record is itself not complete. With a few isolated exceptions, I do not, for example, have the copy of submissions which I would certainly have annotated at the time. Issues would have been discussed in meetings and less formal conversations which I am now unable to recall unless a minute of the meeting is available. Against these limitations. I have done my best throughout this statement to answer the Inquiry's questions as fully as I am able.

0.7. This Inquiry is important for individuals and their families. It can also help adjust and improve how ministers and their advisers can best serve the public interest and public health, remembering the impact on individuals and their families when procedures work well and when they work badly or fail.

Section 1: Introduction

- 1.1. I am a trained social scientist. Before entering politics, I spent two years as a researcher for the Child Poverty Action Group (1971-1973) and eleven years as a psychiatric social worker attached to the Maudsley Hospital. I am a former Chairman of the Inner London Magistrates' Juvenile Court but gave up work as a Magistrate when elected to Parliament.
- 1.2. I was elected to Parliament in May 1984 in a by-election for the constituency of Surrey South West. I remained the MP for the same constituency until the 5 May 2005 election after which I was created a life peer.
- 1.3. The below table outlines the positions I have held within government and the dates for which I held these positions.

Date	Position
1984	Elected as Member for South West Surrey
1985 – 1986	Parliamentary Private Secretary to Chris Patten, Minster
	for Education and Science
1986 - 1987	Parliamentary Private Secretary to Chris Patten, Minister
	for Overseas Development
1987 - 1988	Parliamentary Private Secretary to Sir Geoffrey Howe,
	Secretary of State for Foreign and Commonwealth
	Affairs
25 July 1988 –	Parliamentary Under-Secretary, Department of the
28 October 1989	Environment
28 October 1989	Minister of State; Department of Health
- 10 April 1992	
10 April 1992 – 5	Secretary of State for Health
July 1995	
5 July 1995 – 2	Secretary of State for National Heritage
May 1997	

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- 1.4. In opposition, I was briefly Shadow Secretary of State for National Heritage from2 May 1997 11 June 1997.
- 1.5. I will address the role and methods of decision making in my time as a Health Minister in Section 2 of this statement.
 - 1.6. My membership of Parliamentary Committees outside my time as a Government Minister were in areas unrelated to this Inquiry. When in the Commons, for a time, I was a vice chair of the all-party pharmaceutical group. Theyworkforyou.com records my Commons contribution on 10 November 1999 in a debate on the National Institute for Clinical Excellence relating to the meningitis C vaccine campaign, and an earlier oral guestion on 27 January 1998 on the future of the pharmaceutical price regulation scheme. In the Lords, I am recorded using the word pharmaceutical five times: debates on the Mental Health Bill (28 November 2006), Psychology and Counselling: Regulation (5 February 2007), Health: Addiction to Prescribed Drugs (6 October 2010), Health: HIV (5 September 2016) and Gene Editing (30 January 2020). My words in the Health HIV debate indicated my long-term concerns and awareness of stigma, together with expressed respect for the chief medical officer and continuing concern for the impact of HIV and AIDS. I attach a copy of my contribution to the debate on that occasion at [WITN5289002]. (Hansard HL Deb. vol.774, 5 September 2016).
- 1.7. In terms of my current interests, memberships and interests, I do not consider that any are likely to be relevant to the Terms of Reference of this Inquiry. I am a Director and shareholder of Odgers Group Ltd (formerly International Resources Group Ltd) (t/a Odgers Berndtson) (executive recruitment). A proportion of the recruitment searches involve health appointments. I am Chancellor of the University of Hull; Sheriff of Kingston upon Hull; an Emeritus Governor of the London School of Economics and a Trustee of the Economist Newspaper. I retain a shareholding in Smith and Nephew plc (medical technology). I am a member of the Council of the Ditchley Foundation. I am also a member of the board of International Overseers of Sabanci University, Turkey.

- 1.8. In terms of past interests, memberships and interests:
 - (1) After leaving the Department of Health, I remained active and interested in health issues, the National Health Service and public policy. As part of that ongoing interest, I have written articles and given lectures and training sessions on health-related questions as well as other matters to a range of different audiences. Between leaving Government after the 1997 election and about 2000, I would occasionally receive training or consultancy fees from a range of organisations including pharmaceutical companies.
 - (2) I was a Member of the Supervisory Board of AkzoNobel NV from 2000 – 2012;
 - (3) I was a Non-executive Director, Smith & Nephew plc (medical devices) from 2012 April 2021;
 - (4) I was a Member of the International Advisory Council (formerly Board), Chugai Pharmaceutical Company Ltd from 2012 to June 2021;
 - (5) I was a Non-executive non-remunerated Director (formerly Governor), UK International Chamber of Commerce (from c 2006 until my interest ceased on 1 May 2021);
 - (6) I was a Non-Executive Director of Bupa from 2006 2012;
 - (7) I was made a Fellow of the Industry Parliamentary Trust in 1987 and was a Trustee from 2002-2005;
 - (8) I was Vice Chairman of the British Council from 1998 2001;
 - (9) I was formerly Vice President of the Carers National Association;
 - (10) Between 1987 and 1988, I was a Director of the Mid Southern Water Company;
 - (11) I was a member of the Medical Research Council from 1987-1988. My work with the MRC mainly involved human fertilisation and embryology research. At that time (1988) I approached the Chair, Lord George Jellicoe concerning the appointment of Margaret Jay as the first director of the National Aids Trust and continued to take a close interest in the issue:
 - (12) I was Pro-Chancellor of the University of Surrey from 2005 to 2011;

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- (13) I was a Member of the Board of the Prince of Wales International Business Leaders Forum from 2002 2010;
- (14) I was President of Farnham Castle, Centre for International Briefing from 2003 2010;
- (15) I was National President of the Abbeyfield Society (a housing charity) from 2003 to 2009;
- (16) I was a Governor of the University of the Arts, London from 2000– 2006;
- (17) Before 1984 I had served on the Council of the Church of England Children's Society for its 100 social work projects and 1,000 staff.
- 1.9. During 1998 I provided a statement and gave evidence in relation to the BSE Inquiry. A copy of my statement and the transcript of oral evidence that I gave on 14 December 1998 has been provided to the Inquiry [MHRA0018946_059] [MHRA0018946_019]. I have not been involved in other inquiries, investigations, criminal or civil litigation in relation to HIV, HBV or Hepatitis C.

Section 2: Decision-making structures

Structure and Organisation of the Department for Health

- 2.1. The BSE Inquiry was interested in the structure and organisation of the Department of Health and in how we as Ministers worked. I reproduce below extracts from my BSE statement which may help this Inquiry in terms of how ministerial responsibilities were organised and the methods of working and decision making.
 - (1) Parliamentary Under Secretaries of State. "Parliamentary Under-Secretaries were assigned their own areas of responsibility, documented in a list of ministerial responsibilities. They shared the workload of replying to correspondence and were responsible for answering the bulk of Parliamentary Questions, and for speaking in routine health debates. Unless a particular issue touched directly upon the specific responsibilities of the Minister of State for Health, Parliamentary Under-Secretaries would deal directly with the Secretary of State if they needed to involve a more senior Minister."
 - (2) Minister of State for Health. "The Minister for Health also had specific areas of responsibility, often for large and/or high profile subjects. For example, when I was Minister for Health, I had particular responsibility for personal social services, and for NHS management. My successor, Dr Mawhinney, was responsible for NHS reforms, and European Community and international affairs."
 - (3) Secretary of State for Health. "A summary of the Secretary of State's responsibilities in the directory of ministerial responsibilities for May 1992 read as follows ..." ... overall responsibility for the work of the Department and the Office of Population Censuses and Surveys. In particular she takes the lead on issues arising from the NHS review and major political strategies and policy matters affecting health and personal social services". I regard that as being a fair summary. The workload was different to that of the Junior Health Ministers. The

Secretary of State would answer fewer Parliamentary Questions, would delegate much routine correspondence and would not normally speak in adjournment debates. The Secretary of State had overall responsibility for DoH policy, as well as the wider responsibilities that came with membership of the Cabinet. As Secretary of State for Health, I sought to pursue a "collegiate" approach to the division of responsibility between Ministers. It was important that the Junior Ministers had genuine responsibility for their portfolio of subjects and that I avoided over-interference in their decision making. I sought to be receptive to Junior Ministers. I insisted on meetings, formal and informal, to allow discussion of areas of concern and important issues."

- (4) Permanent Secretary (Sir Christopher France (until 1992) then Sir Graham Hart). "A significant part of the Permanent Secretary's responsibilities was the management of the Department, both in terms of personnel and management structure. The Secretary of State would expect to be consulted on structural changes to the Department ...The Permanent Secretary also had a responsibility for liaison with the Cabinet Office. In broad terms, the Permanent Secretary's input would be greatest where matters of administration, implementation and resources were concerned. In contrast, public health issues demanded that the Chief Medical Officer took the lead."
- (5) Chief Medical Officer (initially Sir Donald Acheson then Sir Ken Calman). "The Chief Medical Officer fulfilled a significant role in advising Ministers on public health. The position of Chief Medical Officer (CMO) was important. Constitutionally, the CMO was medical advisor to the Department of Health, to a number of other individual Departments, and to the Government as a whole. In contrast to most other civil servants, the CMO had the option of making public statements in his own right. He also had the responsibility of producing an annual report on the state of the public health. During my period of office in the Department of Health, there were a number of health problems and scares. Examples other than BSE/CJD included the incidence of 'Indian plague', the flesh eating virus, the safety of vaccines, salmonella, the safety of various seafoods, the incidence and causes of cot deaths, the safety of breast implants and

the ongoing issue of HIV/AIDS. The CMO (and his medical staff) had a key role in advising Ministers on these difficult subjects, and in obtaining the advice of specialists in the relevant scientific and medical discipline: When the CMO advised on such subjects, he provided an independent, authoritative, professionally detached voice within the Department. The independence of the CMO was emphasised not only by his unusual constitutional position, but also by the tradition of recruiting the CMO from outside the Department of Health ... I consistently and strongly supported the CMOs role in public health issues. I was confident that the CMOs gave advice based upon a scientific assessment of what was in the interests of public health, irrespective of political considerations."

- (6) **Organisational Change**. "There were a number of changes in the structure of the Department of Health in the period 1989-1995. The last such change introduced by the Permanent Secretary within my period of office was the integration of the medical and administrative divisions of the Department. The advantages of that change, on which I was consulted, included minimising the duplication of work (which had been reported as a feature of the previous parallel hierarchies), and providing a better career structure for officials."
- (7) Private Offices. "As Secretary of State, I had a private office of around seven staff. My principal private secretary would take the lead on keeping me informed on a number of key issues, as well as having the responsibility of liaison with Number 10, the Permanent Secretary, the Chief Executive of the NHS, and the CMO. Assistant private secretaries would take responsibility for those subjects not covered by my private secretary. The work of the four other ministers would have been shadowed by junior secretaries from my private office. I had a diary secretary with responsibility for arranging my appointments. The Inquiry has asked me to address how advice from officials was conveyed to me. I held many meetings to listen to advice and to discuss the best action. Where information and advice were conveyed by written submissions, the submissions would normally be placed in the boxes to be read by me overnight, or at weekends. This reading material was divided into separate files relating to:

- Engagements, diary requests, and briefing material for engagements;
- Appointments to public bodies;
- Decisions;
- Papers to note;
- Political material;
- Inter-ministerial correspondence, letters and other correspondence;
- Constituency material.¹

My general aim was to keep as fully informed as was reasonably possible. I would have seen the majority, but certainly not all, of the documents sent to my private office. Where submissions were sent to me for decision, it was my practice to read and consider the submissions in full, overnight. In contrast, submissions sent to me for information only could be assimilated more quickly."

(8) Communication. "During my time as Secretary of State for Health, the Health Ministers aimed to meet three times per week. On Wednesday, a "Top of the Office" meeting was held ("TOTO"). TOTO had, I believe, been introduced by Mr. Waldegrave when he was the Secretary of State. TOTO was attended by the five Ministers, the Permanent Secretary, the Chief Medical Officer, the Chief Nursing Officer, the Chief Inspector of Social Services and the Chief Executive of the NHS. On Tuesdays, Ministers held a meeting which concentrated on parliamentary business (adjournment debates, early day motions, parliamentary questions, statements, delegations, legislation, select committees) and on media issues which had arisen over the weekend. On Thursdays, we held broader political meetings which all the Health Ministers would attend. The relevant Government whips, Parliamentary Private Secretaries and one of my private secretaries would attend the meetings on Tuesdays

¹ "Constituency material was prepared by my House of Commons private secretary and was not handled by my ministerial office, but might be transported to me with ministerial papers."

and Thursdays. Aside from these regularly time-tabled meetings, there were many other meetings, both formal and informal. Where necessary, TOTO would be followed by other meetings. The Ministers shared the same corridor in the Department which helped us to keep in touch. The private secretaries' network was also an important part of communication within the Department. Senior staff held their own management meetings."

- 2.2. I gave these explanations to the BSE Inquiry when things were fresher in my mind and I stand by them. I add the following recollections and reflections:
 - (1) In terms of other senior officials, I remember in particular Strachan Heppell, an outstanding Civil Servant. He was originally the Grade 2 Head of the Health and Personal Social Service Group. Similarly, Dr Jeremy Metters when he became one of the Deputy Chief Medical Officers was impressive. When the Department was re-organised into integrated Groups, Mr Heppell and Dr Metters headed the Health and Social Services Group. I also remember Dr Diana Walford. I had great confidence in her and her judgement. Other good officials who were involved will be apparent from the submissions and notes of meetings.
 - (2) The CMO had regular access to me. By the time I was Secretary of State this was Sir Ken Calman but as Minister of State both Sir Donald Acheson and Sir Ken Calman would have easy access to me, as they did to Mr Clarke and Mr Waldegrave.
 - (3) Part of the purpose of the Top of the Office meetings was to ask what was on the minds of the senior officials attending and their key priorities.
 - (4) I had excellent support from my Private Secretaries (including Robert Creighton, Alan Davey and Tim Sands). I had full confidence in my Private Office Staff who worked closely with the Permanent Secretary when I was Secretary of State.
 - (5) I tried to remain alert and available to MPs and the broader health community. I believe I developed relationships with NHS staff where they would approach me informally if they were unhappy with an official line. In addition, many of my family and close friends were medically engaged at a senior level. If serious matters had not emerged through the

departmental route, I would frequently pick them up through information coming through these less formal channels. And I would then revert to officials on the Monday and raise them where I felt this was appropriate. I do not now have a specific recollection of this happening on Blood Products, although the briefing that I asked for on the funding of pure Factor VIII following the article in "Hospital Doctor" (which I address in paragraph 6.42) may be an example of this.

(6) No minister gets everything right. As a minister I was diligent and conscientious. I did paperwork for hours at night and from early morning. There were meetings, work in the Commons and visits all day. I would take as many as 11 boxes home at the weekend. I did not sign letters or papers without reading them carefully.

Responsibilities as Minister of State for Health

- 2.3. The Inquiry has asked for me to describe, in general terms, what responsibility I had as Minister of State and Secretary of State for Health for matters relating to blood and blood products.
- 2.4. Initially my areas of delegated areas responsibility as the Minister of State were listed as follows:

"The Minister of State (Minister for Health) (Mrs Virginia Bottomley JP MP) has specific responsibility for NHS management, personnel and pay issues. She is also responsible for personal social services (including childcare services), primary and community care, AIDS, preventative health care (excluding drug and alcohol abuses). Nursing services, women's health matters, disablement services, hospices and action on waiting lists".

As I set out in my BSE statement, in August 1990 there had been a degree of re-organisation in the Department, with further subjects added to my portfolio of responsibilities. These were "medical manpower and education (including junior doctors' hours of work), special health authorities, pharmaceuticals, abortion and family planning, the Warnock Report". I will come back to the

question of pharmaceuticals in Section 5 of this statement because I clarified in my oral evidence to the BSE Inquiry that I had a responsibility for pharmaceuticals even before August 1990.

- 2.5. Blood Products were listed in the portfolio of the Parliamentary Under Secretary in the Lords, Baroness (Gloria) Hooper. That is consistent with the fact she dealt with the submissions on both screening blood products for Hepatitis C (see section 7 below) and the reorganisation of the Blood Transfusion Service, in what became the National Blood Authority (see Section 3 below). When I became Secretary of State, it was Tom Sackville who took on this portfolio.
- 2.6. Although blood products and the blood transfusion service were not within my areas of delegated responsibility, the available documents show that I had material involvement. In particular:
 - (1) On the HIV litigation the overall strategy was directed at Secretary of State level (by Mr Clarke and then by Mr Waldegrave). I was involved in this and on some issues in the litigation officials came to me at least initially, although the records show that I quite frequently deferred to the views on the Secretary of State given his legal background. I address this further in Section 4.
 - (2) On ongoing support for the Macfarlane Trust, a number of submissions came directly to me when I was Minister of State. I address this further in Section 6.
 - (3) There was some limited overlap with my broad responsibility for AIDS.

Responsibilities as Secretary of State for Health

2.7. I was appointed Secretary of State for Health on 10 April 1992. Dr Brian Mawhinney was appointed Minister for Health, and the Parliamentary Under Secretaries were Tim Yeo (succeeded by John Bowis), Tom Sackville, and Baroness (Julia) Cumberlege (the Department of Health Minister in the Lords).

- 2.8. As Secretary of State, I was accountable to Parliament for the actions of the whole Department. I have already cited above that my BSE evidence included the summary of responsibilities as
 - "... overall responsibility for the work of the Department and the Office of Population Censuses and Surveys. In particular she takes the lead on issues arising from the NHS review and major political strategies and policy matters affecting health and personal social services".
- 2.9. As Secretary of State, I was assisted by a team of junior ministers who each managed a portfolio of delegated responsibilities and were responsible for decisions in their allocated areas. Tom Sackville took on responsibility for the Blood Transfusion Service which had previously been within Baroness Hooper's portfolio. He continued the work, for example, towards the creation of the National Blood Authority.
- 2.10. There was a balance to be struck. As I have explained, Junior Ministers needed to have genuine responsibility for their delegated areas, and I wanted to avoid over-interference in their decision making. I wanted to be receptive to them and encourage discussions and meetings in areas of concern and importance. Overall, we worked well as a team and were well served by officials who we respected and trusted.
- 2.11. I have explained later in this statement some areas where I did have relevant direct involvement as Secretary of State.
 - 2.12. The main route by which matters were brought to my attention by officials, whether as Minister of State or as Secretary of State, was by written submission. These could take different forms; submissions seeking a decision which would have a recommended course of action and analysis of the pros and cons; but other submissions would be 'for information'. If my Private Office (whether as Minister of State or Secretary of State) was the main recipient of the submission i.e. I was the Minister expected to make the decision, I would almost invariably have seen the submission. As I have explained, it was my practice to read and consider the submissions in full, overnight (or over the

weekend if it was in my weekend boxes) and comment on them accordingly. Submissions sent to me for information could be assimilated more quickly.

- 2.13. As Secretary of State, I may not have seen all the submissions which were directed to other Ministers and only copied to my Private Office.
- 2.14. Beyond the submissions there would be meetings with officials both on specific issues and the regular Top of the Office meetings to which I have already alluded.
- 2.15. There were not specific formal criteria for determining whether a matter was of sufficient importance to be brought to my attention. This would be a matter of judgement for officials in all the circumstances. In general, I had trust and confidence in the group of Senior Officials and Private Office Staff with whom I worked, and they worked their best to ensure that we as Ministers received the relevant information. There was, inevitably and even with the control of the Private Office staff a very large volume of information and decisions to be taken. Hence the 11 weekend boxes to which I have already referred.

Relationship with relevant departments concerning Scotland, Wales and Northern Ireland

2.16. The Inquiry asks about my interactions with the Territorial Departments in relation to blood, blood products, pharmaceuticals, and related issues of blood borne viruses. I do not now have any independent recollection of dealing directly with the Secretaries of State for the Territorial Departments in these areas. As I have addressed the subject areas later in this statement, I have referred where appropriate to liaison with the Territorial Departments. For example in the spring of 1995, when further consideration was being given to whether there a payments scheme should be extended to those infected with Hepatitis C, I asked officials to ascertain the views of the Territorial Departments and this informed the paper that officials then developed. Aside

from local health issues, so far as possible we tried to present a consistent line across the four nations on matters of health policy.

2.17. It is unlikely that I would have had direct interaction with the health-related bodies in Wales, Scotland or Northern Ireland (such as the Scottish National Blood Transfusion Service) because normally this would be handled at official level. There may have been discussion at conferences or similar. I have no specific recollection of this.

Section 3: Safety of Blood and Blood Products

- 3.1. I have been asked to provide details to the Inquiry about what, if any, advice or information or briefing I was given when I first took office as Minister for State of Health, and then again when I became Secretary of State for Health, in relation to the National Blood Transfusion Service and how it was organised; the risks of infection from blood or blood products, and in particular the risks of the transmission of Hepatitis; and the nature and severity of different types of blood borne Hepatitis (including, in particular, Hepatitis C which was previously known as Non A Non B Hepatitis).
- 3.2. I have no independent recollection of what information I was provided on assuming office either as Minister of State or Secretary of State. I would very likely have received a series of briefings, both oral and written, on key issues within my areas of responsibility as Minister of State and facing the Department on assuming the role of Secretary of State. In the oral evidence I provided to the BSE Inquiry in 1998, I explained:

"I was appointed, of course, at the time ... of Nigel Lawson's resignation so evidently Departments prepare briefing for appointment and disappointments at certain times of the year. I do not think anyone could have expected the arrival of a new Minister then, so maybe arrangements were irregular. Any briefing I had it would be my nature to look at thoroughly, and frankly not only to want to look at the documents but to meet the relevant people." (BSE Oral Evidence, 14 December 1989, page 16, line 6).

The matters within Baroness Hooper's portfolio at this time would not have been part of the early briefings to me. If I did not receive an initial briefing on the HIV litigation on first appointment, briefing and information on this certainly came in the early weeks as I have addressed in Section 4 of this statement.

3.3. A minute from Dr Rejman to Dr Abrams on 23 March 1992 included a draft section for the CMO briefing for incoming Ministers following the 1992 election [DHSC0003591_081]. It stated:

"National Blood Authority

This Authority would involve the merger of the NBTS Directorate and the Central Blood Laboratories Authority. The first meeting of the Technical Working Group to consider operational aspects is due to take place on 3 April. Contracts form a major part of the considerations, and so the proposal may need revision in the light of views of incoming Ministers."

3.4. As the newly appointed Secretary of State promoted from within the Department from Minister of State, I doubt that I would have received the prepared briefings for 'new' Ministers coming to the Department for the first time. Instead, I would have received detailed briefings on subjects as they arose particularly those in which I had not previously been involved as Minister of State.

Establishment of a National Blood Authority (NBA)

- 3.5. A submission dated 12 July 1991 was sent from Mr Dobson to Mr Waldegrave and Baroness Hooper. It concerned proposals for the future management of the NBTS and the CBLA and included a recommendation that a National Blood Authority be established [DHSC0004245_017]. Officials also recommended to 'decouple' the CBLA's manufacturing arm, the BPL, to allow it to operate on a more commercial basis in order to pave the way for possible future privatisation of the BPL. Officials stated they considered privatisation would be in the interest of the NHS but would be politically sensitive. The submission was not copied to my private office and I have no independent recollection of the document prior to being shown it.
- 3.6. A separate submission was sent to Mr Waldegrave from Baroness Hooper dated 16 July 1991 [DHSC0004245_004]. It presented her views on Mr Dobson's submission of 12 July 1991. She stated she would welcome the opportunity to discuss the proposals in that submission with Mr Waldegrave and

noted the matter was "touched on at 'Ministers' the other day". That was a reference to the regular Ministers' meetings.

3.7. Baroness Hooper stated her support for the proposal to create the NBA. She also expressed support for what she described as the "linked but logically separate" proposal, which she described as:

"to "decouple" BPL from CBLA to allow it to seek new markets for products not derived from British plasma, thus enabling the BPL plant to be used to full capacity. The first step would simply be a matter of changing CBLA's internal accounting procedures to show BPL as a separate cost centre, but the proposers suggest that the full benefits of this decoupling would be realised only if BPL was privatised. Some commercial firms have already shown interest".

- 3.8. Baroness Hooper commented of the second proposal "though it also offers clear benefits to patients, could be politically controversial." She concluded "My judgement is that we should accept both proposals and, by announcing them simultaneously, seek to emphasise the overall benefits to NHS patients of the combined change but I would welcome your views."
- 3.9. A minute dated 17 July 1991 from Mr Waldegrave's private office to Baroness Hooper summarised his views on the submissions of the 12 and 16 July 1991. It stated that Mr Waldegrave was "content to combine the functions of the NBTS National Directorate and the CBLA into a new national blood authority" but did not accept other recommendations made in the submission [DHSC0004245_003].
- 3.10. I have no independent recollection of being involved in this matter when I was Minister of State. The documents to which the Inquiry has referred me were not copied to my private office and as such, it seems highly unlikely that I would have seen them. Baroness Hooper was dealing with this area and to the extent that she required it, the documents indicate she sought input and guidance on this from Mr Waldegrave. Unsurprisingly, the documents suggest that the

reform may have been touched on in our meeting of Ministers, but I do not think I would have been involved beyond that sort of level of discussion.

- 3.11. As I have explained, once I was Secretary of State, Tom Sackville took on the responsibility for National Blood Authority. The Inquiry has referred me to the following:
 - (1) A minute from Mr Canavan to Mr Sackville dated 5 November 1992 attached a draft note that it was proposed be sent to me providing details on key developments in relation to the NBA [WITN5289003] [WITN5289004]. The document provides the note in draft form. I cannot recall whether a final version of this document was put in front of me, and no final document has been discovered and shown to me.
 - (2) A minute from Mr Canavan to Ms Bateman dated 3 March 1993 included a briefing note for a meeting I was due to attend with the Treasury on privatisation issues. It addressed the status of BPL [WITN5289005]. The "line to take" in the note stated:

"Recognise the operational advantages to BPL if it were put into the private sector. However, we must also take account of the possible repercussions for our system of voluntary, unpaid blood donation and our national and EC policies of seeking self-sufficiency in blood products made from unpaid donations for both ethical and health reasons.

Those wider concerns caused us to reject privatisation of BPL in the past. In view of the increasing emphasis on core activities and greater collaboration between the NHS and the private sector, the NBA has been asked to review all the options for BPL. We shall consider proposals seriously but at this stage cannot be committed to change. We would need to be satisfied that any new arrangements protected our wider interests in the blood services."

(3) A further briefing note provided by Mr Scofield to Ms Bateman dated 11 March 1993 in anticipation of the proposed meeting with the Treasury on privatisation issues included a summary of the arguments for and against privatisation [WITN5289006].

- 3.12. The Inquiry notes that Mr Dobson's submission dated 12 July 1991 made the point that the NBTS was a "national service in name only" given that the Regional Transfusion Centres were managed by Regional Health Authorities. I do not recall being aware then, or becoming aware subsequently, of the detailed history of the arrangements for the RTCs and their management; I do not think I am well placed to comment on why the situation had persisted for so long that the transfusion service was a national service in name only.
- 3.13. As to the advantages and disadvantages of the creation of the NBA, the submission from Mr Dobson to Mr Waldegrave dated 12 July 1991 provides a contemporaneous summary of the thinking. He stated that stronger central control would result in greater consistency in quality standards and cost effectiveness. No obvious disadvantages are noted.
- 3.14. The Inquiry has asked me whether I had then, or possess now, views on whether it would have been preferable for a national body to have been created at an earlier stage. Again, I should stress that I was not aware of the detailed history. In general terms my experience is that such points are easier to spot in hindsight. This was a time of significant structural change for the health service and health related bodies.

Section 4: HIV Haemophilia Litigation

Initial Briefings on the HIV Litigation

- 4.1. I did not recall any involvement in the HIV litigation prior to taking up post as the Minister of State for Health in October 1989. So far as I can recall, I did not have any knowledge of the litigation either. It is possible I read about it in the media.
- 4.2. On 7 November 1989, shortly after taking up post as Minister of State, a submission from Mr Heppell to Mr Clarke was copied to my Private Office and to the other Ministers [DHSC0004415_156]. The submission referred to a meeting with Robert Key MP, also a Vice President of the Haemophilia Society which I had attended that day, along with Mr Heppell. Mr Heppell noted that he and I had discussed matters after the meeting with Mr Key. In his note, Mr Heppell described my aim as being to identify proposals which would:
 - "* sufficiently meet the aspirations of the Haemophilia Society so that they are prepared to recommend their members not to proceed with the legal action.
 - * are accepted by the public, and if possible the campaigners, as being an adequate response to the situation of haemophiliacs with AIDS/HIV.
 - * do not set any unacceptable precedents for the future e.g. by implying NHS liability for treatment which reflects the best available medical information at the time but turns out later to be wrong or accepting a duty of care for the approval of particular new drugs."
- 4.3. He went on to suggest proposals that might 'fit the bill' of which the financial element was:
 - "... increasing the Macfarlane Trust funds by 2½ or 3 times to £25 or £30m over the next 3-4 years say another £5m this year, and £5m in each of the next 2 or 3 years. This would give each family roughly £25,000, about the average German and Danish figure. Mr Keys thinks

this might be enough although he thinks £40-£50m has a better chance of success and starting off thinking in terms of £100m. The Society would like to settle out of court for £75,000 a family, he said."

- 4.4. Robert Key was a respected colleague. The available documents do not appear to include any note of the meeting. A submission sent from Mrs J R Walden at the AIDS Unit to my Private Secretary dated 1 November 1989 noted that I was due to attend a briefing meeting with the AIDS Unit on 2 November 1989 [DHSC0002536_065]. In relation to the claim in the HIV litigation, Annex A to Mrs Walden's submission highlighted that one of the wide range of issues of which I needed to be made immediately aware was the HIV litigation [DHSC0002536_066]:
 - "29. Some haemophiliacs treated before mid-1985 with HIV contaminated blood clotting agent Factor VIII have become infected with the virus. They are now suing the Government for compensation and the main hearing is expected to be in early 1991. The Sunday Times has been running a campaign calling on the Government to compensate them as a matter of urgency. The lead on this lies with HS Division, but the AIDS Unit advise on AIDS aspects."
- 4.5. The available documents also do not seem to include any record of my meeting with the AIDS Unit on 2 November 1989 or a more detailed or further briefing I may have received from the relevant officials. However, Mrs Walden's submission suggests that I would have been briefed on the HIV litigation generally and ahead of the meeting with Mr Key and others on 7 November 1989. My Private Office team were diligent about preparation ahead of important meetings like this, and I in turn worked hard on the briefings to ensure that I assimilated the necessary information.
- 4.6. In relation to Ministerial responsibility for decision making on the claim at this stage, the overall direction and policy was being handled by Mr Clarke as Secretary of State. That is evident, for example, from Mr Clarke's note to the Prime Minister of 17 November 1989 to which I return below. However, as Minister of State, I was also involved. The documents show that on some issues

officials came to me at least initially. I was generally mindful of the fact that Mr Clarke was a lawyer by profession and it is evident that on some issues I deferred to him not only because of his seniority as the Secretary of State, but also because of his legal knowledge.

- 4.7. I have been asked by the Inquiry whether I had a fixed position in November 1989 on the HIV litigation and whether this was in accordance with "the Government's official position". I would not describe my position as "fixed". The HIV litigation involved intensely difficult and emotional issues. I sincerely wanted to do more for those infected and affected. I was aligned with the Government's developing official position at the time. Our approach was still being formulated but we were moving towards trying to make a further addition of funds into the Macfarlane Trust which were not tied to the litigation (and not therefore an offer of settlement) but with the hope that it would be sufficient to lead to the litigation not being proceeded with. The difficulty was in finding proposals that would go far enough to meet the aspirations of those representing the infected and their families and satisfy supportive opinion, but which did not set an unacceptable precedent in relation to no-fault compensation.
- 4.8. In addition to Mr Heppell's submission of 7 November 1989 [DHSC0004415_156], the Inquiry also refers me to:
 - (1) A further submission from Mr Heppell to my Private Office dated 10 November 1989 [DHSC0004415_155]. This reported on Mr Heppell's meeting with the Haemophilia Society on 9 November, suggesting that a sum of £120 million would be required to bring the litigation to an end. Mr Heppell was doubtful whether the Society would be able to commend any payment by the Government of the order we had in mind.
 - (2) A minute from Mrs Farr sent to my Private Office dated 16 November 1989 [DHSC0002536_061]. She provided information on a phone call from Mr Watters in which he had indicated that a sum of £86 million would be required to bring the litigation to an end (not the £120m previously indicated).

- 4.9. The general arguments and proposals in respect of the HIV litigation outlined in these documents look to be in line with my thoughts at that time.
- 4.10. I think I had some hope at the time that the proposals outlined in Mr Heppell's submission of 7 November 1989 might be sufficient to persuade the Haemophilia Society to recommend not proceeding with the legal action to its members [DHSC0004415_156]. I was hopeful that the suggested increase to Macfarlane Trust funds would offer tangible benefits to the lives of those infected and affected. Mr Heppell had noted that Mr Key had himself indicated that this might have been enough to meet the objectives of the Haemophilia Society though £40-50m had a better chance of success. Set against this, however, Mr Heppell's later submission of 10 November expressed doubt about whether the sort of sums we had in mind were going to commend support from the Haemophilia Society.
- 4.11. It was important that a settlement could satisfy the Haemophilia Society, the public and campaigners without setting any "unacceptable precedents" such as accepting any Government/NHS liability "for treatment which reflects the best available medical information at the time but turns out later to be wrong or accepting a duty of care for the approval of particular new drugs" (which was my aim following the meeting with Robert Key). The potential consequences of setting any such precedents were serious and required careful consideration; we were all aware of the potentially vast cost of litigation. It is for these reasons that I agreed with Mr Heppell's statement in that submission that "the Government cannot give way on the principle of liability". We were concerned that the appearance of conceding Government/NHS liability by way of settlement would have had very significant financial ramifications for the NHS. This point was clearly central to official advice at the time. The point was reenforced in a minute from Ronald Powell (a Departmental Solicitor), sent to my Private Office on 15 November 1989, in which he cautioned that:

"Any payment to the plaintiffs which is linked to the court proceedings and brings them to an end, runs the risk of being seen as an admission of liability by the government. This will be so, it seems to me, even if

there is a statement, agreed with the plaintiffs, that the payment is made without liability being admitted.

Any payment which is <u>not</u> linked to the court proceedings and does <u>not</u> bring them to an end, by definition will <u>not</u> prevent a plaintiff or plaintiffs continuing with the proceedings." (Original emphasis) [DHSC0006271_033].

- 4.12. Mr Heppell referenced two financial settlement figures in his submission of 7 November 1989 i.e. increasing Macfarlane Trust funds to £25-30 million over 3-4 years and the £40-50 million mentioned by Mr Key. Paragraph four of the submission indicated that there were financial uncertainties about how the proposed further funding for the Macfarlane Trust would be sourced, for example "there was no obvious money in our kitty for this year" and the Treasury were likely to resist any further claim on the Contingency Reserve. The Inquiry asks if I had a "preference" for the lower or the higher figure. I am not sure that "preference" is the right way to look at it in light of the concern we all had for misery of those who had suffered (see further below).
- 4.13. Given the financial constraints on increasing funding for the Macfarlane Trust and the precedent risks, I think I would have been accepting of the position that we would have to try for the lower figure. It is apparent from a submission from Ms Stuart dated 17 November 1989, which was not copied to my Private Office, that the mechanics of "additional grants of up to £20 million over the next 3 years to the Macfarlane Trust" were being discussed with the Secretary of State at the time, with various options being presented to Mr Clarke for his consideration [DHSC0006485_015]. Mr Clarke's response is recorded in a minute from his Private Office to Ms Stuart dated 20 November, which was copied to my Private Office [DHSC0004415_114]. Mr Clarke made a series of comments in respect of the sources of the additional Macfarlane Trust funds. In his submission of 10 November 1989, Mr Heppell reported that the Haemophilia Society was "interested in promoting an out of Court settlement as the Court action is likely to drag on over a number of years and any compensation awarded would come too late for many of their members" [DHSC0004415 155]. As to whether the life expectancy of Haemophilia

Society members was considered by the Government at the time and, if so, if this had an effect on the Government's position on the HIV litigation, this was a serious matter indeed. I was very concerned about the ongoing misery Haemophilia Society members were enduring and the short life expectancy of those infected. I wanted the Government to reach a resolution as soon as possible and within the lifetimes of the victims affected so that any payments would have a meaningful impact on the lives of these individuals. I can only repeat that these were intensely difficult issues. Yes, the expectation of remaining life was considered, and it was considered important.

- 4.14. Paragraph 7 of Mr Heppell's submission of 10 November 1989 recorded that he had indicated to the Haemophilia Society (though not in so many words) that, "Ministers would want to listen very carefully to what the Society, which they hold in high regard, had to say. But the sort of figures they had in mind were very high. And we must take into account the implications eg for others apparently infected with HIV through treatment." In relation to whether the situation of other potential claimants, such as non-haemophiliacs also infected with HIV through blood transfusions, was a factor influencing my thinking and/or the Government's thinking at that time, every adverse outcome of those infected with HIV through blood or blood products had great personal costs. Our primary concern at the time was to ring fence payments for haemophiliacs infected with HIV through blood products and arguments about the double jeopardy of haemophiliac patients were taken into consideration on this point. These were victims who had suffered HIV infection on top of the serious condition of haemophilia and that was seen as the grounds of distinction at this stage.
- 4.15. As I have indicated, in Mrs Farr's submission of 16 November 1989, the downward revised figure of £86 million had been put forward by the Haemophilia Society [DHSC0002536_061]. As to whether I thought that this settlement figure was realistic and/or whether any consideration was given to settling the litigation for this sum, the available documents do not appear to record discussions about the possibility of settling the litigation for this sum at the time. I would have been guided by official advice on whether settlement at

this sum was possible. I do not specifically recall discussion of settlement at this level of £86 million or similar levels. I think it is a fair inference from the various minutes that this sum was far in excess of what officials thought was realistic. They likely saw figures at the level as too high having regard to the legal merits, the pressures of finding the immediate sums necessary, and the problem of wider precedent coupled with the need to gain approval from the Treasury.

4.16. The Inquiry refers me to a Treasury submission dated 13 November 1989 which I would not have seen at the time [HMTR000001_005]. The submission was from R B Saunders to the Private Office of the Chancellor (then John Major) copied to the Chief Secretary (at the time Norman Lamont). Mr Saunders provided a Treasury Line to Take if the compensation issues was raised. In comments under 'Not for use' informing Treasury Ministers of further background, it was indicated that Mr Clarke would be considering the matter at an internal DH meeting on 4 November and that:

"He is said to be sceptical about the need for any further payment (the Trust still has £8m in the kitty), but Mrs Bottomley is said to think that the Government must be seen to be doing more. The outcome is likely to be a further payment of perhaps £5m to the Trust next year, to be found from within the agreed provision for 1990-1991."

4.17. The Inquiry asks if the words, "Mrs Bottomley is said to think that the Government must be seen to be doing more" was an accurate characterisation of my views. I don't think that I just wanted the Government to be seen to be doing more, I actually wanted to do more. Evidently, there was great anguish and public concern about those affected and I was keen to respond, whilst also balancing this against the almost infinite priorities and demands on the budget. The issue of haemophiliacs infected with HIV through blood products had reached a moment of urgency, concern and importance and I was eager for the matter to be resolved. I was therefore keen for the Government to take action on the issue by increasing funds for the Macfarlane Trust if we could.

- 4.18. As set out above, Mr Saunders gave Treasury Ministers the indication that, "The outcome is likely to be a further payment of perhaps £5m to the Trust next year, to be found from within the agreed provision for 1990-91." The Inquiry asks if I believed that this 'likely' outcome would be sufficient. This seems to me to be hypothetical. I would not have seen this minute at the time, and I have not seen within the Department of Health papers suggestion of increasing the funds to the much lower level of £5 million. I had confidence in Mr Heppell's views expressed in his submission dated 7 November 1989. Had it been suggested to me at the time, I doubt I would have viewed a single further increase of £5 million as being realistic to achieve our aims. Indeed, letters from the Macfarlane Trust to the Prime Minister praised Mr Heppell and his officials' work and noted the commitment from the Prime Minister to keep under review the funding available to the trust [DHSC0002472 161].
- 4.19. On 17 November 1989 Mr Clarke sent a letter to the Prime Minister Mrs
 Thatcher on the topic of increasing funds for the Macfarlane Trust
 [HMTR0000001_006]. Mr Clarke's letter included the following:
 - "... I do recognise the degree of public sympathy aroused on behalf of this particular group. I therefore believe we need to act quickly to restore some perspective. One solution, which involves no admission of negligence and creates no difficult precedent, would be to increase the funds available to the Macfarlane Trust. You will recall we allocated £10 million in 1987 specifically to help those haemophiliacs who were in actual financial need because of their HIV infection, and we made it clear then that the Trust Fund was not compensation."
- 4.20. Mr Clarke proposed "a further allocation of £20 million" and that I would make "a Statement in the House about the new cash injection for the Trust". It is apparent from a letter dated 20 November 1989 from the Prime Minister's Private Office that a meeting had taken place between the Prime Minister and Mr Clarke on 17 November 1989 to discuss the proposal set out in Mr Clarke's letter [HMTR0000001_012]. Also at that meeting were John Major as Chief Secretary to the Treasury and the Attorney General Sir Patrick Mayhew.

- 4.21. At the time, I think I was satisfied with Mr Clarke's proposals, and felt that they were seeking to meet our aims as set out in Mr Heppell's submission of 7 November [DHSC0004415_156]. But it was intensely difficult. It was unlikely that any amount we could realistically offer would be seen as enough by those infected and their families. Mr Clarke's proposals nevertheless represented a significant increase in the Macfarlane Trust funding that would benefit those affected whilst also not amounting to financial compensation, therefore avoiding any implication of perceived Government/NHS liability.
- 4.22. I am asked if I agreed with the view that the increase in funding to the Macfarlane Trust could be announced without conceding, or appearing to concede, any legal liability and/or moral obligation towards those affected. Looking at the record of the discussion held on 17 November (at which I was not present), two relevant points were made on this:
 - (1) On the legal position, the Attorney advised that, "...a further £20 million allocation would have no effect on the legal actions...As regards the timetable for legal proceedings, the preliminary issue of whether the NHS has any duty to an individual which, if broken, might give rise to action for damages, would be heard on 13 December. He thought that the court was likely to rule that there was no such duty";
 - (2) In the record of discussion, it was said that:
 - "In presenting such a package, it would be desirable, as well as avoiding any acceptance of legal liability, to avoid conceding any moral obligation. Rather the emphasis should be on the special circumstances of this particular case although distinguishing the position of the haemophiliacs from other difficult cases like vaccine damage was not easy. It was also reasonable to point out that, without the treatment they were given with the blood products, many of the haemophiliacs would have died; your Secretary of State would consider whether information about their life expectancy was available." [HMTR0000001_012].

On the question of whether the payment could be made without appearing to concede legal liability I would have deferred to the legal advice. The moral obligation point was I think being raised in the context of the difficult precedent that such a payment might still set. The concern was that if it was presented as being a payment made out of a moral obligation, many other cases would be presented arguing for similar payments based on a similar moral obligation. It was in that context that the discussion at this senior level (Prime Minister, Health Secretary, Attorney General and Chief Secretary to the Treasury) was in favour of the presentational emphasis being on the special circumstances of the haemophiliacs who had been infected. They recognised that this distinction would not be easy.

- 4.23. On 23 November 1989, Mr Clarke announced the increase in funding to the Macfarlane Trust in a Written Answer to a PQ from Mr Key [HMTR000001_023]. I do not remember why it was Mr Clarke rather than me who ended up making the announcement, as had originally been suggested. As Secretary of State for Health, Mr Clarke had played a leading role on this issue and the increase in funding was essentially his policy. The fact that he did announce the additional funding gave recognition to his involvement and commitment to this issue.
- 4.24. On 21 November 1989, Paul Gray in the Prime Minister's Private Office minuted Mrs Thatcher in relation to a meeting with Mr Key and other backbenchers the following day [CABO0100003_002]. I was due to attend alongside the Prime Minister. The Prime Minister was provided with two briefing notes; one (Flag A) internal from No. 10, and the second (Flag B) from the Department of Health [DHSC0002471_043] [DHSC0003989_043].
- 4.25. Mr Gray's minute indicated that Mr Key and the other backbenchers were, "concerned about the position of haemophiliacs infected with the HIV virus". I shared those concerns and I understood them. At the same time, as Minister of State for Health seeking to support the almost infinite requirements of vulnerable groups across many areas, I was also acutely aware of the need to balance the competing needs of these groups within the constraints of a limited

NHS budget, which would be impacted not just by the direct payments to those infected, but by the precedents that might be set.

4.26. As highlighted in the DH briefing note for the meeting, we were concerned about the precedent that might be set and that is why, at this stage, we were looking to make a further Macfarlane Trust payment that was not tied to the litigation:

"Any out of court settlement of the litigation would carry with it a tacit admission of negligence and could set an unacceptable precedent by implying NHS liability for treatment which reflects the best available medical information at the time but turns out later to be wrong. The implication of liability could also undermine the medicines licensing system. The Licensing Authority (i.e. UK Health Ministers) and the Advisory Committees have been involved in a number of court actions. They have consistently denied liability and resisted any moves towards any out of court settlement. Any such move could encourage further litigation and expectations of similar settlements. Constant litigation would be damaging to the integrity of the licensing system, could lead to over defensive licensing decisions and could lead to problems in attracting members to sit on advisory committees. For these reasons Health Ministers are not considering an out of court settlement."

[DHSC0003989_043]

I knew the potential loss of life that could follow over-defensive licensing decision-making.

4.27. As to the meeting that then took place on 22 November 1989, there is a record of it in the letter from Mr Gray to my Private Secretary sent on the same day [DHSC0002536_031]. I am afraid that I do not now have any recollection of the meeting. Mr Gray noted that Mr Key had emphasised that he was "most grateful for the prompt action that the Government had taken two years ago in providing the initial funding for the Macfarlane Trust" but that if the Government did not act now "there could be serious political repercussions". Mr Key emphasised that "[n]o-one was suggesting that the Government was responsible for the

misfortune which had befallen the haemophiliacs treated with Factor VIII, but this was nonetheless a problem to which the Government should respond. He recognised that the Department of Health's budget might not be able to bear a substantial extra load without the provision of extra funds".

- 4.28. The Prime Minister is recorded as having said that:
 - "... the Government recognised the need to provide additional assistance. She 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 haemophiliacs. The position was that 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."
- 4.29. Mr Gray's summary of the meeting recorded that the Prime Minister had hoped the delegation would feel able to claim the announcement regarding further funding for the Macfarlane Trust to be made the following day "as a victory for their campaign". I too would have hoped that would be the case. Those campaigning would be able to say they had succeeded in securing a sizeable further payment of funds. But in saying that, I would have been well aware that the sums would be below what those infected and their families were looking and hoping for.
- 4.30. The summary of the meeting recorded John Hannam MP as raising the difficulty that the current trust could only make payments on a needs-basis and the delegation pressing the case for substantial lump sum payments to be made instead. The Inquiry asks if I supported this. I find it difficult to recall now what I thought on this aspect at the time. However, from the available documents including Mr Clarke's earlier letter to the Prime Minister of 17 November, it is

clear that we were ourselves proposing that at least a significant element of the additional funding would be for lump sum payments to be made to each person infected (or their family if they had died). So I think we were accepting at this stage that there needed to be some non-needs based lump sum payments.

- 4.31. The Inquiry has referred me to correspondence exchanged in late 1989 and early 1990 about the mechanism by which the lump sum payments were to be paid to those entitled to receive them, and the need to set up a new discretionary trust.
- 4.32. On 29 November 1989, Mr Dobson sent a submission to my Private Secretary [DHSC0003849_065]. Mr Dobson highlighted that, following the announcement of increased funding for the Macfarlane Trust, the Charity Commission was:

"...firmly of the view that the payments of £20,000 across the board are not possible within the terms of the Macfarlane Trust's Deed as this requires the Trustees to take account of need. Changes to the Deed to enable the lump sums to be paid would remove the Trust's charitable status; and it may not be possible simply to effect a change of status but would require the existing Trust to be formally wound up. It is unlikely that the Trustees would willingly agree to this."

Mr Dobson explained that the alternative was to set up a new discretionary trust for the lump sum payments.

- 4.33. Also on 29 November 1989, a further submission was sent from Mr Heppell to my Private Secretary [DHSC0003352_004]. It noted that Mr Dobson's submission followed meetings with the Macfarlane Trust and DH officials as well as the Macfarlane Trust, DH officials and the Charity Commission.
- 4.34. On 19 December 1989, a further submission was sent from Mr Dobson to my Private Secretary reporting on progress [DHSC0046948_040]. The submission noted that I had agreed to the proposals in Mr Dobson's submission of 29 November 1989, and that further meetings had since been held with the

Macfarlane Trust to set up the new discretionary trust, to be named the Macfarlane (Special Payments) Trust:

- ""2. Following MS(H)'s agreement to the proposals in my submission of 29 November we have held further discussions with officers of the Macfarlane Trust about the setting up of a new discretionary trust (the "Macfarlane (Special Payments) Trust") to handle the payments. No fundamental difficulties have emerged but solicitors acting for the Trust in drafting the new Deed have been a little slower than all parties would have wished and some legal points have still to be resolved. We are having a meeting this evening with trustee's and officers of the Trust and their legal advisors, at which we hope to settle the remaining details. However we understand that it is now very unlikely that the 4 people who will be trustees of the new trust will be able to complete the formalities until after the Christmas break even if a final version of the Deed can to be agreed today. The lump sum payments are therefore likely to begin in early January." [DHSC0046948_040]
- 4.35. A further submission was sent from Mr Canavan to my Private Secretary on 29 January 1990 [DHSC0002536_013]. This submission confirmed "that the arrangements were completed today for setting up the Macfarlane (Special Payments) Trust to administer these payments" and that the Macfarlane Trust planned to begin making the payments on 31 January 1990.
- 4.36. I do not now independently recall when the difficulties in distributing the lump sum payments were first brought to my attention. However, the documents show that the submission on 29 November 1989 raised the problem of the Charity Commission's view with me very shortly after the announcement, and at the same time officials proposed a solution to which I agreed.
- 4.37. In his submission of 29 November 1989, Mr Dobson also raised the difficulty of funding the new payments through a new Trust [DHSC0003849_065]. There were now significant difficulties with the original idea of using the Macfarlane

Trusts' £5 million and the Government providing a further £19 million. One option for funding presented was:

"... to approach the Treasury again, with a view to increasing our use of the Reserve. We would need to seek the full £24m (or something very close to it) from the Reserve this year, with the "repayments" of £7m next year. The question of any possible "repayment" of the additional £5m would need to be negotiated. Any proposal would not be welcome to Treasury, and we cannot predict their reaction."

4.38. In relation to funding the lump sum payments, Mr Heppell's submission to my private office of the same date emphasised that:

"The best way through looks like an approach to the Treasury for a further advance of £5 million from the Reserve to be repaid in April 1991. The clinching factor is that the Trust have tied up money in long term gifts. So if they transferred £5 million they would run short of available cash before 1991 when we would otherwise "return" the £5 million." [DHSC0003352_004]

I do not think it likely that I was directly involved with the negotiations with the Treasury concerning the advance from the Reserve. However, I was involved in the discussions about how DH was to fund the cuts to its intended spending that were required by having to repay £7 million to the Treasury the following financial year and I have addressed this further in Section 6 of this statement, below.

4.39. On 29 November 1989, I answered a written PQ from Sir Russell Johnston MP [DHSC0038657_149]. Sir Russell had asked the following:

"To ask the Secretary of State for Health, what arrangements have been made by each of the governments of the 12 European countries to arrange for compensation to haemophiliacs accidentally infected with the

AIDS virus through contaminated blood transfusions, listing the actions taken, country by country, including the United Kingdom."

In response, I set out financial information about the schemes set up by governments in the UK, European Community countries and elsewhere (HC Deb 29 November 1989 vol 162 c295W) [HSOC0004720].

- 4.40. The Inquiry has provided me with a copy of a letter dated 7 December 1989 from David Watters of the Haemophilia Society to Sir Russell in which he questioned some of the figures in respect of other countries' schemes mentioned in my Written Answer [HSOC0004720].
- 4.41. The final written answer would have been directly based on the suggested answer provided by officials and I would have been reliant on the information they had obtained in relation to payments made by other countries. I cannot say what the source for the officials' information was which fed into the suggested reply save that in my general experience, officials would have had contacts with health officials in other countries as well as the ability to call on our FCO / embassy staff to make enquiries of the situation in other countries. I had no reason at the time to query the accuracy of the material produced by my officials. If I had such reason to query the accuracy, I would not have approved the answer.
- 4.42. We had regards to the schemes operating in other countries when deciding on the amount of increased funding for the Macfarlane Trust though this was only one of many factors we had to consider. In his letter to Mr Major dated 17 November 1989, Mr Clarke noted that in considering further allocation of funds to the Macfarlane Trust, "This is in line with the better European schemes although it is less than the Canadians will announce shortly (we understand this will be £60,000 per case over four years as an out-of-court settlement of litigation)". [HMTR0000001_006].
- 4.43. I have no recollection as to whether I was made aware of the alternative figures put forward by Mr Watters, however, I note there is a handwritten note at the

top of the second page of the suggested reply which noted "based on returns from Embassies as at November 1989 - similar analysis by Haemophilia Society appended".

- 4.44. The Inquiry has referred me to a letter from David Watters of the Haemophilia Society to Lord Trafford dated 25 August 1989 [DHSC0003315_003]. David Watters stated that those haemophiliacs affected "have a right to [have] control over their financial affairs: a right to make their own decisions without going cap in hand to a welfare body, no matter how generous and anxious to help that body might be".
- 4.45. Lord Trafford had died in GRO-C 1989, and I responded to David Watters' letter on 2 January 1990 [HSOC0023147]. I summarised the announcement of the additional funding for the Macfarlane Trust as follows:

"You know of course that we have announced a trebling of the £10 million ex-gratia sum which we made available to the Macfarlane Trust. This is a tangible expression of our concern. Our intention is that the new allocation will be made in the form of £20,000 lump-sum payments and I believe this will help address the point you raise about people making their own decisions over financial affairs."

- 4.46. The Inquiry asks if I considered the lump sum payments of £20,000 would "...provide the financial independence to those affected that Mr Watters highlighted as a priority". I considered that the lump sum payments from the Macfarlane Trust would provide a significant contribution for those affected and a substantial degree of support. But we did not see the payments as providing compensation. Nor did we believe, or suggest, that they would give recipients financial independence in the sense that the infected or their families would not need to call on benefits or the wider welfare state.
- 4.47. At the end of my letter to Mr Watters dated 2 January 1990, I emphasised that it was the Government's "objective that the Trust would be able to continue this work on a more generous scale and we shall be discussing with them how this

can be achieved". I had the upmost respect for the work of the Macfarlane Trust, and I wanted the Trust to continue with the work they were doing to support those affected. The letter would have been based on a draft by the officials dealing with the Trust and, looking at it now, this could have been a reference to follow-up discussions with Department of Health officials about how the Trust may further assist its beneficiaries. Below in section 6, I go into further detail about the topping up of the Macfarlane Trust funding from November 1990.

- 4.48. I have been asked by the Inquiry about the views I formed, the decisions I made and why I made them in respect of various aspects of the HIV litigation. I am being asked for details of my thinking 27-33 years ago. I am reliant on the paper records available to the Inquiry and to the Department of Health.
- 4.49. On 23 November 1989 Mr Wilson at the MCA sent a submission to my Private Secretary which was copied to Mr Clarke's Private Office [DHSC0046959_075]. Mr Wilson sought my views ahead of "a conference with Counsel on 29 November to discuss the preliminary legal issues to be raised in the HIV litigation" and before "a Court session on 5 December at which these issues will need to be identified and timetabled for later Court proceedings".
- 4.50. One such matter on which Mr Wilson sought my views was on the issue of duty of care. Counsel had argued that he should raise as a preliminary issue the argument that, "as a matter of law" (original emphasis) neither the Licensing Authority nor the Committee on Safety of Medicines ('CSM') owed a duty of care to individuals and, as a result, there was no case to answer. I was asked if I was content that this should be advanced in the HIV and Valium litigation. Mr Wilson noted that "Counsel has also proposed that the no duty of care argument should be made in respect of the Secretary of State's responsibilities under NHS legislation." (original emphasis)

4.51. Mr Wilson also noted that:

"Counsel has also proposed that, in respect of allegations which concern questions of policy (e.g. on priorities and resource allocation) for

determination by the Secretary of State, he should argue, as a preliminary issue, that these should be struck out as <u>non-justiciable</u> leaving only allegations concerning other aspects of the Department's involvement, i.e. its administrative/operational functions, as issues to be tried in the main proceedings." (original emphasis).

- 4.52. On 29 November 1989, a conference with counsel took place at which I understand these preliminary arguments were discussed further. The Inquiry has referred me to the note of this conference [DHSC0007045 006].
- 4.53. On 1 December 1989, I received a minute from Mr Clarke's Private Office to my Private Office [DHSC0046948_081]. The minute stated that:

"S of S has seen Mr Wilson's submission of 23 November. His view is that Counsel should argue all three points listed at paragraph 7 of the submission. This includes the duty of care argument in respect of S of S's responsibilities and NHS legislation. S of S has commented that it would have wide implications for Government if the Government itself, as well as the Health Authority, is found to owe a duty of care to an individual patient."

4.54. The Inquiry asks what view I formed of the duty of care argument in respect of the CSM/LA; the duty of care argument in respect of the Secretary of State's responsibilities under the NHS legislation; and in respect of the non-justiciability argument. I have no recollection of this now and moreover within the available papers, I have not seen any contemporaneous response from me or my Private Office to the issues raised by Mr Wilson. Rather, the Secretary of State's Private Office gave Mr Clarke's view on these matters in the minute of 1 December 1989. Although I have no specific recollection of doing so, it is possible that in discussions I may have asked Mr Clarke to address the issue or take the lead. These were largely legal matters, and I would have been guided by the advice of external counsel and mindful of the Secretary of State's own legal background. It is likely that I would have agreed with the advice of external counsel supported as it was by the Secretary of State's own view.

- 4.55. On 18 December 1989, my Private Secretary was sent a further submission from Mr Wilson [DHSC0046948_041]. This submission sought my decision on:
 - "a) whether to seek leave to appeal against the High Court decision not to hear preliminary issues, including the duty of care argument;
 - b) whether the Government should indicate that it will not seek any order for costs against plaintiffs who withdraw from the action by a due date (to be determined by the Court)."
- 4.56. In respect of whether to seek leave to appeal against the High Court decision not to hear the preliminary issues, the reasons for counsel's advice not to seek leave to appeal were outlined at paragraph 4 of Mr Wilson's submission. He noted that, "[o]fficials see strength in Counsel's arguments and would advise against seeking leave to appeal, given the poor prospects of success and the possibility that the attempt could be seen in the media as Ministers seeking to delay the case." I was guided by the advice of counsel and officials at the time.
- 4.57. In respect of the option of seeking an order for costs against plaintiffs who withdrew from the action, following the announcement of the increased funding for the Macfarlane Trust, some plaintiffs had "indicated that they may discontinue their action and have asked if the Government will waive any order for costs against them." Mr Wilson indicated that Pannone Napier, solicitors for the plaintiffs, had written to the MCA seeking urgent clarification on this point [WITN5289036]. Officials advised responding to Pannone Napier "as soon as possible indicating that the Government will be willing to forego its costs in respect of plaintiffs who withdraw by a due date" (original emphasis). Counsel had suggested writing a without prejudice letter to all the plaintiffs indicating that costs would not be sought if they discontinued but officials were against this on the grounds that they thought it might be seen in the media as putting pressure on the litigants.

4.58. There were two replies to this submission which appear to have crossed in the system. On 3 January 1990, Mr Clarke's Private Office replied to Mr Wilson stating,

"He agrees with the conclusions set out in paragraph 12. He has noted that if Counsel's advice is sought on a particular case then it should be followed unless there are compelling political reasons to the contrary." [WITN0758071].

On 4 January 1990 (the minute is incorrectly dated 4 January 1989), my Private Office replied to Mr Wilson stating:

"Mrs Bottomley has considered this and agrees with your advice, but would like to give S of S the opportunity to comment. I am copying this minute to Mr McKeon so that he can seek S of S's views." [WITN0758072].

I cannot expand meaningfully now on this brief indication of my views. Again, it reflects that on legal areas such as this I would have been guided by the legal advice supplemented by officials' views, and mindful of the Secretary of State's greater legal experience.

[DHSC0046957_111]. What appears to be the final version of this document indicates that the submission was sent on 30 May 1990 [DHSC0038699_023]. This submission was "...seeking Ministers views on whether the Department, Medicines Licensing Authority and Committee on Safety of Medicines should plead the defence that the haemophiliacs action for damages is out of time". Although the Health Authorities and the CBLA had pleaded the limitation point in response to the individual statements of claim, Mr Canavan's advice was that, on balance, we should not take the limitation point at all (option (ii)). The other options presented by Mr Canavan were to plead the limitation defence in every case where it was technically possible (option (i)) or to reserve our position on limitation (option (iii)), which was the option favoured by counsel.

note that on 6 June 1990, Lady Hooper's Private Office indicated that she was against pleading the limitation defence at all [DHSC0046957_044].

4.60. On 19 June 1990, my Private Secretary responded to Mr Canavan's submission [DHSC0046957_045]. My Private Secretary noted my comment as being:

"... that on balance she would prefer to go for option iii) i.e. reserve our position. She very strongly feels that <u>not</u> to plead would be a sign of weakness, but would like to defer to Secretary of State's legal expertise in this. I am therefore copying this to Mrs Shirley-Quirke for her to put to S of S."

While I was not blind to the difficulties of being seen to reserve our position on limitation, my response is clear. I would have noted that while officials were in favour of not taking the limitation point at all, counsel was in favour of reserving our position. I was clearly concerned that not to plead an available defence may look like weakness but again, I was keen to defer to the Secretary of State on this issue for the reasons I have already explained. In the event, on 25 June 1990, Mr Clarke agreed with the approach of reserving our position on limitation [DHSC0046957 026].

- 4.61. On 26 June 1990 Mr Desai (for the Treasury Solicitor) sent a minute to Mr Powell, which was not copied to my Private Office at the time [DHSC0046964_031] [DHSC0046964_024]. The minute attached a copy of Mr Justice Ognall's statement delivered in an interlocutory court hearing on 26 June 1990. The Inquiry has referred me to a copy of this statement, where Mr Justice Ognall invited the parties "to give anxious consideration to the prospect of any compromise of these proceedings" [DHSC0046964_024].
- 4.62. Following Mr Justice Ognall's statement, the CMO at the time, Sir Donald Acheson, wrote to me and Mr Clarke on 20 July 1990 [HSOC0017025_004]. The CMO set out his hope that, "Secretary of State will take account of my view that the problem of HIV infection in haemophiliacs can in fact be regarded as a unique catastrophe". The CMO advocated for an ex gratia settlement for those

affected. I certainly respected the points made by Sir Donald, who was a distinguished CMO who had done a lot of work on the AIDS agenda and in many other areas.

- 4.63. Mr Heppell sent a submission on the same topic to the CMO, Mr Clarke and myself dated 24 July 1990 [DHSC0046964_003]. The submission attached a detailed note from Mr Dobson outlining the various options on how the Government might wish to proceed with the HIV litigation in light of Mr Justice Ognall's statement [DHSC0004360_147]. Mr Heppell noted in his submission that the detailed note had been prepared by Mr Dobson "following wide consultation with colleagues in the Department". Mr Dobson's note attached a copy of the Judge's comments as well as views from the Regional Directors of Public Health ('RDPHs') [DHSC0046962 186].
- 4.64. Mr Heppell's view was that there were effectively two options on how to proceed:

"<u>First</u>, we continue to resist firmly the present action against the Government whilst being ready to consider further help through the MacFarlane Trust; or

Second, seek a settlement out of Court, in one form or another."

4.65. Briefly summarising the arguments in favour of Mr Heppell's first option, Mr Heppell noted:

"Very understandably there is wide public sympathy for the plight of the families concerned, recognising the difficulties they already face as haemophiliacs and the prospect of infection being passed from one member of the family to another. There is, moreover, the continuing difficulty in the relationship between the families concerned and their medical advisers while the case is unresolved. And there is the cost of the case and the pressure which it brings to bear on all concerned."

In relation to Mr Heppell's second option, Mr Heppell noted:

"Notwithstanding this background, the reasons why the Government has been reluctant to concede the case or settle out of court remain valid. Indeed, the note by Mr Justice Ognall at Annex A of Mr Dobson's paper strengthens rather than weakens this view. In the sixth paragraph on page 1 it appears to contemplate a higher duty of care for the NHS provision of medical services than that applying to any other provider and also a readiness to accept responsibility outside normal legal liability. This tends to underline the fact that any settlement, however presented would be a precedent — if not legal, then political — for NHS liability for any harm caused by medical treatment even though that treatment was given on the basis of the best available knowledge and skills at the time."

- 4.66. Mr Heppell concluded his submission by recommending against Mr Justice Ognall's approach advocating out of court settlement, but to perhaps consider further payments under the Macfarlane Trust, which would "help to make the Government's position look less hard-nosed and unyielding". Mr Heppell noted that finding the money for this would be difficult. It is inevitable that every Secretary of State for Health and Minister of State for Health will, at times, be regarded as 'hard-nosed and unyielding' on certain issues. The ministerial roles necessarily involved tough choices to be made and the competing priorities of vulnerable groups to be balanced, which invariably involved making very difficult decisions.
- 4.67. Mr Dobson's note noted that leading counsel (Andrew Collins QC), had confirmed his earlier view that:
 - "... we have a very good chance of a successful outcome for the great majority of cases. In particular, he considers that the plaintiffs could not sustain a case against the Licensing Authority and the Committee on Safety of Medicines. (There are a small number of cases, some involving plaintiffs who can prove that they were infected at a relatively late stage in the developing understanding of the method of transmission of AIDS, and an even smaller number in which the plaintiffs may be able to argue successfully that they were treated with unnecessarily large

quantities of Factor VIII, for which the legal arguments are more finely balanced.) Counsel agrees that if we successfully defend this case it should discourage future litigation." [DHSC0004360_147].

My understanding on the strength of the Central Defendants' position, was guided by the legal advice provided by counsel at the time as summarised in Mr Dobson's note. I accepted that advice.

4.68. Mr Dobson summarised counsel's further views in this way:

"Counsel nevertheless suggests that we should consider seriously the judge's proposal. His personal view is that the government 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. He believes that this could be contrived in a way which would avoid setting any legal precedent for other groups (see below). He accepts that any kind of deal might arouse expectations that other groups could look for similar treatment if they mounted an effective public campaign linked to legal action, and that the final judgement is a political not a legal one."

I agreed with counsel's view that the final judgement was a political and not a legal one; the important political consideration of setting any precedent in respect of Government/NHS liability was at the forefront of our minds. This made the decision as to whether to accept Mr Justice Ognall's proposal highly political, as is always the case when any precedent is to be set.

4.69. Mr Dobson referred in his note to "some modest additional help for the haemophiliacs through the Macfarlane Trust, as already agreed in principle, subject to negotiation with Treasury". I do not have any independent recollection of when, why and by whom this had been agreed at the time or whether the additional help through the Macfarlane Trust was contingent on any particular outcome in the HIV litigation. But Mr Dobson's reference to such further payments to the Macfarlane Trust, is consistent with Mr Heppell's submission which commented that such further payments would be very

welcome and would help to make the Government's position look less hardnosed and unyielding. Below in section 6, I go into further detail about the topping up of the Macfarlane Trust funding from November 1990.

4.70. On 27 July 1990, my Assistant Private Secretary wrote to Mr Clarke's Private Office referencing Sir Donald's minute of 20 July and Mr Heppell's submission of 24 July. [DHSC0046964 008]. My comments were conveyed in these terms:

"MS (H) has commented that she thinks we should maintain our present position. Once we move towards conceding on cases like these it will have inevitable long-term implications for the Department."

This minute outlined my view that the Government should maintain its present position in the HIV litigation due to the precedent conceding or making any out of court settlement could set and the associated long-term implications for DH. It was not a question of disagreeing with what had been suggested by Mr Justice Ognall when he encouraged consideration of settlement or disagreeing with the CMO. But the factors had to be weighed against the contrary arguments and my assessment of the balance of the arguments at this stage was in favour of continuing our defence of the litigation. As the note from my Private Office conveys, uppermost in my mind was the precedent that would be set in practice.

4.71. On 31 July 1990, Mr Clarke's Private Office conveyed to Mr Heppell the Secretary of State's own views and his decision:

"S of S has seen your submission of 24 July, together with Mr Dobson's paper, CMO's minute of 20 July and Mr Sand's minute of 27 July. He has commented that he is 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 Plaintiffs' solicitors in strict confidence. He would like officials to work up detailed proposals for this with Counsel and then to put up to him a handling

submission before proceeding. He has also indicated that he is content for officials to take advice of the Law Officer's Secretariat." [DHSC0046964_007]

- 4.72. The documents which I have seen do not refer to any discussion between Mr Clarke and me before our respective views were set out in writing. I cannot now recall whether we did discuss it before our Private Offices set out our views on 27 and 31 July respectively. In the event, my views as conveyed by my Private Office on 27 July were broadly aligned with, and supportive of, the views of the Secretary of State.
- 4.73. The minute from Mr Clarke's Private Office of 31 July 1990, referred to Mr Clarke having considered a minute from Mr Sands (my Private Secretary) dated 27 July 1990. I assume this is just a referencing error and it intended to refer to the minute sent by Mr Jex (my Assistant Private Secretary) on that date. I have not seen any other minute from my Private Office on this topic dated 27 July 1990.
- 4.74. The Inquiry has referred me to two documents where there was mention of whether an application should be made to ask Mr Justice Ognall to disqualify himself from hearing the case:
 - (1) At paragraph 7 of Mr Dobson's note, counsel's view was conveyed in the following terms:
 - "... in his experience for a Judge to make comments of this nature was unique. On the face of it we could ask the Judge to disqualify himself from further involvement in the case on the basis of bias but he did not consider that the Central Defendants should take the lead in such an application. He felt happy to support an application if other defendants or plaintiffs made one, but if he was to initiate such an application himself he considered he would need express instructions from the Attorney General to do so."

 [DHSC0004360_147]

(2) On 18 September 1990, Mr Dobson sent a submission to Mr Clarke's Private Office on the handling of our decision to continue the defence of the litigation and updating on some recent developments. [DHSC0020866_091]. Under 'Other handling issues' at paragraph 6, he said:

"We have considered further the proposal from the RHA defendants to ask Mr Justice Ognall to step down from the case. Ministers had indicated that they would not wish to be seen to initiate such a step, but would be prepared to support it if the other defendants (RHAs and the CBLA) made the first move. The RHAs still believe that this would be a justifiable tactic but they are not prepared to initiate it unless all the defendants join in from the outset. There does not seem any way out of this impasse and we therefore suggest that the proposal should be dropped."

- 4.75. I did not have a view on this matter and was guided by the legal advice of counsel at the time. Counsel seemed to consider that there might be a basis to make such an application but was not keen on the Central Defendants being the ones to initiate such action. I think it is a fair inference that Ministers were ultimately content that this proposal should be dropped.
- 4.76. I have been referred by the Inquiry to three letters that I sent in response to the following MPs who had written to me or Mr Clarke regarding the HIV litigation: Tam Dalyell MP dated 6 September 1990 [DHSC0046936_115]; Christopher Butler MP dated 15 October 1990 [HSOC0008591] and Peter Snape MP dated 16 November 1990 [WITN0008003].
- 4.77. I expect there were letters from other MPs expressing similar areas of concern in respect of the HIV litigation.
- 4.78. The letters set out the Government's official position at the time of writing on the HIV litigation. For example, my letter to Mr Butler stated:

"On the question of compensation, it could be argued that all those who are injured by any kind of medical accident should receive compensation from the State, whether or not anyone had been at fault. The Government does not believe that a general scheme of "no fault compensation" of this kind would be fairer than present arrangements. The Pearson Commission carefully considered the matter in 1978 but came down against changing our system for seeking compensation through litigation in the Courts. There have been no substantial changes in the basic arguments since then. While no fault schemes remove the perceived unfairness between those who can prove negligence and those who cannot, they create unfairness between those disabled as the result of a medical accident and those who are equally disabled through natural causes." [HSOC0008591]

- 4.79. In general, my views reflected the Government's position at the time.
- 4.80. I do not recall whether I was aware of the proposed scheme of compromise put forward on behalf of the plaintiffs when I wrote to Mr Snape on 16 November 1990. As explained below, I was not involved with discussions on the proposed scheme of compromise as this was being handled at Secretary of State level however it is likely that I was made aware of it by colleagues at the time. I was of the opinion that the settlement of the litigation was a realistic prospect.
- 4.81. On 22 November 1990 a submission was sent from Mr Canavan to my Private Secretary [DHSC0004365_039]. It recorded that I had requested a note to be prepared on haemophilia and HIV infection to be issued to MPs outlining the Government's position on the associated issues to assist with constituency enquiries. Mr Canavan's correspondence attached a draft of this note [DHSC0046962_331].
- 4.82. I thought it was necessary to have a note prepared for MPs because the topic of haemophilia and HIV infection, and the associated issues, was one of great complexity and sensitivity, as well as one that had caused individuals to experience considerable personal suffering. MPs were concerned and I thought

that it was important that they were equipped with background information and the Government's position on the litigation as well as on compensation for their own understanding and to handle enquiries from constituents.

- 4.83. I do not recall who had input into the note to MPs attached to Mr Canavan's submission nor would I have been expected to be aware of this at the time. I trusted the officials that were preparing advice for my consideration and the processes in respect of the same.
- 4.84. Mr Canavan's submission stated that the note to MPs had been drafted "in such a way that its contents are suitable to fall into the public domain" [DHSC0004365_039]. I do not recall what precisely was meant by this, but the possibility of policy documents becoming available in the public domain was material in the Department of Health. Health matters hit the headlines and it was easy for the press to present issues to the public without being aware of the complex background and full extent of the issues involved. There was no desire to create additional difficulties when we wanted to settle this matter. A document being circulated to a large number of MPs would obviously enter the public domain.
- 4.85. Mr Canavan noted that the Department of Health had "not submitted a draft note earlier, as we wished to be sure that the new Secretary of State was taking the same line" [DHSC0004365_039]. I do not recall exactly what Mr Waldegrave's view was on the line that we should take at that time and how this compared to Mr Clarke's view.

The settlement proposals

4.86. On 9 November 1990, the Department of Health received a proposed scheme of compromise from the plaintiffs' counsel to settle the HIV litigation claims for about £42 million [DHSC0046962_067]; [DHSC0003653_117]. On the same date Mr Heppell wrote to Mr Waldegrave's Private Office in respect of the proposal [DHSC0046962_065]. Mr Heppell's short advice covered a note from

Mr Dobson of the same date [DHSC0046962_067]. Mr Heppell outlined the following initial assessment of the scheme of compromise:

"The proposals as they stand look on the high side especially as the plaintiffs' counsel are looking for high legal costs and disregard of all payments for social security purposes. But the most important missing link, as Mr Dobson says is the involvement of the plaintiffs themselves. We do not want to get down to discussion of detail until we can be confident the plaintiffs are ready to settle on something like the basis proposed. Otherwise we would be at clear risk of being bid up in a public auction."

- 4.87. Mr Heppell noted that full advice would follow as soon as possible. Neither Mr Dobson's minute nor Mr Heppell's appear to have been copied to my Private Office.
- 4.88. On 12 November 1990 Mr Canavan wrote to Mr Dobson and Mr Waldegrave's Private Office on this topic [DHSC0046962_028]. Mr Canavan set out "our considered assessment of those provisions which present difficulty" in the scheme of compromise. On its face, this minute appears not to have been copied to my Private Office at the time.
- 4.89. I do not recall how or precisely when it was brought to my attention that the Department of Health had received a proposed scheme of compromise from the plaintiffs' counsel. As I have set out above, from 9 November, the relevant minutes were going to the Secretary of State's Office directly and were not being copied to my Private Office. This is indicative of Mr Waldegrave, as the new Secretary of State, wanting to take the lead on the HIV litigation and dealing with this issue directly.
- 4.90. Through Ministerial meetings with Mr Waldegrave and the other Ministers and through our Private Offices, I am sure that I would have been kept broadly advised of developments, but it is impossible now for me accurately to comment upon the level of detail to which I was briefed. It is also unlikely that I was in

attendance at any meetings with legal counsel when advice was given concerning the proposed settlement as this was being dealt with at Secretary of State level.

- 4.91. I expect that I would have been aware that the headline figure now being put forward was £42 million. I do not recall what my initial views were at the time on the reasonableness of the proposed scheme or the figure of £42 million. Looking at it now, officials were cautioning that "[t]he proposals as they stand look on the high side" (Mr Heppell, 9 November [DHSC0046962_065]) but equally this was significantly lower than the figure of around £86 million that had been mentioned in November 1989.
- 4.92. The Inquiry asks what my understanding was at the time of the extent to which individual plaintiffs were aware of, and in support of, the proposed settlement. I do not think I would have known at the time to what extent individual plaintiffs knew of and supported the proposed heads of compromise which their own counsel had put forward. Looking now at the available documents:
 - (1) The proposal as received by the Department stated that it was "... made on the instructions of the Plaintiffs' Steering Group of solicitors but without the knowledge of the lay clients and their individual solicitors; accordingly it is subject to Counsel advising their clients and taking appropriate instructions from lay clients." [DHSC0003654_117]
 - (2) Mr Dobson, Mr Heppell and Mr Canavan all raised in the submissions to the Secretary of State, the importance of establishing whether the proposals would have the support of the overwhelming majority of plaintiffs.
- 4.93. The Inquiry has referred me to a press release by the Haemophilia Society dated 22 November 1990 which mentioned a new "ALL Party Group for Compensation for those with haemophilia who have been infected with HIV from contaminated blood products" consisting of "Twenty-eight MPs, drawn from every party" [HSOC0012354_002].

- 4.94. I do not recall whether I had dealings with the All Party Group for Compensation as a body or the impact the Group had on our approach to the litigation, however I knew some of the MPs involved, for example, Alf Morris, Patrick Cormack and Rosie Barnes, and I certainly valued their views. I received, considered and responded to correspondence and questions from members of the Group at various points. Some of my exchanges with Mr Cormack and Mr Morris are explored further in this statement below.
- 4.95. The Inquiry has referred me to the fact that, after the announcement of the agreement of settlement terms in principle in December 1990, representatives of the Department of Health (and the other Central Defendants in the litigation) negotiated with representatives of the plaintiffs about the terms of the final agreement in the months that followed.
- 4.96. As demonstrated by the detail outlined below, I had minimal direct involvement in these negotiations and had confidence in the team of officials and Ministers dealing with this matter. Correspondence was largely only copied to my Private Office so that I could keep up-to-date on the latest developments, but my direct involvement in any negotiations were not significant. This issue was largely handled at Secretary of State level and also sometimes involved No. 10 and other Cabinet Ministers.
- 4.97. In relation to the documents to which the Inquiry refers me on the negotiations, it is likely that I was provided with many of them at the time the negotiations were taking place. However, much of the correspondence on the negotiations was being copied to my Private Office on a for-information basis. In light of this, I am not aware of any matters on which I should have been provided with further documentation or information.
- 4.98. On 14 December 1990 Mr Heppell minuted the Secretary of State's Private Secretary "to keep you up with the state of play" [DHSC0003664_173]. On its face this update does not appear to have been copied to my Private Office.

- 4.99. The Inquiry has referred me to two contemporaneous newspaper articles: a Daily Mail article dated 8 April 1991 [DHSC0003661_066] and a Sunday Times article dated 14 April 1991 [DHSC0002433_108]. The Daily Mail article noted that "Solicitor Dennis Collins, of the steering group acting for hundreds of victims, blamed civil servants and Government lawyers for the delay" whilst The Sunday Times article had the headline, "Red tape holds up £42m Aids payout".
- 4.100. In relation to The Sunday Times article, a submission was sent to Mr Waldegrave's Private Office on 15 April 1991 by Mr Dobson [DHSC0020822_075]. My Private Office was copied in. Mr Dobson noted that Mr Waldegrave had requested a briefing on the article. Briefing supplied earlier that day to No. 10 was provided by Mr Dobson at Annex A of his submission [DHSC0041209_050]. The briefing highlighted to No. 10 that there was "Certainly no delay by civil servants or Government lawyers. This is a complex settlement and, understandably, both sides want to be satisfied that it is right before it can be concluded." The briefing note Mr Dobson sent to No. 10 and then subsequently to Mr Waldegrave gave a detailed explanation under the heading "background" as to why agreement had not yet been reached on the detailed terms of settlement with the plaintiffs' solicitors by this point in time:

"On 11 December 1990 the Government agreed in principle to proposals costing £42m put forward by the plaintiffs' lawyers. Since then the detailed terms of the settlement have been under discussion with the plaintiffs' lawyers. The main items have been the legal form of the settlement document, the deed for the new Macfarlane Trust which will make the payments, definitions of categories of plaintiff, the social security disregard, and questions whether allegations of a general nature can be used by the plaintiffs in medical negligence cases.

In the course of the discussions, Departmental lawyers have met members of the plaintiffs' steering committee of solicitors on at least 7 occasions, including appearances in court. There has been much written correspondence and numerous telephone calls. There has been Counsel to Counsel contact almost on a daily basis.

Particular problems arose over the social security disregard. Mr Waldegrave's statement on 11 December said that "payments from the [new] Macfarlane Trust will not affect entitlement to social security ... benefits". It was not made clear whether this disregard would apply only to the primary beneficiaries – as with payments under the existing Trust – or would extend further to other recipients, eg partners receiving the money by inheritance. In drafting the regulations to give effect to the disregard, DSS solicitors have offered two extensions:

- a complete disregard for money left by haemophiliacs to their partners and children
- a 2 year disregard for money received by parents for haemophiliac children who have died.

We believe this will be acceptable to the plaintiffs' solicitors.

Recently it became clear that plaintiffs (sic) solicitors had done little work in categorising their clients for payment purposes and marshalling the supporting evidence. (We are asking for the bare minimum to ensure that the right payments are made, eg to plaintiffs who are claiming to have a dependant partner.) The onus is on the plaintiffs' solicitors to bring this to a satisfactory state and payments can only be made after this work is complete. The plaintiffs' solicitors have known since December that this information would be required.

It is hoped that a Court hearing can be held on 1 May to finalise the settlement. We are cautiously optimistic that all the loose ends can be tied up by then."

4.101. Mr Dobson also noted to Mr Waldegrave that the remaining areas of disagreement with the plaintiffs' solicitors "over the social security disregards and categorisation appear to be on their way to resolution" and that the outstanding issues would hopefully be resolved before the next Court hearing scheduled for 1 May 1991.

- 4.102. Mr Dobson's submission also included an additional Q and A briefing at Annex B [p. 4 of DHSC0041209_050] and briefing notes on the two main allegations of delay in The Sunday Times article. In summary these were allegations of delay in respect of negotiations over: (i) the extent of social security disregards (see Annex C [p. 5 of DHSC0041209_050]); and (ii) what supporting evidence would be required to confirm the allocation of plaintiffs to the various payment categories (see Annex D [p. 6 of DHSC0041209_050]). As illustrated by Mr Dobson's briefing note, these were clearly complex issues that required careful consideration with the plaintiffs' solicitors.
- 4.103. Following this, on 17 April 1991 Mr Dobson provided draft letters to Mr Waldegrave's Private Office (copied to my Private Office) that could be sent to answer the allegations of delay in the Daily Mail and Sunday Times articles [DHSC0003662_109]; [DHSC0003662_110]; [DHSC0003662_111]. The sending of the letter at least to the Sunday Times must have been approved because the same day, 17 April, Mr Thompson, the Solicitor to the Department wrote to the Editor of The Sunday Times in accordance with the draft that had been prepared [DHSC0003661_008]. Mr Thompson refuted the allegations of undue delay and red tape as follows:

"From the moment that the settlement was announced, we have been under instructions to work out the details so that the payments can be made as quickly as possible. We are nearly there; but progress has been slowed by the need to reach agreement in two particular areas, one concerning social security and the other the application of the terms of settlement to individual claims.

On the social security point, the settlement was drawn up to honour Ministers' commitment that payments would be ignored in determining the entitlement to social security of those infected by the virus and, further, that dependents to whom the money passed on succession would not have to bring it into account either. The Department has never

sought to resile from this. It was, however, suggested on behalf of certain plaintiffs that the exemption for dependants should be extended to non-dependent parents as well. An extension has now been agreed.

As for the application of the settlement to individual cases, the purpose is to establish how much each claimant would be entitled to be paid so that they can make an informed decision whether or not to accept. This is a necessary step in any settlement but it has taken longer than usual in the present case because of the unusually large number and variety of claims. Incidentally, government lawyers have <u>not</u> been insisting on the production of birth and marriage certificates in every case, as suggested in the article, but only the minimum evidence needed for the evaluation of the claim. Happily this work is now almost completed; payment may be expected to follow shortly."

- 4.104. Progress was not immediate. There were reasons for this. We wanted to resolve the areas of difficulty at the earliest opportunity. These were complex issues, and we did not want ill-thought-out solutions to create more difficulties down the line. For example, Mr Dobson's submission of 15 April 1991 outlined "loose ends" that needed to be tied up in relation to the social security disregard and carving out matters for the plaintiffs who wished to continue with their clinical negligence actions [DHSC0020822_075]. Further details of the complexities of the settlement that took some time to resolve are outlined in Mr Thompson's letter to The Sunday Times which I have set out above. The Government's position on allegations of delay was also outlined in a "Best Points" brief provided by Mr Burrage to No. 10 on 23 April 1991 [DHSC0003560_048].
- 4.105. On 19 April 1991, Mr Dobson provided a submission to Mr Waldegrave's Private Office², copied to my Private Office [DHSC0003662_089]; [DHSC0003662_090]. The submission included a note at Annex A entitled

² This appears to have been an updated version of a submission sent the day before 18 April 1991 [DHSC0003662_124] but which the Secretary of State had not yet considered.

"Main Issues Outstanding on the Settlement" [DHSC0003662_091] and a draft letter to the plaintiffs' solicitors at Annex B [DHSC0003662_106]. The submission invited Mr Waldegrave:

- "i. to make a final offer to the solicitors for the plaintiffs in the HIV/haemophiliac litigation
- ii. to make payments to <u>individual</u> plaintiffs on receipt of a letter of discontinuation, rather than wait until a preset number of such acceptances have been received."
- 4.106. Mr Dobson indicated that negotiations with the plaintiffs' solicitors had "...reached the point at which, in our judgment and that of the majority of the plaintiffs' solicitors no further worthwhile progress is likely" and that a "minority faction among the plaintiffs' solicitors, led by the Mersey firm of J Keith Park, were until very recently attempting to prolong the negotiations in the hope of securing further concessions, but the latest indications are that they too will now recommend their clients to settle".
- 4.107. Setting out the advice of the officials Mr Dobson said that,
 - "...the time has come to call an end to the negotiations and that a final offer should be made. Once payments have begun for the great majority of plaintiffs, we believe that there will be great pressure on any remaining waverers among the provincial solicitors to fall into line".

Mr Dobson urged against the offer letter being contingent on a certain threshold of plaintiffs accepting the settlement and advocated for the Government to make payments to individual plaintiffs on receipt of a letter of discontinuation accepting the terms of settlement. I presume this was to allow payments to be made to those affected as quickly as possible. Mr Dobson's advice was that to do otherwise would be seen as grudging and would seriously delay making any payments.

- 4.108. Mr Dobson's covering minute requested that Mr Waldegrave consider the submission in conjunction with a submission from Mr Kendall on the source of the funding of the settlement, which was sent to Mr Waldegrave's Private Office on the same date [DHSC0003662_101]. Mr Kendall's submission was not copied to my Private Office. While I may well have been kept aware of the thrust of negotiations with the Treasury, Mr Waldegrave was leading on that and dealing with the Treasury on it in correspondence.
- 4.109. On 22 April 1991, a minute was sent from Mr Waldegrave's Private Office responding to Mr Dobson [DHSC0003662_080]. The minute noted that Mr Waldegrave was content "to convey the Government's final offer as soon as possible to the Plaintiff's solicitors; and for payments to be made on receipt of a letter of discontinuation". This minute was copied to my Private Office. Mr Waldegrave also asked for a detailed note on the position of those infected who were not haemophiliacs.
- 4.110. On 30 April 1991 I sent a letter to Patrick Cormack MP [DHSC0003399_001]. This was in response to his letter of 16 April 1991 [DHSC0014965_151] concerning a letter he had received from a constituent [WITN5289007]. In relation to the allegations of delay, I noted that "[t]his is a complex settlement and understandably, both sides want to be satisfied that it is right before it can be concluded". I pointed out that the outstanding points in the negotiations with the plaintiffs' lawyers had "now been largely resolved" and that I was "keen to see the settlement concluded as soon as possible and given the goodwill that exists on both sides, I am sure that the payments can begin very shortly."
- 4.111. On 1 May 1991, Mr Mellor confirmed to Mr Waldegrave that £47 million (£42 million of additional funding for the Macfarlane Trust and £5 million towards the plaintiffs' legal costs) could be funded by giving access to the Treasury Reserve [DHSC0003100_001]. This letter from Mr Mellor was copied to my Private Office and that of the other Ministers once received in the Department.
- 4.112. In light of this confirmation from the Chief Secretary to the Treasury, Mr Dobson sent a submission to Mr Waldegrave on the same date [DHSC0003398 026].

Mr Dobson's submission was not copied to my Private Office but it confirmed that a settlement offer would be made to the plaintiffs' solicitors on the same day. Subsequently on 1 May 1991, Mr Powell from the Solicitor's Office wrote to the solicitors for the plaintiffs attaching the proposed terms of settlement [HSOC0023174].

4.113. On 3 May 1991 Mr Waldegrave responded to a Written Question from John Marshall MP [WITN5289008]. Mr Waldegrave stated:

"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."

4.114. On 10 June 1991, following a Court hearing on the claim, Mr Waldegrave confirmed by way of a written answer in the Commons, "... 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". He stated that the payment amounts were those put forward by the steering committee of solicitors representing the HIV infected haemophiliacs and their counsel and agreed by the Government. Mr Waldegrave stated that,

"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 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." [DHSC0002451 011]

- 4.115. As illustrated by the chronology of the settlement negotiations from the documents available to me outlined above, the issues of the settlement were complex and required time to consider internally, with the plaintiffs' solicitors and to resolve. The reasons why it took from December 1990 to May 1991 to arrive at an agreement of the terms of settlement is evident from these documents.
- 4.116. From these documents and from my recollection, I consider that the government generally did all we could in the period of time to arrive at an agreement on these complex terms of settlement with the plaintiffs. I do not have any further comments on the settlement negotiations that I consider to be relevant to the Inquiry's Terms of Reference.
- 4.117. The Inquiry has referred me to paragraph 5(2) of the settlement terms, the effect of which was to prevent fresh claims in respect of Hepatitis infection caused by the past administration of the relevant blood products, and not just prevent fresh claims in respect of HIV infection [HSOC0023174]. A similar undertaking was required before payments were to be made from the Macfarlane (Special Payments) (No. 2) Trust [MACF0000086_225].
- 4.118. I do not recall being aware of this as an issue. The documents do not suggest that it was raised with me for consideration, still less that it was flagged as an area of significance or concern.

HIV transfusion settlement

- 4.119. I have been referred to a number of documents by the Inquiry in relation to questions from MPs from January 1990 onwards concerning the issue of financial help for non-haemophiliacs who developed AIDS as a result of whole blood transfusions which were HIV infected.
- 4.120. On 18 January 1990 Alfred Morris MP asked the following question:

"To ask the Secretary of State for Health if he will set out in the Official Report the terms in which his Chief Medical Officer stated recently that the outcome for HIV carriers is likely to be the same irrespective of cause; and what consideration he has given to its relevance to the claim for financial help for people who acquired the virus from blood transfusions equal to that given to people with haemophilia who contracted the virus after the injection of contaminated blood products under the National Health Service." [MACK0000068_001]

4.121. Whilst recognising that there was no known difference in the number of people developing AIDS when comparing the different routes of transmission of the virus, I provided the following Written Answer:

"The ex-gratia payments given to provide help for haemophiliacs with HIV and their families recognised their wholly exceptional circumstances. Haemophiliacs were already suffering from a disability which affected their employment prospects, insurance and mortgage status. Also the hereditary nature of haemophilia means that more than one member of the family may be infected with HIV."

4.122. I provided Written Answers to further questions from Mr Morris on 6 February 1990 [DHSC0003328_001] and 13 February 1990 [DHSC0002840_010]. These outlined the same point as made previously to Mr Morris: that haemophiliacs had been particularly disadvantaged, living with haemophilia and having been infected with HIV.

- 4.123. I was asked a further question, and provided a further Written Answer, about financial help for individuals who contracted AIDS as a result of blood transfusions infected with HIV by David Alton MP on 2 March 1990 [DHSC0002840_005].
- 4.124. Also on 2 March 1990, Mr Canavan sent a submission to my Private Secretary [DHSC0002849 004]. Mr Canavan noted that I had requested information on: (i) compensation schemes in other countries for individuals infected with HIV having received a blood transfusion; and (ii) diseases also transmitted through transfusion where special payments were not awarded. In respect of (i), Mr Canavan provided information on the Canadian (which definitely extended to blood transfusion recipients) and Australian arrangements (which seemed to cover transfusion recipients). He added that "It lie information we have on the other countries only mentions haemophiliacs but this does not necessarily mean that blood transfusion recipients are not covered. We have asked the FCO to obtain better information as quickly as possible". In respect of (ii) Mr Canavan set out other diseases transmitted by blood transfusions for which special payments were not made, including Non A, Non B Hepatitis. On 8 March 1990, my Assistant Private Secretary responded to Mr Canavan [DHSC0038699 132]. This minute noted that I "... would be most interested to know of the position of French, West German, Norwegian, Belgian, Dutch, Irish and American people with HIV infection as a result of blood transfusion".
- 4.125. On 28 March 1990, Mr Canavan provided an updating summary in respect of responses received so far on financial assistance schemes in other countries; some responses were still awaited [DHSC0002848_005]; [DHSC0046951_068]. My Private Office was sent a further update on 5 April 1990 [DHSC0046951_064] [DHSC0046951_065].
- 4.126. I requested this information at the time because I generally wanted to review wider evidence before making decisions as Minister of State. I wanted any scheme that we adopted to be informed by the experience in other countries. I have no specific recollection of whether consideration was being given at this time to making financial payments to non-haemophiliac recipients of HIV

infected blood in March 1990. My request for further information probably reflected that there had been increasing attention being drawn to the transfusion cases and I wanted to know how other countries had responded. In general terms, I think the information provided concerning arrangements made in other countries did have some influence on the Government's decision-making but it was only one factor.

- 4.127. I was also engaged in correspondence with MPs who had written to me on the same topic. Examples are my letter to Sir Peter Emery MP dated 6 April 1990 [DHSC0002859_002] and my somewhat later letter to Samuel Galbraith MP dated 19 February 1991 [DHSC0014966_144].
- 4.128. My letters to both Sir Peter and Mr Galbraith made clear that I had (and have) the greatest sympathy for those infected with HIV through blood transfusions, but we argued that the situation for haemophiliacs was unique. I averred to the problem of setting a wider precedent in my letter to Sir Peter [DHSC0002859_002] as follows:

"More widely, it would be difficult to maintain a distinction between blood transfusion cases and the recipients of skin grafts or organ transplants who have been infected with HIV, people with other transfusion transmitted diseases or people who have suffered catastrophic side effects of other medical treatment.

We have never had a general system of no fault compensation for medical accidents in this country. The Pearson Commission carefully considered the matter in 1978 but came down against changing our system for seeking compensation through litigation in the Courts. There have been no substantial changes in the basic arguments since then. No fault schemes can be costly and while they remove the perceived unfairness between those who can prove negligence and those who cannot, they create unfairness between those disabled as a result of medical accident and those who are equally disabled through natural

causes. No fault compensation also removes an incentive for doctors to maintain standards of practice."

- 4.129. The Inquiry asks what I knew before these questions and correspondence about the position of non-haemophiliacs who developed AIDS as a result of HIV-infected blood transfusions. As mentioned above, on 29 November 1989 (very soon after taking up the post of Minister of State for Health) I answered a written PQ from Sir Russell Johnston MP on this topic [DHSC0038657_149]. The further correspondence and questions from MPs would have emphasised the issue but I was certainly already aware of it. As I have mentioned, both my GRO-C and I had benefitted from blood transfusions, something I inevitably thought about when considering those who had been infected via this route.
- 4.130. In relation to why non-haemophiliacs infected with HIV via treatment by the NHS were not financially assisted in the same way, and at the same time, as people with haemophilia, the reasons are apparent from my correspondence with and responses to MPs. The central concern was that providing payments to non-haemophiliacs who developed AIDS as a result of HIV infected blood transfusions would be moving closer to a scheme of no fault compensation. Moves towards no fault compensation had been raised in the National Health Service (Compensation) Bill, put forward by Harriet Harman MP and then taken up by Rosie Barnes MP. That Bill had sought to provide compensation for injuries suffered during NHS treatment without needing to show negligence on the part of the Health Service. On 14 December 1990, Mr Chinque had sent a briefing to Mr Waldegrave's Private Office on this Bill, which was copied to my Private Office [WITN5288018]. Mr Waldegrave's memorandum of 12 December 1990 for the Cabinet Home and Social Affairs Committee, included within this briefing pack, highlighted the broader difficulties the Government had with any scheme of no fault compensation at the time and its reasons for opposing no fault compensation. We saw, understood and genuinely sympathised with the argument that those infected through blood transfusions should be treated the same as haemophiliacs infected through blood products. But at this stage, our judgement was that those arguments were outweighed by

the need to protect against falling into a no-fault compensation system to which the Government was firmly opposed.

- 4.131. On 20 January 1991 I answered an oral PQ from Gavin Strang MP (PQ 747). The briefing papers for Mr Strang's PQ outlined the Government's position on any no fault compensation for medical accidents at the time namely, "...that a scheme of no fault compensation for medical accidents would be unfair, impractical and costly". Moreover the Government's position against no-fault compensation had recently been accepted by Parliament in a free vote [DHSC0006901_069]. On the question of whether the payments awarded to haemophiliacs had set any precedent for those infected with HIV during NHS treatment, the briefing note gave the suggested line that:
 - "* The haemophiliacs are widely accepted as a special case. We acted accordingly.
 - * [IF PRESSED we have not been convinced that the blood transfusion cases are a special case (but we would consider any new arguments).]"
- 4.132. On 23 April 1991, I have seen from the available documents that Mr Dobson provided a brief submission to Mr Waldegrave on HIV infected blood transfusion recipients [DHSC0003560_051]. This would appear to have been in response to the request from Mr Waldegrave made the previous day when he approved the making of the final litigation settlement offer (see paragraph 4.109, above). Mr Dobson provided information on the costs of extending the ex gratia payment scheme to transfusion patients which he said would not be trivial ("probably some £3-5 million depending on assumptions"). However, he emphasised that:

"But the real difficulty over granting a concession would be to re-establish a credible "ring-fence" to prevent any further movement towards a general system of no-fault compensation. 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 <u>any</u> logical distinction between the HIV-infected blood transfusion cases and other victims of medical accidents. If ministers wish to reconsider the case for some general system of no-fault compensation that is another matter, but in my view the worst of all possible worlds would be to slide into no-fault compensation through a series of reluctant concessions to well-orchestrated campaigns."

4.133. On its face, Mr Dobson's submission does not appear to have been copied to my Private Office. However, Mr Waldegrave's response of 25 April was copied to my Private Office [DHSC0002433_058]. This stated:

"The Secretary of State has seen your submission of 23 April and agrees that we need to hold the line on these cases. He has added that we must emphasise the more complex history of what caused these tragic cases and say that the NHS cannot be pushed into taking general responsibility for cases like this."

- 4.134. On 11 May 1991, an article was published in *The Times* reporting that some individuals that had contracted HIV through blood transfusions had started claims for compensation against the Government [DHSC0006473_028].
- 4.135. The Inquiry refers me to a Scottish Office submission dated 29 April 1991 from Mr Tucker to the Secretary of State for Scotland Ian Lang.³ [SCGV0000233_124]. This concerned correspondence from J&A Hastie Solicitors in Scotland on behalf of Scottish transfusion-infected patients. While I would not have seen this submission at the time, I note the comments that Mr Tucker made disagreeing with aspects of the arguments put forward by the Department of Health. On causation in blood transfusion cases, he suggested

³ The rule 9 request suggested that this was a submission to Mr Waldegrave copied to my Private Office but it was in fact a Scottish Office submission.

"in relation to the matter of causation, while it is the case that if any claim were to come to Court it would be for the pursuer to establish a cause or link between transfusion and infection, the difficulties for the pursuer in proving the cause or link would largely be occasioned by the reluctance of Government to allow the pursuer access to blood transfusion records. Without access to those records the pursuer could not identify the donor of the transfused blood."

One of the issues raised in the Scottish Office submission was whether DH or the Scottish Office should lead on the response to this correspondence. In the event, I can see that I replied to the correspondence from this firm on 20 May 1991 [DHSC0014965_077].

4.136. I have been asked by the Inquiry whether I believed there was any merit in the argument that the Government's desire to restrict disclosure of blood donor records would hinder the ability of transfusion patients to pursue litigation, and that there was therefore an argument in support of helping those affected in another manner. I do not recall whether I formed a view on this at the time. From review of the available papers rather than from any current recollection, I note that the Department did not consider that this would create the suggested hindrance. When this same point was raised later by Mr Ross, the reply from Mr Dobson (see paragraph 4.145 below) included the following explanation:

"We do not believe that the Scottish precedent which you cite, which we are advised was intended to protect the anonymity of an individual donor, would prevent a claim of negligence against a health authority (e.g. for failing to operate adequate systems to screen out at risk donors in the light of medical knowledge available at the material time). Indeed the grounds of such a claim would be very similar to those in the haemophiliac litigation.

We accept your point that as a matter of public policy it would be undesirable for individual donors to be sued for any resulting accident (this would have applied in the haemophilic litigation also); but I am afraid

we do not accept your conclusion that this significantly reduces the remedy available to blood-transfusion recipients." [DHSC0002938 014]

- 4.137. On 13 May 1991, Mr Canavan sent a submission to my Private Office attaching "a line to take and background note on HIV infected blood transfusion recipients, following the Sunday Observer and Times articles over the weekend" on 11 and 12 May 1991 [DHSC0002434_108] [PRSE0004551] [MDIA0000062].
- 4.138. On 16 May 1991 Graham Ross of J. Keith Park & Co. Solicitors, representing some of the blood transfusion patients infected with HIV, wrote to Mr Waldegrave [SCGV0000237_173]. Mr Ross requested that the Government extend the payments being made to haemophiliacs to individuals infected with HIV through blood transfusions. Mr Ross noted that his letter had been copied to the press and to interested MPs.
- 4.139. The Inquiry refers me to a submission with draft minute dated 20 May 1991 from Mr C Kendall to my Private Office [WITN5289009] [DHSC0003355 008]. This concerned the need to lay a minute before Parliament because the settlement for HIV-infected haemophiliacs involved a commitment to make future payments (to any further haemophiliacs who may come forward) which was in theory unlimited. Such commitments by convention had to be drawn to Parliament's attention. On 22 May 1991, my Private Office minuted the Secretary of State's Private Office noting that I wanted the submission drawn to Mr Waldegrave's attention and that I feared, "...that there will be a row about transfusion cases" [DHSC0003663_014]. Looking at this now, I expect that I fully understood that there was no alternative to laying the minute before Parliament, but I would have been concerned to alert the Secretary of State to the issue because emphasising the theoretically uncapped nature of the financial support granted to haemophiliacs infected with HIV was likely to fuel the case being made by the transfusion victims. My assistant private secretary Mr Jex took this up with the Secretary of State's Private Office and reported back to Mr Kendall on 27 June 1991, that:

"Secretary of State sees this as a matter of Parliamentary procedure which needs to be done and is, therefore, content for the minute (as drafted) to be laid, though with careful attention to the timing to avoid it clashing with any other announcement of interest to the Lobby supporting the extension of compensation to the non-haemophiliacs." [DHSC0006927 065].

- 4.140. On 26 May 1991, The Observer published an article noting that political pressure was growing to compensate those infected with HIV through blood transfusions [HSOC0001454].
- 4.141. The Inquiry refers to a letter from Mr Waldegrave, also on 28 May 1991, written to Miss S Edwards [DHSC0002863_005]. That letter set out our reasons for not extending the payment scheme to those infected through blood transfusions.
- 4.142. On 6 June 1991 I replied to Mr Ross' letter of 16 May [DHSC0002879_002]. I set out that,

"...the Government does not accept that those infected with HIV as a result of blood transfusion have a stronger claim for compensation than other patients who may have been injured as the unfortunate result of medical accidents or as an unintended side effect of medical treatment."

I referred to the exceptional circumstances experienced by haemophiliacs and a rejection of any move towards any scheme of no fault compensation. The Inquiry has specifically asked whether this letter was one which Mr Waldegrave had seen and approved. The draft response to Mr Ross had been sent to my Private Office on 5 June 1991 [DHSC0003642_037]. It does not appear that this draft was sent to Mr Waldegrave's Private Office, but it had been cleared with Mr Dobson. It would not be necessary to clear a letter like this with the Secretary of State when it was continuing an existing Government position.

- 4.143. I received a further letter from Mr Ross dated 7 June 1991 [DHSC0002878_010]. It outlined that "the transfusion victims clearly have a stronger claim than the general run of patients suffering from medical accidents for precisely the same reasons as did the haemophiliacs, and indeed the very decision of Government to compensate the latter adds to the strength of the claim of the former". Mr Ross sent a further letter to me dated 13 June 1991 [DHSC0002875_003]. In this letter Mr Ross put forward further arguments in support of payments to those infected with HIV from blood transfusions.
- 4.144. On 18 June 1991, Mr Waldegrave confirmed in answer to a written PQ from Sir David Steel, that the Government had no plans to extend the special financial help available for haemophiliacs to those infected through NHS blood transfusions [HSOC0001432].
- 4.145. On 21 June 1991, my Private Office minuted Mr Dorrell's Private Office asking if he would take on the further correspondence with Mr Ross given that Mr Dorrell had responsibility for complaints [DHSC0002938_015]. I do not know whether this was at my personal suggestion or that of my Private Office that the correspondence be re-assigned in this fashion. Either way, it reflects that the correspondence had reached the stage where Mr Ross perfectly legitimately had put forward views on behalf of his clients and the Government, through me, had responded with our policy position; but Mr Ross remained unhappy at the policy we were adopting.
- 4.146. Mr Dobson responded to Mr Ross' letters on 26 June 1991 [DHSC0002938_014]. Mr Dobson reiterated the reasons for not financially assisting those infected with HIV via blood transfusions in the same way as haemophiliacs already highlighted in this statement namely setting a precedent in respect of any scheme of no-fault compensation and the exceptional circumstances of haemophiliacs infected with HIV. Mr Ross sent further letters to Mr Dobson on this matter dated 27 June 1991 [DHSC0003641_010] and 24 July 1991 [DHSC0003641_011].

- 4.147. MPs understandably continued to be concerned about this topic. I was receiving and responding to further correspondence from MPs at this time (see for example my letter to Anthony Coombs MP dated 24 June 1991) [DHSC0002893_006].
- 4.148. The Inquiry asks whether my responses to solicitors and MPs reflected my personal views on whether financial assistance ought to be provided to those infected with HIV through blood transfusions and if my views changed over time. As Minister of State for Health I always wanted to make progress, but the constraints of departmental resources meant that this was not always possible. It would have been inhumane not to want to go further and faster for those infected with HIV via NHS blood transfusions if resources were infinite or readily available and could be diverted from pressing needs, including life-saving initiatives. However, this was not the case, and we did not want to end up with a situation where we were making ex-gratia payments in all cases of NHS treatment causing injury or disease where there was no finding of medical fault. That was the precipitous slope down which none of us wished to fall for fear of opening up massive liability that the Government could simply not afford to pay. We were certainly not blind to the arguments that HIV infected transfusion patients were in many ways analogous to the HIV infected haemophiliacs and the campaigns in newspapers and elsewhere were effective in pressing those arguments on the Government. We had sought to ring-fence the earlier decision to make ex gratia payments to the infected haemophiliacs because of these concerns about the wider potential massive liability.
- 4.149. On 2 December 1991, Mr Waldegrave wrote to David Mellor, Chief Secretary to the Treasury, regarding those infected with HIV through blood transfusions [DHSC0002921_009]. He noted that they had spoken after Cabinet the previous Thursday. Mr Waldegrave said that he had looked very carefully at the issue and that his conclusion was that "... we 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". Mr Waldegrave indicated that this could be achieved by: (i) awarding the same financial payment given

to haemophiliacs following the HIV litigation; and also potentially (ii) giving the same financial assistance provided to haemophiliacs earlier.

4.150. Mr Waldegrave envisaged that the financial assistance scheme would be funded as follows:

"As to the financing of this, I have already topped up the haemophiliacs money by £3 million because numbers and costs were higher than expected. Nevertheless, I am prepared to pay a third of the £12m costs. I hope that the other Health Departments will be able to make a contribution in respect of cases arising in their countries and that it will be possible for the treasury to meet the balance from the Reserve."

- 4.151. The Inquiry refers me to a number of related documents on this development.
- 4.152. A draft of the letter Mr Waldegrave sent to Mr Mellor was copied to my Private Office (see submissions from Mr Heppell dated 28 November 1991 [DHSC0002894_011] and 29 November 1991) [DHSC0002537_262].
- 4.153. Mr Heppell's submission of 29 November 1991 noted that:
 - "2. Secretary of State will want to reflect on the financial and policy aspects of the letter before he writes.
 - 3. On <u>finances</u>, 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, the 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." (original emphasis).

4.154. On 2 December 1991, Sir Christopher France, Permanent Secretary, sent a minute to Mr Waldegrave's Private Office, to which my Private Office was copied [DHSC0002931_005]. Sir Christopher expressed a similar view to that of Mr Heppell as follows:

"The ringfence around the haemophiliacs is bound to be attacked, but we are unlikely ever to find a better one if we abandon it. The haemophiliacs were doubly disadvantaged by their existing, hereditary disease which already affected their position on employment, insurance and the like. They can be separated from other victims of medical accidents, but the next defensible boundary is not easy to see. I advise long reflection before we move further in to no-fault compensation for medical accidents."

- 4.155. On 4 December 1991, the Parliamentary Branch provided Ministers with updated list of proposed for the Early Day Motion (249) which had been tabled on 25 November and which proposed that financial assistance should be extended to non-haemophiliacs infected with HIV by NHS blood/tissue transfers [DHSC0003577_061].
- 4.156. On 5 December 1991, Mr Waldegrave asked for ministers' views including mine on the Permanent Secretary's minute [DHSC0002537_063].
- 4.157. Baroness Hooper conveyed her response the same day:

"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." [DHSC0002537_062].

- 4.158. On 10 December 1991, my Assistant Private Secretary responded to Mr Waldegrave with my own views [DHSC0002938_004]. This minute noted that I had "always been cautious in this area for the reasons outlined in Permanent Secretary's minute of 2 December. However, given the current circumstances she [I] supports moves seeking a further extension". Although I respected the advice of the Permanent Secretary and Mr Heppell, I also respected the fact that the Secretary of State wanted to go further. I certainly shared the concerns that officials put forward at the time.
- 4.159. On 11 December 1991, Stephen Dorrell's Private Office, sent conveyed Mr Dorrell's view that:

"Without enthusiasm I am in favour of extending the concession to Blood Transfusion etc., victims. The initial concession was a political fix - this would simply redefine what essentially the same fix is."

[DHSC0002537_242]

4.160. On 12 December 1991, Sir Michael McNair-Wilson MP spoke in the motion for the Christmas Adjournment debate arguing the case for compensating nonhaemophiliacs infected with HIV through blood transfusions [DHSC0002436_071]. The response of the Leader of the House (John MacGregor) was that

> "My hon. Friend the Member for Newbury (Sir M. McNair-Wilson) made a most moving speech. We understand not only his tremendous interest in such matters but his outstanding concern. His point has been substantially considered already and raised on many occasions in the House. I have great sympathy with the plight of those who have been infected with HIV as a result of blood transfusion."

The Hansard extract was copied to my Private Office on 13 December 1991 [DHSC0002436 070].

4.161. On 20 December 1991, the topic was again raised in the House of Commons by Gavin Strang MP in an adjournment debate [DHSC0002932_010]. I responded in the House on behalf of the Government. I concluded noting that:

"In short, we share the great sympathy that the hon. Gentleman feels for this particular group of patients. We are committed to developing first-rate, effective and supportive services for the treatment and care of those with HIV and AIDS. The Government have not been persuaded, however, that blood transfusion and tissue recipients constitute a special case. We shall, of course, consider carefully the views which have been expressed by the hon. Gentleman. We have great sympathy for these tragic cases and for their families."

- 4.162. On 13 January 1992, Mr Mellor responded to Mr Waldegrave's letter of 2 December 1991 [HMTR0000003_051]. Mr Mellor said he understood why we wanted to provide compensation to blood transfusion patients with HIV and sympathised. But he expressed serious reservations about whether it would be possible realistically to ring fence any compensation awarded to recipients of HIV infected blood from blood transfusions from other cases of non-negligent treatment. He warned of the risk that this would be taking a further long stride towards no fault compensation. Mr Mellor also noted that there was no room for manoeuvre in relation to additional access to the Reserve. Mr Mellor added that I had "...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." He raised a separate point about overpayments to doctors and dentists and said that this left him no room to help DH or the other Health Departments on accessing the Treasury Reserve.
- 4.163. As to how I felt about how any concession should be approached and if I was consulted on this, I would not have expected to have been consulted on the

approach and framing of any concession made as this was a matter for options and advice on choices by officials. In the adjournment debate on 20 December 1991, I was simply presenting the carefully considered Government policy at that time (on this date, I would of course have known that Mr Waldegrave had approached the Treasury but without the Treasury response, we were bound to hold this line for the time being). It is always easy, and indeed it is common, to make a popular concession, so I did not consider the difficulties presented by Mr Mellor too much of a barrier if this were the path the Government chose to go down. At the end of my speech in the debate, I noted that the Government would consider carefully the views put forward by Mr Strang.

- 4.164. On 17 January 1992, Mr Kendall sent a submission to Mr Waldegrave's Private Office, copied to my Private Office [DHSC0002929_007]. Mr Kendall outlined options for the funding of payments to blood/tissue recipients who had contracted HIV.
- 4.165. On 27 January 1992, Mr Waldegrave replied to Mr Mellor [DHSC0002925_009] and this was copied to me and the other Health Ministers. Mr Waldegrave took issue with the Treasury's attempt to link the doctor and dentist overpayments to funding payments those infected with HIV through blood transfusions. Having addressed the overpayments issue he said:

I hope you can accept that this linkage should not be made. For my part, I recognise the difficulty in providing resources from the Reserve which your officials have explained to mine. I will investigate what scope there may be for longer term action on the blood transfusion patients.

[Manuscript addition]

- Though I remain firmly of the opinion that the provision of £6m from the reserve to match £6m which I believe I can find (just) from existing provision – remains politically and morally the correct course".
- 4.166. On 6 February 1992, Mr Scofield sent a submission to Mr Waldegrave's Private Office, copied to my Private Office [DHSC0002585_017]. The submission attached a progress report on the latest position on payments to recipients of

HIV infected blood by blood transfusion, including the negotiations with the Treasury. Mr Scofield indicated that he understood that Mr Waldegrave was "... minded to send a robust personal note to the Prime Minister seeking his intervention with the Treasury to enable a settlement to be reached."

- 4.167. The Inquiry asks if I had discussions with Mr Waldegrave about the change in Government policy and if it surprised me. Now many years after the events, I am unsure whether Mr Waldegrave discussed his intention with me in advance; he may well have done.
- 4.168. The Inquiry has asked me who or what was the source of this initiative. Mr Waldegrave's letter to Mr Mellor records that the Ministers had discussed the matter after the meeting of the Cabinet on 28 November 1991 [DHSC0002921_009]. From the available documents and to best of my recollection, I think it was Mr Waldegrave's initiative to speak to the Treasury. I would have been supportive of his aspirations to do more for this group.
- 4.169. The Inquiry has asked why and when I changed my "mind about the efficacy of the transfused patients' campaign". I do not think it was a question of changing my mind about the efficacy of the campaign. My minute to Mr Waldegrave of 10 December 1991, explained why I had previously been cautious about extending the payment scheme which was for the reasons which the Permanent Secretary had recently re-emphasised. Despite our efforts to hold to, and explain the ring fence, there was unrelenting pressure in Parliament and the media on this issue. I understood the reasons why Mr Waldegrave pushed for this change in policy and the plight of those affected, to whom we had genuinely always been sympathetic. This is why I was supportive of his stance.
- 4.170. I do not think that I was involved in the negotiations taking place between Mr Waldegrave and the Treasury concerning the funding of the scheme. Mr Waldegrave was leading on this. It is likely that I was kept broadly informed in our Ministers' meetings and discussions. As I have noted, Mr Waldegrave's letter of 27 January 1992 was copied to all the other Health Ministers including

- me and that was also the case for Mr Mellor's subsequent reply of 7 February 1992 [CABO000044_024].
- 4.171. The announcement of the extension of payments to those infected with HIV as a result of NHS blood transfusion or tissue transfer was made by Mr Waldegrave in his answer to a PQ from Sir Michael McNair-Wilson on 17 February 1992 [DHSC0003625_043].
- 4.172. On 20 February 1992, Mr Scofield sent a submission to Mr Waldegrave's Private Office, copied to my Private Office [NHBT0015117_001]; [DHSC0002642_004]. Mr Scofield sought Mr Waldegrave's agreement to the outline of the financial payments scheme for those infected with HIV through blood transfusion and tissue transfer, "[n]ow that financial help for the blood transfusion and tissue recipients infected with HIV has been announced".
- 4.173. On 2 March 1992, Mr Waldegrave's Private Office responded to Mr Scofield [DHSC0002653_004]. This minute was copied to my Private Office. Mr Waldegrave's Private Office conveyed that the Secretary of State was content to proceed with the scheme as outlined in Mr Scofield's submission [DHSC0002653_004].
- 4.174. The available documents do not indicate that I was consulted directly by Mr Scofield on the details of the scheme, nor would I have expected to be since this was not a policy that I had developed. Mr Scofield's submission dated 20 February 1992 was copied to my Private Office. If I had any comments I could have interjected at this stage. This policy was being led at Secretary of State level and I did not have any comments on Mr Scofield's proposals.
- 4.175. The available documents also do not suggest that I had further discussions with the Secretary of State concerning the proposals contained in Mr Scofield's submission and I did not have particular reservations about them at the time. I respected Mr Waldegrave's aspiration to go further for those infected with HIV through blood transfusion and tissue transplants.

- 4.176. I did not have involvement in working out the details of the scheme. I do not think I can therefore comment meaningfully on the Inquiry's question as to whether there were matters not brought sufficiently to my attention on the scheme which in hindsight should have been as I was not involved in considering the mechanics of the scheme at the time.
- 4.177. The Inquiry draws my attention to the fact that Paragraph 5.2 of the Annex to Mr Scofield's submission referred to the requirement that anyone accepting a payment under the scheme would "be required to give an undertaking not to pursue legal action against Government or the Health Authorities over matters of policy or broad operational concerns" [DHSC0002642_004]. I was not involved in discussions at the time in respect of the possible reasons for this undertaking or the terms or breadth of it.
- 4.178. Paragraph 4 of Mr Scofield's submission acknowledged that it may be "necessary to include those non-haemophiliacs infected with HIV through treatment with fractionated blood products, e.g. Factor 8 administered as a coagulant to help stop bleeding during surgery" [NHBT0015117_001]. I cannot say whether I was aware of this group previously. On the face of Mr Scofield's submission, the one case in Northern Ireland, had only recently come to light so this may not previously have been drawn to my attention.
- 4.179. On 11 March 1992, a General Election was called, which took place on 9 April 1992.
- 4.180. I do not recall having further involvement in the establishment of the blood transfusion and tissue transfer scheme prior to the General Election and 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, although there is always a general desire to settle policies prior to elections.

- 4.181. On 10 April 1992 I was appointed as Secretary of State for Health. The Inquiry asks what further steps I took to establish the scheme⁴.
- 4.182. On 13 April 1992, Mr Scofield sent me a submission seeking my approval for officials to implement the scheme along with a copy of the scheme as Annex A [SCGV0000238_025] [NHBT0015113_001]. At paragraph 3 of his submission, Mr Scofield noted that Mr Waldegrave had agreed the main principles of the scheme in response to the earlier submission of 20 February 1992 and that the form of the scheme now proposed did not depart from those principles. Mr Scofield also set out (at paragraph 4 of the submission) that:

"The scheme has been based on the litigation settlement for the haemophiliacs. The same provisions have been made wherever appropriate and where changes were necessary to accommodate the circumstance of the blood transfusion cases we have stuck to the spirit of the haemophiliac settlement. In devising the scheme we have also taken into account the comments made by our panel Chairman, Mr Benet Hytner QC, the Communicable Diseases Surveillance Centre, the National Directorate of the Blood Transfusion Service, the two lead firms of solicitors acting for blood transfusion recipients and of course our Department's legal advisers."

4.183. At paragraph 13 of the submission Mr Scofield explained that:

"It was the intention that the blood and tissue recipients should be put on level terms with the haemophiliacs. This requires they be given access to a special needs fund in addition to the lump sum payments. The arrangements for lump sums have been finalised. We shall go ahead and draft a charitable deed and make the other necessary arrangements for setting up the new Trust as soon as possible."

⁴ The Inquiry refers me in this regard to a minute from Mr Canavan to DH colleagues dated 2 March 1992 [DHSC0003625_027]. However this minute was not copied to my Private Office nor to other Ministers and was while Mr Waldegrave was still Secretary of State. The submission I received was on 13 April 1992.

- 4.184. In conclusion (paragraph 20 of the submission) Mr Scofield noted that officials had devised a scheme in keeping with the principles agreed by the previous Secretary of State and they were now ready to start receiving applications. He sought for officials to proceed with its implementation and for the issuing of a Press Release a draft of which was prepared.
- 4.185. On 22 April 1992, my Private Secretary confirmed to Mr Scofield that I was content for him to proceed with the implementation [WITN5289010].
- 4.186. The Inquiry refers me to the response I gave to a question from James Paice MP in relation to arrangements for the scheme in a Written Answer dated 14 July 1992 [DHSC0004048_086]. My Written Answer noted that parliamentary approval for the new expenditure required for the scheme would be subject to a vote and that, pending this approval, "expenditure estimated at £1.2 million will be met by repayable advances from the Contingencies Fund".
- 4.187. I have addressed separately in Section 6 of this statement, the subsequent establishment of the Eileen Trust for the discretionary element of payments under the scheme on which Mr Sackville took the lead.

Section 5: Factor VIII - Profilate

- 5.1. The Inquiry has referred me to a number of documents concerning an adverse inspection report made to the Department in respect of a Factor VIII blood product, Profilate, produced by Alpha Therapeutic Corporation ("Alpha"). The product had been licenced in the UK since 1985.
- 5.2. My private office received a submission dated 24 November 1989 from Mr Wilson at the Medicines Control Agency (MCA) concerning the issue [DHSC0001368]. The submission estimated that Profilate accounted for approximately 20% of the Factor VIII market in England and Wales at that time and noted that it had (before BPL facilities had been developed) accounted for a larger proportion of the market.
- 5.3. In terms of why this submission of Profilate came to me:
 - (i) as touched upon in Section 2 of this statement, while pharmaceuticals only appeared in the published list of my portfolio areas from August 1990, I recall that the Chief Executive of the Medicines Control Agency, whom I knew well and respected for his commitment and professionalism, reported to me on a regular basis and I recall that I was the responsible Minister for the sponsorship of the pharmaceutical industry. I also understand that Mr Mellor may have had responsibility for pharmaceuticals before me. So it may be that I had some responsibility for pharmaceuticals even before August 1990.
 - (ii) Another reason could have been that Lady Hooper was not available when I was. One of the difficulties with looking at events with such heavy reliance on the documents is that the context of the very numerous visits, conferences, meetings, hospital openings and the like (within the UK but also abroad) is lost. There were times when Ministerial colleagues were away, and we had to cover each other's areas.

- 5.4. Mr Wilson's submission explained that an inspection in February 1988 by the Medicines Inspectorate had identified four major deficiencies, including deficiencies relating to the risk of recontamination of heat treated Factor VIIII powder by untreated powder because of inadequate arrangements for the separation of different stages in the treatment process. The company assured at that time that the deficiencies would be dealt with. Mr Wilson went on to note that:
 - "2... At the time of this inspection the heptane heat treatment process used by Alpha was considered to be the best of available methods then in commercial use. The deficiencies identified related to the way the company operated the process not the process itself. It seems most probably that these deficiencies had existed at least since the product was licenced in the UK in 1985.
 - 3. Subsequent monitoring of the situation indicated that whilst the other deficiencies had been dealt with the situation giving rise to the risk of recontamination had not. A second visit by the Inspectors in October 1989 confirmed that the deficiency still remained and that conditions had deteriorated. On receipt of a further adverse report following that inspection the company say they have instituted a number of changes which should reduce but will not eliminate the risk."
- 5.5. The submission noted that Profilate manufactured in the US was now produced by a new method and that the company had recently applied to have their UK product licence varied so as to market the US version in the UK.
- 5.6. The submission then turned to a risk assessment by the MCA. Against the background that Profilate had a good 'track record' for quality and safety (submission §1), it was noted that Profilate produced by the heptane treatment process has been widely used in the UK and elsewhere for a number of years. The deficiencies in the process were of similar long standing (the inference being that the long-standing deficiencies in process had not in the past led to a

poor safety record for the product). However, the theoretical risks included Hepatitis B; Non A, Non B Hepatitis; and HIV.

- 5.7. The submission explained that there was no clinical evidence of Hepatitis B transmission in the UK from Profilate and that the pool of 'at risk' patients was small because of previous exposure. Profilate produced by the heptane method was a first generation Factor VIII product. All such products were associated with some risk of transmission of Non A, Non B Hepatitis (Hepatitis C). The submission noted that there was no evidence that there was any higher risk from Profilate than from other first generation products, indeed a study had shown that Profilate had a very low transmission rate for Non A, Non B Hepatitis. It also stated that a theoretical risk of HIV transmission could not be ruled out but that there was no evidence of transmission of HIV by the product in the UK, nor any such case outside the UK.
- 5.8. Mr Wilson explained that MCA had been in touch in confidence with Dr Rizza at the Oxford Haemophilia Reference Centre. Dr Rizza's opinion was set out in the submission which was to the effect that we were not aware of any clinical evidence that heptane treatment Profilate was or had been less safe than other Factor VIII products and he hoped that there could be a low-profile resolution of any perceived problem.
- 5.9. The submission then outlined a number of possible responses, in summary:
 - (1) Immediate regulatory action: Suspension of the product licence and a recall of stocks of the product. It was stated this would remove very quickly any prospect of further exposure of haemophiliac patients to heptane treated Profilate. The MCA explained that "...the clinical record of heptane treatment Profilate does not suggest that, on safety grounds, the evidence is there to warrant immediate suspension" (original emphasis). It noted the approach would have caused anxiety within the haemophiliac community and give rise to questions about why action had not been taken earlier (i.e., in February 1988 when the deficiencies were first identified).

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- (2) Non-immediate suspension: It was noted that this approach would have provided the company with time to exercise their right of appeal before the decision took effect and became public. It was noted this could also lead to questions about delay in action.
- (3) Alternatives to regulatory action: As above, Alpha had made an application to vary its UK licence to market the US version in the UK. The submission proposed it would be possible to persuade Alpha to withdraw the old (i.e., heptane treated Profilate) ahead of marketing the new product and expedite the processing of the application to vary the UK licence.
- 5.10. The submission concluded that whilst the process deficiencies revealed by the Inspectorate were a cause for concern, the clinical record of heptane treatment Profilate did not suggest the apparently long-standing deficiencies warranted immediate regulatory action and the better approach would be to pursue the "alternative to regulatory action" noted above. I was asked if I was content to endorse those conclusions.
- 5.11. My response to the 24 November 1989 submission was communicated by my Private Secretary's minute of 6 December 1989 [DHSC0001366]. It stated that I was not happy with the line proposed and that I would prefer regulatory action to be taken. The minute records that I wanted to be provided with advice on the consequences of regulatory action.
- 5.12. On 15 December 1989, Mr Wilson provided the advice I had requested in a further submission [DHSC0001375]. The submission explained:
 - "3. Professional advice is that, on balance, we do not have sufficient evidence to support immediate suspension. This position was reached taking into account the theoretical risk posed by the deficiencies noted by the inspectors, the lack of problems in the batch release of the product from NIBSC and the fact that there is no clinical evidence about the use of the products which gives rise to concern. On the basis of that advice, immediate suspension would cause unwarranted concern to the many

patients who are or have used PROFILATE. Such action has to be seen also in the context that (having studied the company's dossier) we now think that it most likely that the Licensing Authority will be able to agree their application for a variation to their existing licence before the end of January) (The Committee on Safety of Medicines will consider it on 25 January). Once that variation is agreed it will no longer be possible for the company to market further supplies of the heptane treatment PROFILATE in the UK. The company has. (sic) we understand, ample stocks of the new (solvent detergent treated) PROFILATE and will wish to supply it to the UK market without delay.

4. So <u>immediate suspension</u> is now likely only to cut short cessation of supply of the product by <u>a matter of a few weeks.</u> With that in mind and given the lack of clinical evidence of any abnormal safety hazard, the concern immediate suspension would cause to haemophiliacs and the serious public questions to which it would give rise, <u>our advice to Minister must remain strongly against such action</u>. It is true that we cannot say that there is not a potentially greater risk of infection from Profilate because of manufacturing deficiencies. But that risk has to be assessed as very remote given the usage of Profilate in recent years." (original emphasis)

5.13. The submission further stated:

"5. As an alternative, we could however inform the company that we propose to suspend the licence (but <u>not</u> with immediate effect) unless they are willing voluntarily to cease to market the heptane treatment product. A proposal to suspend would leave the company in no doubt that we were dissatisfied both with their lack of progress in putting right the deficiencies and with the present situation regarding the production process. <u>It would seem fully warrantable</u>. Such action by the Licensing Authority would not be made public. The company could then choose to exercise its 'appeal' rights but we think this is unlikely. The company must indicate whether or not it wishes to do so within 28 days. Any such action

would in practice be likely to be overtaken by the grant of the variation before end January and the company will no doubt take that into account in deciding how to respond.

6. We should seek in discussion with the company to press them to exchange existing heptane treatment PROFILATE held by health authorities in the UK for the new product. We believe that the company may be receptive to this approach and will be anxious to co-operate.

Conclusion

- 7. If the Minister wishes regulatory action to be taken we would accordingly advise that this should not be with immediate effect.
- 8. Is the Minister content? If so we will proceed with action at 5 and 6 above. We would be happy to discuss if she wishes". (original emphasis)
- 5.14. My response to Mr Wilson's 15 December 1989 was communicated in my Private Secretary's minute of 19 January 1990 [DHSC0001374]. This indicated to Mr Wilson that I was "... content to accept your advice, and to act as set out in paragraphs 5 and 6".
- 5.15. The Inquiry has asked if I was aware at the time, or was subsequently made aware, as to why "no action was taken when processing deficiencies were first identified ... by inspectors in February 1988". I was not involved at that earlier stage and so cannot answer from direct knowledge. However, I am not sure that the Inquiry's question fairly characterises the information in the submission. Paragraph 2 of the submission suggested that in February 1988, based on the adverse inspection, the company had "assured them [the inspectorate]" that the deficiencies would be addressed. That would suggest that in February 1988 action was taken but in the form of non-regulatory communication to the company that they needed to improve their systems. Based on the submission, three of the four deficiencies were then put right but a subsequent inspection in October 1989 (just the month before the submission) had confirmed that the fourth deficiency remained. It may be that immediate regularly action was not

considered because the deficiencies had been raised and there was an assurance they would be addressed; but the question is really one for MCA and/or the Inspectorate. I note that paragraph 4 of the Annex to the 15 December 1989 submission also stated:

- "a. Any announcement of immediate suspension would give rise to public/Parliamentary questions about the basis for the action proposed which could receive considerable media attention;
- b. It would not be easy to explain why action was being taken <u>now</u> when it could <u>not</u> be shown that the problem was a new one. Attention might rapidly switch to that issue with accusations of negligence by the Licensing Authority. It would be possible partially to answer this by reference to the fact that when our Inspectors first identified the deficiencies (February 1988) the BPL could not have made up the then considerable bigger share of the UK market held by PROFILATE and that we could not be confident that more acceptable products would have been available. Clinicians could have chosen, on a named patient basis, to prescribe products without a UK licence, with a possibly greater risk than PROFILATE. But that response would in turn raise concerns about <u>other products</u> and would be an admission that we had regarded the product as potentially unsafe for nearly 2 years."
- 5.16. The Inquiry has also asked that I explain my reasons for accepting the advice set out by the MCA and endorsing the course of action proposed within the submission of 15 December 1989. I am reliant on the documents. My initial approach was a precautionary one and I was inclined to take regulatory action hence I probed the suggested response set out in the 24 November 1989 submission. The 15 December 1989 submission provided greater clarity as to the rationale against immediate regulatory action, including the significant factors and advice that:
 - (1) There was not sufficient evidence for an immediate suspension of the licence. The submission contained a very clear message from officials ("professional advice is that, on balance, we do not have sufficient

evidence to support immediate suspension" and later "our advice to Minister must remain strongly against such action" (original emphasis). The suspension of a licence is a legal and technical matter and I would have been guided by the further detail and the force of view expressed in Mr Wilson's further submission that there was insufficient evidence for this course.

- (2) Immediate suspension was only likely to cut short cessation of supply of the product by a matter of a few weeks, while causing "...unwarranted concern to the many patients who are or have used PROFILATE";
- (3) The annex alerted to the fact that immediate suspension would cause patients to switch to alternative products. While BPL could supply the bulk of Profilate users for some months at least, there was a risk of a move to unlicensed products and,

"We cannot say that patients switching from PROFILATE to other commercial products would necessarily be transferring to a potentially less risky product. Indeed we suspect that in some cases the reverse might be the case" (original emphasis)

I note, in addition, that my response was endorsing *both* paragraphs 5 and 6 of Mr Wilson's submission of 15 December 1989. So, I was endorsing the view that the company would be told that the MCA proposed to suspend the licence (but not with immediate effect) unless they were willing voluntarily to cease to market the heptane treatment product.

5.17. I am also asked, to the best of my recollection, whether Alpha did in fact voluntarily cease marketing Profilate in January 1990, and whether a variation to the company's Profilate licence was granted before the end of January 1990. I cannot state from direct knowledge nor from the papers supplied when Profilate was withdrawn, or a licence variation was granted. However, had there not been a satisfactory outcome on this issue I would have expected officials to come back to me, alert me to the same and set out options for further action.

Section 6: Financial Support Schemes

6.1. In this section of my statement, the Inquiry asks me to address the administration of the Macfarlane Trust in its ongoing role in providing payments to people with haemophilia, rather than its role to pay sums in settlement of the HIV litigation. There is, however, inevitably overlap with the issues I have addressed in Section 4 of this statement.

Ministerial responsibilities for the Macfarlane Trust

- 6.2. I am asked whether the Macfarlane Trust fell within the area of responsibility for any particular Minister and if so, which one and why. I am also asked to explain the role that the Minister and Secretary of State had in respect of decisions concerning the funding, operation and oversight of the Macfarlane Trust.
- 6.3. As the Inquiry is aware, on 16 November 1987, Mr Newton as the then Minister of State for Health had announced the Government's intention to make an exgratia grant fund of £10 million to set up a special trust fund for haemophiliacs who had become infected by AIDS. The Macfarlane Trust was subsequently established on 10 March 1988.
- 6.4. Between 1989 and 1992 when I was Minister for Health under Mr Clarke and Mr Waldegrave I can see from the documents provided that my private office were sent a number of matters relating to the Trust and copied into others. I understand that my predecessors as Ministers of State, Tony Newton and David Mellor, had been involved in issues relating to the Trust. Based on the documents, rather than any specific recollection, I think it likely that in 1989 and 1990, officials continued to come to me as Minister of State on Macfarlane Trust issues. However, the question of which Minister would deal with Macfarlane Trust issues was complicated by the facts that:

- (1) The Trust was used in the settlement of the HIV litigation which was a Secretary of State led issue so there were issues which crossed over with the litigation; and
- (2) The sensitivities over budgeting and funding meant that on some aspects the Secretary of State took the lead: this was the case for example with Mr Waldegrave in 1991/early 1992 who took the lead on further funding of the Macfarlane Trust.

Logically the Macfarlane Trust funding arguably fitted better with the blood products / and blood transfusion service portfolio of responsibilities. When I was Secretary of State, Tom Sackville was the responsible minister. See for example Mr Sackville's letter of 16 March 1993, advising that an additional £5 million would be paid to the Macfarlane Trust [WITN5289011].

- 6.5. The Inquiry asks about the respective roles of the Department of Health and the Treasury and how they communicated with and in relation to the Macfarlane Trust. Based on the documents I have seen, and from my general experience, I would have expected the majority of the interface with the Macfarlane Trust to have been with the Department rather than direct with the Treasury. The Treasury's role was important in that:
 - (1) Treasury approval was required for novel forms of spending even if it was existing Department of Health allocations that were proposed to be used for the spending; and
 - (2) Treasury approval was also required if funds from a different part of the Health allocation were going to be in a different area; and
 - (3) The Treasury would need to be persuaded of the case if the Department wanted funding to come from the Treasury Reserve rather than from the existing Departmental allocation.

There was a good deal of communication between the Department and the Treasury on such spending issues, and the Macfarlane Trust would have been one of a very large number of such areas.

6.6. From reviewing the documents provided to me, at Ministerial level we were involved in funding levels for the Macfarlane Trust (and subsequently the establishment of the Eileen Trust) rather than in oversight of its operations.

The November 1989 increase in funding to the Macfarlane Trust

6.7. I have set out in Section 4 of this statement early PQs and meetings in which I was involved in November 1989 including that with Robert Key. Much of the focus at that time was on further financial support in the context of the litigation however I would at the same time have been getting up to speed with the background of the original Trust and its funding position. For example, on 6 November 1989, I answered a written PQ from John Butcher MP:

"Mr John Butcher (Coventry South West): To ask the Secretary of State for Health, if he will implement a scheme of compensation over and above the £10 million granted in November 1987, for haemophilia HIV positive people who have contracted the virus from infected imported blood products during National Health Service treatment.

MRS VIRGINIA BOTTOMLEY The £10 million which the government provided to set up the Macfarlane Trust was an ex-gratia payment and not compensation. I understand that the Trust funds are not yet fully committed but as we made clear when the £10 million grant was announced, we shall not be closed to any representations about further funding which may be made at a later date.

Some haemophiliacs who are HIV positive are now pursuing compensation through the Courts and I am advised that this matter is now sub-judice." [WITN0758029]

6.8. As I have set out in Section 4 above, on 23 November 1989, Mr Clarke announced the additional £19 million in funding to the Macfarlane Trust. The stated objectives, as set out by Mr Clarke were:

"First, to the enable the trust, if the trustees see fit, to make individual payments of £20,000 this year. These would go to each person with haemophilia who is infected with the AIDS virus as a result of treatment with blood products in the United Kingdom or to the family of such a person who has died.

Secondly, to enable the trust to continue on a more generous scale its help to families in particular need" [HMTR0000001_023].

This announcement was made less than a month after I had arrived in the Department.

The implementation of, and source of funding for, the November 1989 increase in funding to the Macfarlane Trust

6.9. In paragraphs 4.31 - 4.38 above, I have set out the involvement that I had in November 1989 when that it became apparent that a new discretionary trust would need to be established in order to effect the £20,000 per patient payments. As the Inquiry is aware, this became known as the Macfarlane (Special Payments) Trust.

Further questions about the implementation of the November 1989 increase in funding and the time taken for payments to be made

6.10. The Inquiry refers me to my answer to a written PQ from Sir Michael McNair-Wilson on 26 January 1990:

"Sir Michael McNair-Wilson: To ask the Secretary of State why the haemophiliac sufferers contaminated with the HIV virus have not yet received the capital sum promised them via the McFarlane Trust; and when he expects the payments to be made.

"Mrs Virginia Bottomley: Detailed arrangements for the payment of exgratia sums announced by my right hon. and learned Friend the

Secretary of State for Health on 23 November 1989 at columns 11-12 are being finalised. Discussions with the McFarlane Trust are almost complete and we hope that it will be possible to start making payments within a matter of days. A further statement will be made as soon as possible." [MACK0000124_002].

6.11. I note that I gave a further answer on 30 January 1990, stating:

"The arrangements for paying the ex-gratia sums have now been completed. In co-operation with the trustees of the Macfarlane Trust, a new discretionary trust called the Macfarlane (Special Payments) Trust has been set up to administer the payments. It is expected that payments will begin tomorrow." [WITN5289012].

There was also a DH Press Release on 30 January 1990 confirming the start of payments [WITN0758053].

6.12. The Inquiry asks me why it was that the payments "had been delayed" and what the substance of the discussions were that had been ongoing with the MacFarlane Trust. I have set out in Section 4 the submissions and updates I received on this issue which explained the complications that had arisen from the view taken by the Charity Commission, and the solution adopted. The detailed work on the creation of the new Trust (and liaison with the MacFarlane Trust and their lawyers concerning it) would have been carried out by the relevant officials and Department lawyers. I note that on 30 January 1990, Mr Heppell minuted Mr Canavan (copying in the Secretary of State's Office) acknowledging the amount of work that had been involved and that it was greater than initially envisaged:

"I know that there has been a lot of work involved in getting this done, more than was originally anticipated. But the outcome is very satisfactory since we have been able to carry with us the Macfarlane Trust and the Haemophilia Society" [WITN5289013].

Given that the intended beneficiaries were patients with HIV and AIDS or their bereaved families, it would have been desirable to achieve the lump sum payments more quickly. However, a new Trust had to be established and the arrangements in relation to this made and agreed. From the available documents, it seems to me that officials worked hard to achieve this between the date of announcement (23 November 1989) and the start of payments (end of January 1990).

The decision on consequential cuts to Department of Health budgets

- 6.13. I have set out in Section 4 that in addition to the issues of the legal form of the new Trust, it became apparent that it would not be possible to utilise the Macfarlane Trust's remaining £5 million of funds and this was going to need to be funded by the Government on top of the originally pledged £19 million. The net effect for the Department of Health was that we were going to need to repay an advance from the Treasury Reserve by finding £7 million from savings the next financial year. While I was not involved with the negotiations with the Treasury over this, I was involved in discussions about how these cuts were going to be made, and this is apparent from the documents to which the Inquiry has referred me.
- 6.14. On 22 November 1989 Ms Stuart (a Finance Director in the Finance Division) put a submission to Mr Clarke with proposals on the funding of the further ex gratia payments and how the £7 million in savings should be found [DHSC0002536_033]. Ms Stuart's proposals to the Secretary of State for how to find these savings in 1990 1992 involved two cuts from AIDS budgets (£1 million from the HCHS AIDS money and £1 million from the Health Education Authority's allocation for AIDS). The Inquiry raises a question about terminology. Where in this submission and elsewhere, "HPSS" was referred to, that was a reference to the Health and Personal Social Services. "HCHS" refers to Hospital & Community Health Services. The later reference to "funds earmarked for HISS" was, I believe, a reference to Hospital Information and Support Systems.

- 6.15. On 30 November 1989 Mr Clarke's Private Secretary replied to Ms Stuart. [DHSC0004415_093]. The Secretary of State's view was a slight variation on what Ms Stuart had proposed. It was said that Mr Clarke:
 - "... accepts that £1 million should be sought from territorial departments and that £2 million should be found from underspends emerging in the course of 1990 91. For the remaining £4 million of the £7 million which needs to be found Secretary of State proposes that:
 - £1 million be found from the Disablement Services Authority;
 - £1 million from the Special Hospitals capital allocation;
 - £2 million (rather than the £1 million suggested) should be found from the HEA AIDS money which would leave the HCHS AIDS fund intact."
- 6.16. On 6 December 1989, Ms Barton in the AIDS unit minuted Ms Stuart and others noting my unhappiness "...about the implications for AIDS funding, especially of the HEA" in the minute sent by the Secretary of State's Office [DHSC0004331_050]. Ms Barton provided a draft minute for me to send to the Secretary of State and invited comments on it from the other officials she was consulting. On 8 December 1989 I sent a revised version of this minute to the Secretary of State [DHSC0004331_086]. ⁵ In this note I made my case for restricting the reduction to AIDS budget to £1 million instead of the proposed £2 million. I said:
 - "... we should be in a <u>much</u> stronger position in presenting our overall AIDS strategy if not more than £1 million of the money needed for the Macfarlane trust came from AIDS monies...

If you agree we should try to keep as strong a position on AIDS as possible, could officials be asked to look again at the possibilities of

⁵ The Inquiry has also referred me to an undated draft of this minute [DHSC0004415_088]

finding the necessary extra £1 million saving elsewhere?" (original emphasis)

- 6.17. An undated draft submission, presumably from December 1989, from Ms Stuart, to the Secretary of State, noted I had proposed that £0.5 million be found from the HCHS AIDS budget from the next year and £0.5 million from the HEA allocation for AIDS education and £1 million from elsewhere. [DHSC0004415_070].
- 6.18. On 14 December 1989, Mr Clarke's Private Secretary minuted Ms Stuart with the Secretary of State's final decision on where the savings would have to be made [DHSC0002536_014]. It was noted that Mr Clarke had further considered the points put forward by me on 8 December and agreed that only £1 million should be taken from existing AIDS budgets, this being £1 million from the HEA allocation for AIDS.
- 6.19. Looking at these exchanges, I am sure that Ms Barton was right in describing me as being unhappy about the implications for AIDS spending on how it was proposed that the savings would be found to fund the additional ex gratia payments to the Macfarlane Trust. But, as is apparent from the documents, I was not arguing against finding the additional money for what became the Macfarlane (Special Payments) Trust. My concern was to try to protect the general AIDS spending and encourage a more limited cut to that spending (£1 million not £2 million) and encourage the savings to be found elsewhere. This was not merely presentational. Spending on AIDS education was important to try to limit the rates of infection. Spending on AIDS by Regional Health Authorities and Special Health Authorities (the "HCHS AIDS money") was the delivery of AIDS services by local and special health services. Reductions to either were unwelcome, but this was the reality of the allocation of finite resources to deserving causes. I probably thought that there was no prospect of avoiding a reduction of the AIDS budgets altogether (£7 million needed to be found from existing budgets) but I made my case for limiting it. In that, I was on this occasion successful. What is of note here is that this was the very real

impact of finding additional funds for a deserving additional area: unless the Treasury provided extra money, hard cuts / savings had to be made elsewhere.

6.20. The Inquiry asks if the solution was "acceptable" to me. As I have made clear, I would have preferred not to reduce spending on AIDS at all but the overall reduction on AIDS budgets was half that originally proposed. Yet that also came at the expense of savings being made in other areas. We were all in agreement that we would have to make the savings in order to fund the further Macfarlane ex gratia payments but there were hard choices to make about where the consequential cuts / savings would be made.

Top Up of the Macfarlane Trust Funding November 1990 - April 1992

- 6.21. I have been referred to an exchange of minutes, the first of which was dated 28 November 1990 and sent from Mr Canavan to my private secretary [DHSC0003357_015]. A further £120,000 was requested in order to cover additional payments from the Macfarlane (Special Payments) Trust of £20,000 each to six identified beneficiaries. The letter noted the commitment from ministers to pay a lump sum to those infected and that the money could be located from the Centrally Financed Services budget.
- 6.22. The minute would have been directed to me in the first instance because, as I have indicated, the Minister of State had hitherto been the Minister with delegated responsibility for the Trust. I note from the handwritten comment on the document that I was content for the payment to be made to the Trust but that I felt that Mr Waldegrave, Secretary of State should also agree before the payment was made. This minute was sent to my Private Office in the midst of Mr Waldegrave's consideration of settlement of the HIV litigation which he was personally leading on. While topping up the Macfarlane (Special Payments) Trust, as suggested in the submission, appeared necessary and appropriate, given the complexities of such a sensitive matter, and particularly having regard to the ongoing HIV litigation settlement, I would have sought the input of the Secretary of State so we remained aligned on such decisions.

- 6.23. Mr Waldegrave's response was on 5 December 1990; his Private Secretary noted that Mr Waldegrave and seen the minute and confirmed he was content for the proposed payment to the Trust to be made [DHSC0003357 014].
- 6.24. Such payments were required to be made to continue the operation of the Trust. As noted above, Ministers had committed to pay a lump sum to the infected. There was never any question in my mind of reversing this decision. At the time the Trust was set up, there had been an estimated 1,200 cases, however, by November 1990 this figure had increased to 1,219 potential beneficiaries requiring the top up in the funds for the Trust.
- 6.25. Similarly, roughly four months later (on 14 March 1991), a submission was made to me for an additional £220,000 to be provided to the Trust [DHSC0003659_018]. I approved this on 20 March 1991 [DHSC0041209 058].
- 6.26. On review of the documents, it appears that I was aware of the need for potential further funding requirements in the future due to the uncertainties with the initial grant of funds.
- 6.27. Further consideration was given to increasing the funds for the original Macfarlane Trust. As I have noted above, very soon after taking up the role as Minister of State I had answered John Butcher's PQ in November 1989 with the indication that we would not be closed to any representations about further funding which may be made at a later date. However, my recollection supported by the documents I have seen is that this was an area where Mr Waldegrave took the lead.
- 6.28. I note from the available documents that there was a series of submissions on further funding issues later in 1991 that went direct to the Secretary of State without being copied to my Private Office:
 - (i) 9 May 1991 submission from Mr Dobson to Mr Waldegrave [WITN5289014].

- (ii) 12 August 1991 submission from Mr Canavan to Mr Waldegrave [DHSC0003114_005] and Mr Waldegrave's response of 15 August 1991 [WITN5289015]. Mr Waldegrave was content to top up the Macfarlane (Special Payments) (No 2) Trust (the fund used for the litigation settlement payments). But in respect of the original Macfarlane Trust, he wanted to defer a bid for further Macfarlane Trust funding in the current PES round but come back for further funding the following year.
- (iii) 3 October 1991 submission from Mr Canavan to Mr Waldegrave [DHSC0003387_011] and reply of 7 October 1991 [DHSC0003386 007].

Based on these documents, it is likely that the combination of the overlap between Macfarlane Trust funding and the HIV litigation settlement (on which Mr Waldegrave was leading) together with the sensitivity of PES round negotiations with the Treasury meant that these issues were being raised with Mr Waldegrave directly rather than with me.

6.29. On 16 December 1991, Mr Heppell put a submission to Mr Waldegrave advising him that the Macfarlane Trust was intending to approach relevant officials in the next few weeks about their future plans as officials had previously told the Trust this would be a sensible time to do so. My Private Office was copied into this submission [DHSC0003111_010]. The reference to officials having advised the Trust about when the sensible time would be to make an approach for further funding indicates the working level liaison that was in place over Macfarlane Trust funding. The Trust expected to be about halfway through their resources for paying means tested grants by the end of the 1990 / 1991 financial year. Mr Heppell noted that:

"At this stage the best line to take is that the Department will, as in the past, consider carefully and sympathetically whatever proposals are put forward by the Trust/Society. We have very good working relations with them and have been very grateful for the good work that has been done by the Trust.

If any of the MPs presses the issue I suggest Ministers underline our positive response to the Trust in the past although without commitment. The fact is that we shall want to keep faith with our original approach to the Society/Trust and do our best to find any necessary topping-up money."

6.30. On 27 January 1992, I wrote to John Marshall MP in response to his letter to Mr Waldegrave dated 17 December 1991 [DHSC0041343_109]. I explained that:

"When the £10 million made available to set up the Macfarlane Trust was announced, the Government gave an undertaking that the funds available to it would be kept under review. Ministers have re-affirmed that undertaking both in the House and in correspondence, more recently in the Prime Minister's letter of 19 February 1991 to the Haemophilia Society.

At the end of the last financial year, the Trust reported that the funds available to it amounted to some £7.25 million, and its rate of expenditure was about £2 million a year. I understand that the Trust expect to be able half way through their resources for helping those in special need by the end of the current financial year. The funds available to the Trust are therefore sufficient to enable it to continue its work at its present level of expenditure for the next three years. I am not aware that the Trust is experiencing any difficulties at present, and we expect to receive shortly an approach from the Trust about its future plans.

We will consider very carefully any proposals the Trust may put forward about its future funding, and take into account its views in making our decisions. I am sure you will understand that I would not wish to pre-empt our discussions with the Trust.

I know that the Department has enjoyed very good working relations with the Trust, and I take this opportunity to say that I am very grateful for the work which has been done by the Trustees and their administrators." [DHSC0043937_015]

- 6.31. I recall there being regular dialogue and an openness between officials and the Trust which can be demonstrated by the correspondence between Mr Waldegrave, Secretary of State and Reverend Alan Tanner, Chairman of the Trustees of the Macfarlane Trust during March 1992. [MACF0000076_049; [MACF0000072_052]; [MACF0000072_051]. Mr Waldegrave confirmed in this exchange that the Government would look again at funding in the autumn of 1992 for the financial year 1993/1994.
- 6.32. The Inquiry asks whether, when I became Secretary on of State on 10 April 1992, such issues would have continued to have been brought to my attention. As explained above, Mr Sackville handled this area once I was Secretary of State. His letter of 16 March 1993, when he wrote to the Trust to advise that an additional £5 million would be paid to the Trust, correlates with the promise that Mr Waldegrave had given that the Government would look at funding further for the financial year 1993 /1994 [MACF0000072_046]. I cannot specifically recall whether Mr Sackville did come to me on issues relating to further funding for the Macfarlane Trust; this would have been approached consistently with the methods of working which I have explained earlier in this statement.
- 6.33. The Inquiry has referred me to a number of documents listed below and has asked me to what extent I was informed of and involved in decision making around ensuring that improving in life expectancy were taken into account in the funding of the Trust:
 - a) Letter from Mr Watters to the Prime Minister, 22 January 1991 [DHSC0020824_054]
 - b) Letter from the Prime Minister to Mr Watters, 19 February 1991 [DHSC0003376_004]
 - c) Letter from Rev Tanner to the Prime Minister, 25 February 1991 [DHSC0002472 161]
 - d) Minute from Mr Chapman to Mr Ahearn, 27 February 1991 [DHSC0041453_051]

- e) Minute from Mr Ahearn to Mr Chapman, 7 March 1991 [DHSC0003374_004]
- f) Letter to Mr Waldegrave from John Marshall MP, 17 December 1991 [DHSC0041343_109]
- g) Response from me to Mr Marshall dated 27 January 1992. [DHSC0043937_015]
- 6.34. Given my wider responsibility for AIDS, I was aware of the improvements in life expectancy for those infected with HIV. Correspondence such as that listed by the Inquiry and particularly my exchange with Mr Marshall in December 1991 / January 1992 would have emphasised the significance of this so far as funding of the Macfarlane Trust was concerned. We had committed to keeping the funding under review and increasing demands on the Trust because of increased life expectancy was part of the need to do so.

The Eileen Trust

6.35. The Inquiry has asked me about my involvement in the establishment, oversight and funding of the Eileen Trust. As I have set out in Section 4 of this statement, ahead of the 1992 election, at Ministerial level Mr Waldegrave led on the scheme for those infected with HIV through blood transfusion and tissue transplant. Days after the 1992 election, I was sent and agreed a submission seeking approval to implement the scheme. As set out at paragraph 4.183, the submission of 13 April 1992 included reference to the fact that in addition to the lump sums,

"It was the intention that the blood and tissue recipients should be put on level terms with the haemophiliacs. This requires they be given access to a special needs fund in addition to the lump sum payments. The arrangements for lump sums have been finalised. We shall go ahead and draft a charitable deed and make the other necessary arrangements for setting up the new Trust as soon as possible." [SCGV0000238 025]

- 6.36. On 27 April 1992 details of the lump sum element of the payment scheme were announced. [NHBT0015110]
- 6.37. The Inquiry asks why it was decided to establish the Eileen Trust. Once the decision was taken to extend the ex-gratia payment scheme, the approach was that there should be parity between transfusion patients and haemophiliacs (see the 13 April 1992 submission referred to above). In addition to the lump sum payments, it was necessary to have a fund to make needs-based payments in the way that the original Macfarlane Trust provided such support to haemophiliacs. From the subsequent documents, a separate Trust was required because the Macfarlane Trust did not wish the same Trust to be used for both patient groups.
- 6.38. The Inquiry asks about the time taken to establish the Eileen Trust. Once I had agreed the principles of the transfusion payments scheme in April 1992, approval for the Trust to provide needs-based payments would have been raised in the first instance with Mr Sackville. I have seen from the available papers that he was sent submissions on:
 - (1) 16 February 1993 [WITN5289016] this sought Mr Sackville's approval to approach three Macfarlane Trust Trustees to be Trustees of the new Trust. I was not copied into this submission at the time. But I note that it indicated that:
 - "The Macfarlane trustees have reservations about formally extending their Trust to cover the blood and tissue recipients and there would be legal difficulties in amending the deed. However the trustees are very willing to support the new trust by having common trustees and providing administrative services."
 - (2) 11 March 1993 [DHSC0002745_002] (a further submission on appointment of Trustees; naming/registering of the Trust).
 - (3) 31 March 1993 [WITN5289017] (announcement arrangements) and [DHSC0002756_002] (confirmation of the understanding reached with the Macfarlane Trust over its administrative support to the Eileen Trust).

None of these submissions were copied to my Private Office, nor do I think that they needed to be unless difficulties were being encountered in the arrangements for the new Trust of which I needed to be made aware or which required my input.

- 6.39. I cannot speak from my own knowledge about why it was not before February 1993 that officials were in a position to go to Mr Sackville for approval of appointments to the new Trust. Within the available documents, there is a minute from Mr Scofield to Mr Heppell dated 2 February 1993 which sets out the progress that had been made and further action that was proposed [DHSC0002732_004]. However, this was not copied to Ministers. The officials concerned (Mr Canavan and Mr Scofield) would be able to explain the detail of the work (legal Trust deed drafting, Trust funding, liaison with the existing Macfarlane Trust, appointments consultation, administrative arrangements, etc.) that was required in the lead up to the establishment of the new Trust, and why it took the time it did.
- 6.40. I note from the documents further referenced in the Inquiry's request that:
 - (1) the Declaration of Trust Deed for the Eileen Trust was dated 19 March 1993 [EILN0000016 016]
 - (2) On 29 March 1993, Mr Scofield wrote to The Reverend Tanner to confirm the funding of the new trust and the understanding reached on the links between the two trusts for the administration arrangements for the new Trust:

"I am writing on behalf of the Secretary of State to formally confirm that the Government is making available today an ex- gratia payment of £1/2 million to endow the Eileen Trust for the purpose of providing financial assistance to needy HIV infected blood and tissue recipients and their needy dependants throughout the United Kingdom.

I would like to take this opportunity to place on record the understanding between us in relation to the links between the Eileen Trust and the Macfarlane Trust.

We are agreed that the new trust for HIV infected blood and tissue recipients is an independent trust and that its Trustees are appointed in their own right by the Secretary of State to serve the interests of the new beneficiaries.

Equally, all of us recognise the advantages to the new trust of sharing the experience of Trustees of the Macfarlane Trust and receiving administrative support from it. The trustees of the Eileen Trust will decide the administrative arrangements but in anticipation of agreement of the new trustees we have discussed such links between the two trusts.

We recognise the Macfarlane Trust's concerns that its primary interest in serving the needs of those with haemophilia and HIV should not be put in jeopardy through the demands of the new trust. We fully understand that the Macfarlane Trust wishes to reserve the right to terminate support services for the Eileen Trust if the burden of those services becomes such that the Macfarlane Trust no longer thinks it right to provide them.

We therefore propose, and seek confirmation of the Macfarlane Trust's agreement to the following understanding. For as long as the Macfarlane Trust is providing the administration for the Eileen Trust, the Secretary of State will seek nominations from the Macfarlane Trust for 3 of the trustees, which will include one of the Secretary of State's appointees on the Macfarlane Trust. It is also understood between us that if the new trust uses the Macfarlane Trust for its administrative support, the Macfarlane Trust will have the right to terminate the agreement subject to giving 3 months notice to the Eileen Trust." [PRSE0002838]

(3) At the start of June 1993, the Department of Health began to write to those eligible to advise them about the Trust. [DHSC0006190_095]

Funding of High Purity Factor VIII from the AIDS Budget

- 6.41. The Inquiry has asked me a series of questions in relation to the funding of high purity Factor VIII during 1992 and 1993 and has referred me to the series of documents below:
 - (1) A letter dated 26 October 1992 from the All Party Disablement Group to the Prime Minister but copied to me DHSC0002464_016. I think it very unlikely that I would have discussed this issue with the Prime Minister at this time. It was common for letters of concern to be written to the Prime Minister and copied to the relevant Department or Secretary of State. Officials at No 10 would liaise with the Department concerned and decide whether the Department should reply or the Prime Minister. The line to take in reply would most often be drafted from officials within the relevant Department. In this case, a draft reply for the Prime Minister was supplied by DH officials which I reference below.
 - (2) The Haemophilia Society's "The Bulletin" article dated November 1992 [HSOC0023004];
 - (3) A letter from Mr Watters to me dated 5 November 1992 [DHSC0004002_046]. I note that this has a handwritten comment "very urgent please. Advice" which reflects that my Private Office on my behalf had asked for very urgent advice on the terms of a reply.
 - (4) My reply to Mr Watters dated 18 November 1992 [UHMB0000005_097];
 - (5) A letter from J. Keith Park & Co solicitors dated 19 January 1993 to the Mrs James in the Solicitor's Division, Department of Health [DHSC0022420_001];
 - (6) A letter from Peter Brooke to me dated 10 March 1993 [DHSC0004031_142] on behalf of a constituent whose letter was dated 3 December 1992 [DHSC0004031_143];
 - (7) My reply to Peter Brooke dated 25 March 1993 [DHSC0004031_114].
- 6.42. So far as I can ascertain from the available papers, my own personal involvement on this issue started on 19 October 1992 when I asked for a briefing on a critical article in "hospital doctor" [WITN5289018] [DHSC0004002_136].

- 6.43. I received briefing in response to this request on 30 October 1992 from Mr Canavan. His briefing concluded that:
 - "(a) the department is in no way advocating denial of treatment to anyone;
 - (b) it is a matter for Regions to decide what services to develop and to allocate resources accordingly;
 - (c) the mainstream NHS allocations are sufficient, with growth money to fund new treatments as and when they come on stream;
 - (d) in those instances where AIDS funds have been used to fund high purity Factor VIII for HIV positive haemophiliacs, sufficient time should be allowed to secure alternative sources of funding." [DHSC0002463_024]
- 6.44. As noted above, I asked for urgent advice on receipt of Mr Watters' letter of 5 November 1992.
- 6.45. I note from the available papers that Mr Sackville sent a letter of reply to Sir John Hannam MP on 6 November 1992 setting out the Department's position on this issue. [HSOC0002577]
- 6.46. My reply to David Watters dated 18 November 1992 [UHMB000005_097] would have been based on a draft response prepared by officials⁶ and set out an explanation of our position consistent with the briefing I had earlier received from Mr Canavan. I said that:

"The Department is not in any way advocating the denial of treatment to haemophiliacs with HIV infection.

The UK Recommendations of the Haemophilia Centre Directors Committee issued to clinicians earlier this year on the choice of therapeutic products for the treatment of haemophilia were consensus, unanimous recommendations. As rightly say, not vou the recommendations were for the replacement of intermediate purity VIII (IP) with high purity Factor VIII (HP) in the treatment of haemophilia

⁶ See [DHSC0003985_041] where Mr Canavan provided the draft reply on 16 November 1992

patients who have tested positive for HIV antibody and for transition from IP to HP with appropriate surveillance of safety and efficacy for other patients. This product is currently more expensive than the intermediate product. Concern still exists among some clinicians about the relative advantages of HP and differences between the different forms of HP Factor VIII. The decision about which product to prescribe for particular patients is one for individual clinicians to make within locally agreed priorities and availability of resources.

Because it is currently more expensive than IP, any increased usage of HP Factor VIII would, of course, have resource implications for health authorities. This is true of many of the advances which the medical profession is continually developing to implement. The Government would expect regions to finance the introduction of HP Factor VIII from the growth money for the health service secured within the public expenditure process.

Regions are best placed to make decisions on how fast any particular medical advance should be introduced. The Department does not and would not wish to get involved in detailed decisions on the application of resources for individual treatment. This could only be done in any case, by some central funding initiative which could be funded only by top-slicing health authorities allocations. Earmarking money in this way for medical advances is considered inappropriate by the Department and has never been intended for the introduction of HP Factor VIII.

Nor is it appropriate to use earmarked AIDS funds for this purpose. Traditional methods of allocating funds to the National Health Service could not take account of the uneven incidence of HIV infection and AIDS which has placed the overwhelming financial burden on the four Thames regions. Earmarking of AIDS money was accordingly introduced in response to this new infectious disease, with no cure or vaccine, to ensure that adequate services were developed and essential prevention programmes initiated to contain the epidemic. Funding this new product,

high purity Factor VIII, which is essentially for the treatment of haemophilia, is therefore not regarded as an appropriate use of these AIDS funds.

To clarify the position the Department wrote to Directors of Haemophilia Centres stating that the resources set aside specifically for the development of HIV/AIDS services should, therefore, not be used to fund HP Factor VIII.

I understand that there are some instances where AIDS funds have been used to fund the high purity product for HIV positive haemophilia patients. It was never the intention that these patients should no longer receive high purity factor VIII. If in individual cases the abrupt withdrawal of funding would have a detrimental effect on treatment we accept that it may be necessary to allow time to make the transition to other funding sources."

6.47. On 4 December 1992, Ms Johnson-Laird sent a submission to the CMO and to my Private Office seeking our agreement to a shift in policy on funding high purity Factor VIII [DHSC0032075_064]. Under background it was explained that:

"Problems have arisen over sources of funding for the price differential between high and intermediate purity Factor VIII for HIV seropositive haemophiliacs since the publication of the guidelines from the Haemophilia Centre Directors in the Spring advocating use of the high purity product for haemophiliacs with HIV. The conclusion was reached that earmarked AIDS funds should not be used to fund this price differential as the new product was principally a treatment for haemophilia not HIV and its particular benefits for people with HIV were inconclusive. The new products like any other medical advance should therefore be funded from NHS main allocations which include growth money for such advances. The decision that it was an inappropriate use of earmarked AIDS funds to cover the price differential was relayed to health authorities

in August and this decision was confirmed and explained by SofS in her letter of 18 November to David Watters of the Haemophilia Society. This letter which was copied to HAs on 20 November also made it clear that where AIDS money was already being used to pay for high purity Factor VIII, it would be acceptable to continue doing so until alternative funding sources were established."

The reason for the proposed change in policy was new evidence that had recently been drawn to the CMO's attention:

"New Developments

Data have since been accumulating which are tipping the balance of probability that the high purity product is beneficial in respect of HIV in seropositive haemophiliacs. This view was given further support when Dr Christine Lee, Director of the Haemophilia Centre at the Royal Free presented an abstract just published in the USA Scientific Journal 'Blood' copy attached at (A) which appears to lend further weight to the view that high purity Factor VIII benefits seropositive haemophiliacs by slowing down the rate of decline in CD4 count, a marker of immune suppression and disease progression. These data when added to previous information have led medical and administrative colleagues in the Department to the view that, on balance it appears more likely than previously thought that high purity Factor VIII is of benefit."

- 6.48. The CMO and I were invited to agree that the high purity Factor VIII could be a legitimate use of use of earmarked AIDS funds. Handling options were set out, with concern being expressed about the presentational aspects of so speedy a change in policy which "might be interpreted not only as a hasty reaction to a vigorous piece of lobbying but also as perhaps undermining the position of the SofS." [DHSC0032075 064].
- 6.49. On 4 December 1992 the CMO provided a holding reply to Dr Lee [DHSC0002464_052].

- 6.50. On 9 December 1992 Ms Johnson-Laird provided a further submission to me and Lady Cumberlege on the issue [DHSC0002440_065] and [DHSC0002464_037]. I was invited to agree to the change in policy on high purity Factor VIII to be made by means of a CMO letter accompanied by a press release both to be issued on 18 December. The submission attached draft letters consequent on the decision including an amended draft for the Prime Minister to send in response to the All Party Disablement Group's letter of 26 October 1992.
- 6.51. On 14 December 1992 Sir Ken Calman then sent me a brief submission through his Private Secretary [DHSC0032075_024]. He wanted to communicate the changed position on the issue to the medical field as soon as possible and provided amended draft letters with a view to the matter being communicated that same day. Ms Johnson-Laird provided my Private Office with a covering note to set out the background and explain the delay in providing draft responses for the letters in reply from the Prime Minister [DHSC0004002_012].
- 6.52. The new guidance was accordingly announced to the profession on 14 December 1992 with the Department making clear that the price differential for high purity Factor VIII could be an appropriate use of earmarked AIDS funds. A press release followed on 15 December 1992 [DHSC0004764_052]. My Private Office wrote to No 10 to update on the position and provide revised drafts for the Prime Minister's replies [DHSC0002464_007].
- 6.53. Although I was not directly involved, the original reasons for declining to use earmarked AIDS funding for high purity Factor VIII were set out fully in my letter to Mr Watters of 18 November 1992. The Inquiry asks if consideration was given to funding high purity Factor VIII from any other source. I do not think that I can expand on what I wrote to Mr Watters on 18 November. The Department was not preventing the provision of high purity Factor VIII but the funding decisions were for the Regional Health Authorities. The only other funding approach would be central funding but that would have involved top-slicing health authorities' allocations which was not considered an appropriate way to finance the provision of new treatments. However once there was firmer

evidence that made it appear more likely than previously thought that high purity Factor VIII was of benefit to seropositive haemophiliacs, we reversed the objection to earmarked AIDS funds being used to fund the price differential.

Section 7: Hepatitis C Virus (HCV) screening, lookback exercise and compensation

Screening blood donations for Hepatitis C

- 7.1. On 21 December 1990, Mr Canavan put a submission to the Chief Medical Officer and Baroness Hooper concerning the introduction of Hepatitis C antibody screening tests in the National Blood Transfusion Service. [PRSE0004667]. The submission noted that the Advisory Committee on the Virological Safety of Blood (ACVSB) had unanimously recommended the introduction of screening as soon as possible. The recommendation of officials was in favour of the introduction, and it was noted that the other UK Health Ministers were being asked to approve the introduction in their transfusion services. While some arguments against screening were identified in the submission, the conclusion was that further delay in the introduction of HCV testing in the UK would be difficult to defend. Baroness Hooper was asked if she was content that preparations should be made to introduce screening as soon as practicable. The submission noted that it was unlikely that routine screening could be introduced before 1 April 1991.
- 7.2. So far as Ministers were concerned, Mr Canavan's submission went to Baroness Hooper alone and was not copied to Mr Waldegrave's Private Office, to mine or to Stephen Dorrell's. Accordingly, I would not have seen this submission at the time.
- 7.3. On 16 January 1991, Baroness Hooper approved the recommendation that screening should be introduced as soon as was practicable commenting, "I don't see that we have any option" [NHBT0000191_013]. As with the submission, Baroness Hooper's response was not copied to my Private Office, so I would not have seen it at the time.
- 7.4. I was not personally involved in this area, nor would I have expected to be involved with the decision making on this issue at that time. It was within

Baroness Hooper's portfolio. Junior ministers would generally escalate a matter to the Secretary of State if we were concerned. But Baroness Hooper had already said that the testing should be introduced as soon as possible when the matter was put to her in this submission. I am asked if I would have expected the Secretary of State to be involved. It is hard to say when it is an area with which another minister was dealing. Baroness Hooper was extremely able and she was giving the decision that the screening should be introduced as soon as practicable. On that basis it may not have required Secretary of State involvement. We discussed matters of then current concern at ministers' meetings. Each minister could bring issues they wished to the Secretary of State.

7.5. A further submission went to Baroness Hooper on 30 July 1991 in respect of a press release to announce the commencement of screening tests [NHBT0000192_125; NHBT0000192_126]. My Private Office was not copied into this submission and I would not have seen it at the time. I note that the background section of the submission stated as follows:

"In January 1991 Ministers agreed to the introduction of HCV testing as soon as possible on the unanimous advice of the expert Advisory Committee on the Virological Safety of Blood (ACVSB). At that time the technology was still being developed and evaluations of the screening kits were needed. It was found that the original kits gave many false positive results and so supplementary tests were also evaluated. Suitable second generation testing kits are now available and the Blood Transfusion Service is ready to start routine screening on 1 September 1991."

- 7.6. On 16 August 1991, Baroness Hooper announced the starting of testing which was due to commence on 1 September 1991 [NHBT0000062 098].
- 7.7. In answer to the Inquiry's questions about the July submission, I had no personal involvement in the decision to introduce the screening tests, its timing or funding. As mentioned, the decision making was within Baroness Hooper's

portfolio. The Inquiry asks if I should have been involved in the funding, in particular in relation to whether they should be funded centrally by the Department of Health or by the Regional Health Authorities. If it had been the case that there was an insoluble problem on funding involving a disagreement between the Department of Health and the Regional Health Authorities, that is the sort of matter that might have been raised by one of the Parliamentary Under Secretaries with me as Minister of Health (rather than necessarily to the Secretary of State). I am not aware that this happened on this occasion; it would only have occurred if there was a funding issue that had become a sticking point that the Parliamentary Under Secretary had become worried about or could not resolve.

- 7.8. The Inquiry draws my attention to the facts that: the ACVSB recommended the introduction of the screening test, "as soon as practicable" in November 1990; Baroness Hooper approved that recommendation in January 1991; the screening tests were introduced in September 1991.
- 7.9. The Inquiry asks if I was aware of the length of time it was taking to introduce the screening test, and what responsibility I had as Minister of State to ensure the timely introduction of the screening test. I would not have been aware of, or monitoring, the time taken to implement the screening tests. It was a matter which Baroness Hooper had been dealing with at Ministerial level, and in relation to which there were also clearly expert advisory groups involved. Baroness Hooper had given the direction that the testing should be introduced as soon as practicable.
- 7.10. I am asked about my reflections looking back now on the length of time it took to introduce the screening test and whether more should have been done and if so, 'what, by whom and when'. I am referred by the Inquiry to particular parts of the judgment of Mr Justice Burton in *A and others v The National Blood Authority* [PRSE0003333].
- 7.11. I doubt that I can add meaningfully to the Inquiry's consideration of this issue when it was not my area at the time and I am not apprised of the wealth of

underlying detail so as to enable me to give a fair or valuable opinion. Within the factual chronology in the judgement to which the Inquiry refers me, Burton J dealt with the decision-making after Baroness Hooper's January 1991 decision in the following terms:

"156. On 25 February 1991, at the ninth meeting of the ACVSB, the fact that there were now about to be available second generation Ortho and Abbott assays, obviously improvements on the first generation assays, was considered, and, at the 25 March 1991 meeting of the ACTTD, a decision was made to postpone introduction of routine screening until after an opportunity had been provided to evaluate the new second generation assays. Hence the RTCs were informed on 3 April 1991 of the revised start date of 1 September 1991, to allow such evaluation. Dr Lloyd of Newcastle, impatient to start, in fact started up routine screening at his RTC in advance of the rest of the country, somewhat to the disapproval of his co-Directors, using the second generation assay, and his screening, together with tests at Leeds, Liverpool, Sheffield, Bristol and Glasgow, was used for the purpose of the evaluation of the second generation assays referred to above."

The whole and wider chronology – including advice from two UK expert committees - was clearly subjected to detailed scrutiny in the litigation. I respect that it has been the subject of that independent judicial consideration concluding that the public were entitled to expect screening to have been implemented much sooner, by 1 March 1990.

Look Back Exercise to trace, counsel and treat those who may have been infected with Hepatitis C through blood transfusion

7.12. The Inquiry has referred me to a number of documents relating to the look back exercise announced in January 1995 to trace, counsel and treat those who may have been infected with hepatitis C through blood transfusions.

- 7.13. To deal firstly with the chronology of the documents to which I have been referred by the Inquiry, they can briefly be summarised as follows.
- 7.14. On 16 November 1994 there was an article in the Independent newspaper highlighting a growing concern about the hepatitis risk to haemophiliacs [DHSC0004738_131]. On the same date the Evening Standard reported that Ministers were considering plans to trace patients who may have been infected with hepatitis C following the death of 12 haemophiliacs from contaminated blood supplies and the risk to 3000 patients who underwent blood transfusions [DHSC0004738_087]. The Haemophilia Society published a press release concerning the article in the Independent newspaper [HSOC0021550].
- 7.15. Also, on 16 November 1994 Mr T Kelly sent a submission to my private secretary [DHSC0041152_216]. It appears from the first paragraph that I had asked for a full briefing and legal opinion on 'Hepatitis C infection' and that may have related to the Independent article and the Haemophilia Society Press both of which were referred to in the submission release, [DHSC0004738 123]. There was no legal advice attached to the submission but a short paper from Dr Reiman was annexed. The submission stated:

"The figures quoted in the Independent article relating to Haemophiliacs are believed to be accurate, those quoted in relation to the non-haemophiliac population (3000 possible infections) are more problematic. They emanate from the Standing Advisory Committee on Transfusion Transmitted Infection which is a committee of doctors in the Blood Transfusion Service. This committee submitted a paper to the Departmental Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT) in September 1994. MSBT has asked a small group of its members to examine the claims in the paper and to report back. This will enable a view to be established on the viability and desirability of a "look back" exercise to trace, treat and counsel those who may be affected."

So far as I can tell from the available documents, this appears to have been the first time that the lookback exercise was raised with me.

- 7.16. On the same day, 16 November 1994, Mr Burrage provided me and all the other Health Ministers with a covering note regarding briefing that had gone to No. 10 on Hepatitis C infection [DHSC0003527_008]. He attached the briefing that had been forwarded to No 10 [DHSC0003527_009], a background note [DHSC0014961_040], and a copy of the Haemophilia Society's statement.
- 7.17. The Inquiry also refers me to a minute from Dr Rejman to Mr Kelly on the same day, 16 November 1994 [DHSC0002548_170]. This appears to have been a minute in which Dr Rejman gave input into, or commented upon, Mr Kelly's draft submission to me. In relation to claims for Hepatitis C infection, Dr Rejman said:
 - "6... It would appear that the advice given so far is that where treatment was inappropriate, eg a non-haemophiliac being given Factor VIII, then such an individual might win (and a very small number have won) a court case. However, the chances of winning generic cases for hepatitis C transmission were considered to be extremely low.
 - 7. I would be grateful for Mr Blake's legal comments."

This minute formed Annex 2 to Mr Kelly's submission of the same day.

- 7.18. In addition to the documents to which the Inquiry refers me, there were two submissions on the lookback exercise in December 1994 addressed to Tom Sackville (who had delegated responsibility for this area as the Minister responsible for the National Blood Authority) but which were copied to my Private Office. I was also sent a submission confirming Mr Sackville's decision on the second submission:
 - (1) On 16 December 1994 Mr Scofield noted that the Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantations (MSBT) had met the previous day and agreed that Ministers should be advised to identify anyone who may have been put at risk of HCV

infection through NHS treatment. [DHSC0003544_084]. He indicated that a formal submission would be made early in the following week.

(2) On 22 December 1994, Mr Scofield provided Mr Sackville with a submission paper on the Government's response to Hepatitis C [WITN5289019]. The conclusion of the submission was as follows:

"27 The Department cannot dispute that a number of people have been infected through NHS treatment but deny negligence. The case does not have the same exceptional circumstances as did the HIV infection where those affected were all expected to die very shortly and were subjected to significant social problems including ostracism. Ministers have therefore made clear that they have no plans to introduce a payments scheme. There are practical steps that can be undertaken to assist those affected and those at risk.

28 In particular both the Departments lawyers and the MSBT advise that there is a duty of care towards those who may be at risk. Ministers have been advised by the MSBT that procedures should be put in place to identify those patients at risk and that this should be done on a UK wide basis. Subject to Ministers' agreement an ad hoc Working Party would be set up to put together guidance on counselling and treatment options.

29 In addition to the identification of patients at risk steps should be taken to ensure that treatment is made available and that consideration is given to any additional research which might be required to improve the treatment, and management of those affected. The Department should also give sympathetic consideration to appropriate requests for support from any self help groups which might be able to provide cost effective assist[a]nce to their members."

- (3) On 4 January 1995, Mr Sackville's Private Secretary minuted my Private Secretary advising that Mr Sackville had agreed to the lookback exercise:
 - "1. SoS will wish to be aware that PS(H) has agreed that there should be a look-back exercise as recommended in Roger Scofield's submission dated 22 December to identify those at risk of Hepatitis C infection following blood transfusion or use of blood products. At a meeting today with Dr Metters and officials he considered the letter of 22 December from Lord Fraser and has replied indicating there should be a UK wide look-back exercise with an announcement on Wednesday 11 January (copies of both letters are attached). The pressure applied by the possibility of a Panorama programme on Hepatitis C has been temporarily eased. It was to have been screened 9 January but has now been rescheduled for a later date. However, because of the inevitability of the subject being reported in the Press, PS(H) regarded it important to seize the initiative by making an announcement as soon as possible.
 - 2. PS(H) also agreed that a helpline should be set up; a letter should be sent to GPs; that there should be an inspired PQ and that CMO and Dr Robinson (NBA Medical Director) should front a press briefing." [WITN5289020].
- 7.19. The Inquiry has referred me to a Scottish Office submission dated January 1995, by G. W. Tucker [DHSC0002551_119]. It is very unlikely that I would have been shown this at the time, although I note that it was copied to some Department of Health officials. It referred to the letter that the Scottish Minister of State (Lord Fraser) had written to Tom Sackville on 22 December 1994⁷ to indicate that Scotland was going ahead with its Hepatitis C lookback exercise.

⁷ 22 December 1994 letter from Lord Fraser [PRSE0001781]; 4 January 1995 Mr Sackville's reply [DHSC0032208_136]; 9 January 1995 Lord Fraser's response [DHSC0002551_110]

It also noted that Mr Sackville had proposed that the lookback exercise be announced through an inspired PQ on 11 January as a UK exercise and Scottish officials were in favour of this.

7.20. On 9 January 1995 a minute was sent by Mr Sackville's Private Secretary to Mr Scofield concerning the announcement of the look back exercise [DHSC0003555 128]. The minute stated:

"PS(H) has seen your submission dated 6 January 1995⁸ and commented that we must have agreement between all Territorial Departments before making the announcement. This was addressed in your further minute this morning requesting PS(H) to clear an amended PQ.

PS(H) has cleared the revised PQ as submitted - see copy attached. PS(H) is content with the Press Notice apart from the first sentence in the third paragraph of his quote which, as we discussed, should be amended to read: "We shall do all we can to care for patients who have become infected, through counselling and treatment. I recognise"."

- 7.21. On 10 January 1995, Mr Scofield advised Mr Sackville that all three Territorial Health Departments had signed up to the UK-wide approach and had approved the terms of the announcement by PQ. My Private Secretary was copied in [WITN5289021]. On the same day, my Private Office was advised that Mr Scofield was briefing the Haemophilia Society, while Dr Metters was speaking to the General Medical Services Committee and the Royal College of Pathologists [DHSC0002551_046].
- 7.22. On 11 January 1995, the announcement of the lookback exercise was made by the answer to the inspired PQ [DHSC0004175_105] [DHSC0002551_030] and by a DH press release citing Mr Sackville [NHBT0005792]. Mr Sackville said:

⁸ Submission of 6 January 1995 (misdated 6 January 1994 on its face) which had provided Mr Sackville with the draft inspired PQ to announce the lookback exercise [**DHSC0003555_177**]

"I have accepted the recommendation of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation that a look-back exercise should be undertaken. I have asked Dr Metters, the Chairman of the Committee to bring together an ad hoc Working Party of experts to draw up guidance on the procedures for undertaking the look back exercise and for counselling those identified as being at risk, as well as guidance on the treatment options available."

7.23. Dr Metters was cited in the Press Release as saying:

"Until recently there was no treatment to offer those who might be identified and it was believed that this exercise would have been technically very difficult. However, following a pilot research study procedures have been established which make it possible to trace those at risk and, more importantly, certain drugs have recently been licensed which may be suitable for the treatment of some of those involved. This look-back programme will go ahead without delay."

- 7.24. Co-ordinated with the announcement, the CMO's Office circulated a letter to all Directors of Public Health regarding the lookback exercise with information to be cascaded to GPs and to relevant hospital consultants [HHFT0000002_002].
- 7.25. The Inquiry refers me to a letter from Dr Bogle⁹ to Dr Metters, dated 14 March 1995 regarding the lookback exercise [**BMAL0000036**]. Dr Bogle said:
 - "1. The undertaking will be major and will place a considerable administrative load, not only on the Regional Blood Transfusion Centres, but on hospitals. Hospital blood banks, records departments and doctors are already carrying very heavy loads. If the hospital consultant feels it inappropriate for the patient who has received blood from a donor who subsequently tests HC [Hepatitis C] positive to be contacted, then an equivalent load will fall on the GP.

⁹ Chairman of the BMA Committee

2. Tracing patients who have received potentially HC-positive blood is **probably** worthwhile but it does raise the question as to what the aim of it is. The first response from the patient will probably be terror and the second litigation! It also is vital that **any** chance that the patient will connect Hepatitis C (often called HCV) with HIV and AIDS must be absolutely minimised.

The general points we would make relate mostly to 2. We do not really know how serious Hep C infection is. The more that is known the more it seems likely that chronic morbidity from hepatitis per se, leading to liver cancer in some patients, is going to be found. Initially Hep C was not thought to be too serious, now it is potentially so.

As far as treatment of the recipient found to have contracted Hep C from a transfusion is concerned, others know more than we, but we believe early treatment has a better chance than later and there is no certainty of cure anyway.

Any doctor given the task of counselling one of these patients must receive a detailed, authoritative and up-to-date brief on the condition, its prognosis, symptoms, treatment and so on. This should include a well thought out list of questions patients will ask, and their answers. I do **not** think the letter to GPs at Annex B is any good at all. The GP (and other clinicians) **must** be given a full account as above **before** they approach any patient, even if counselling is to be done by someone else - eg an expert from the Transfusion Centre or wherever." (original emphasis)

7.26. On 15 June 1995 I wrote to Mr Clarke [DHSC0006947_138]. This was sent in response to his letter dated 24 May 1995 [DHSC0003552_107]. Mr Clarke's letter had enclosed a letter from Dr K. H. Bywater (his constituent) concerning amongst other things the scope of the look back exercise [DHSC0003552_108; [WITN5289022] | explained:

"... previous donations from any donor shown to have been HCV positive since screening was introduced are the subject of the look back. The previous donations in many cases will be before 1989 and so the look back is not limited to 1989.

Donations made prior to the introduction of screening and where no further donations by those donors have been made since then are more complex. However, consideration is being given to whether sufficient information is available and what action may be appropriate."

The available documents show that a draft response was formulated with the input of a number of officials dealing with the lookback exercise [DHSC0002549_096].

7.27. On 4 April 1995, Mr Sackville announced the guidance issued by the CMO in answer to a PQ from Piers Marchant:

"The guidance, including counselling guidelines and treatment options, is being issued to the national health service under cover of a letter from the Chief Medical Officer. Copies will be placed in the Library.

This phase of the exercise is to trace, counsel and, where appropriate, treat those identified as being at risk. It will primarily concern hospital consultants in a number of specialties, those working in blood transfusion centres, and general practitioners. We shall do all that we can by way of counselling and, where appropriate, treatment to care for those who may have been infected." [RLIT0000888].

The CMO's letter was issued on 3 April 1995 [NHBT0002796_002].

7.28. Based upon the above documents I believe the issue of a lookback exercise was first drawn to my attention in Mr Kelly's submission of 16 November 1994. That submission had noted that the MSBT was examining the viability and desirability of the lookback exercise. Once the MSBT had made its recommendation, the substantive submissions which followed on 16 and 22

December 1994 were addressed to, and handled by, Mr Sackville who agreed to the lookback exercised being undertaken.

- 7.29. The inquiry asks why a lookback exercise had not been undertaken earlier. This was explained in Mr Scofield's submission of 22 December 1994:
 - 11. ... Until recently it was considered that lookback to identify recipients of blood transfusion who are at risk would be technically difficult; and as there was no effective treatment, to inform people they were at risk, when there was nothing that could be done about it, would increase distress without any benefit.
 - 12 The position has changed on both counts. There is now some confidence that many, but not all, recipients of blood infected with hepatitis C can be identified and some treatment regimes using interferon alpha have been licensed. The Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation (MSBT) at its meeting 15 December agreed to advise Ministers of the four Health departments that:
 - "i. In MSBT's view there is a duty of care towards those infected with HCV as a result of NHS treatment. It follows that procedures should be put in place to identify those patients at risk;
 - ii. Whatever is done should be done equally and uniformly throughout the UK;
 - iii. Guidance should be drawn up as soon as possible:
 - a) on procedures for identifying those at risk, and
 - b) While it was for the medical practitioner responsible for each patient identified as at risk to decide what should be made known to the patient about his/her risk status, and to decide whether and what treatment should be advised, guidance on the counselling and treatment options would be desirable." [WITN5829019]

In the DH Press Release on 11 January 1995 Dr Metters referred to the same issues that until recently there had been no treatment to offer those who might

be identified and it was believed that the exercise would have been technically very difficult.

- 7.30. The decision to proceed with the look back exercise was taken by Mr Sackville on the advice of officials as set out in the papers. I was kept informed of the decision taken. The Inquiry asks whether costs, the limited treatment options and the risk of causing anxiety to patients affected Government thinking and policy at this time. From the available papers, by late December 1994 and early January 1995, the position was simply that the MSBT had issued clear advice on 15 December 1994 that a lookback exercise should be undertaken and we agreed to its implementation on that basis; cost and the restrictions on treatment available do not appear to have been limiting factors. Nor, at this stage, does it appear that the risk of causing anxiety to patients prevented the lookback exercise from being proceeded with, though guidance and counselling to patients was clearly one of the issues deliberated by the working party considering its implementation.
- 7.31. I was not involved in discussions about the scope of the lookback exercise or the parameters of how it should be drawn. I would have expected the technical aspects of that to be reflected on by the advisory committee and working group. Had they thought it necessary for Ministers to make a decision on the scope of the exercise (because, for example, it was controversial or had significant costs implications) it would have been raised in the first instance with Mr Sackville. My letter to Mr Clarke of 15 June 1995 addressed the scope of the lookback exercise and the draft from officials indicated that for donors who tested positive for Hepatitis C after 1991, the lookback was not limited to those who had received donations after 1989.
- 7.32. The concerns expressed by Dr Bogle in his letter of 14 March 1995 were addressed to Dr Metters and were not copied to me. I would have expected them to have been considered and addressed by Dr Metters and other officials in the first place in the context of the guidance that was then being drawn up.

7.33. The Inquiry asks about further steps to progress the lookback exercise while I was Secretary of State. I have referred to the guidance and announcements that were issued on 3 and 4 April 1995 by the CMO and Mr Sackville respectively.

Consideration of ex gratia payments to those infected with Hepatitis C

- 7.34. The Inquiry has also referred me to a number of documents relevant to the question of compensation or financial support to those infected with Hepatitis C through treatment with blood or blood products
- 7.35. On 29 September 1994, a letter was addressed to me by a member of the public, whose father had been infected with Hepatitis C following an operation in November 1981 and had gone on to develop cirrhosis of the liver and died in September 1992. The letter requested consideration of a settlement similar to that put in place for those infected with HIV [HSOC0016786]. Whilst the letter was addressed to me it does not mean I would have been shown it at the time. Some letters would receive responses from ministers while others were responded to by the relevant policy officials. The documents made available to me (from the Inquiry and from searches of the DH records) do not appear to include a response to this letter therefore I am unable to assist as to whether I was made aware of this particular letter at the time. While I do not recall seeing this letter, I was aware that some cases of Hepatitis C infection though blood and blood products led to very serious disease and that some patients died.
- 7.36. I have referred at paragraph 7.15 to Mr Kelly's submission of 16 November 1994. On the compensation issue, Mr Kelly set out that:
 - 1. There are many examples of drug reaction and medical treatments given in good faith where non-negligent harm has occurred, and those suffering as a result could press for Government compensation. We have resisted calls for payments to those who have contracted hepatitis C through NHS treatment along with more general calls for a no fault compensation scheme for medical accidents in the NHS. Each time a

- concession is made it becomes more difficult to re-establish a credible ring fence to prevent further movement towards a general no fault scheme for medical accidents.
- 2. The justification for the payments to the HIV haemophiliacs was that they were doubly disadvantaged; the problems of HIV were superimposed on the health, social and financial disadvantages they already suffered as the result of their hereditary haemophilia. Following a campaign on behalf of those infected with HIV through blood transfusion, the Government extended the payments to this group, concluding that they too were a very special case. Both groups shared the tragedy of becoming infected through medical treatment.
- 3. The hepatitis C virus is carried in blood and can also be transmitted through blood transfusion. 50% of sufferers may progress to chronic hepatitis with varying degrees of ill health. it can cause liver damage and mortality. Some of these will respond to interferon treatment. It is not transmitted as easily as HIV.
- 4. There are several thousand haemophiliacs who may be infected with hepatitis, but not HIV, who did not share in the settlement. It is known that some patients will have been infected through blood transfusions but there is no routine referring of cases which would give us overall numbers.
- 5. Routine screening of donated blood for the presence of hepatitis C began on 1 September 1991. The early screening tests which became available in 1989 were poor and there were no means of confirming whether a positive reaction to the screening test was a true indication of infection.
- 6. There is pressure for compensation for those who received treatment as children with human growth hormone and who may now be at risk of developing CJD (the human condition analogous to BSE "mad cow's disease). There are around 2,000 such people and 13 have died from CJD. The process of litigation has started and we expect to be in court in 1996." [DHSC0041152 216].

- 7.37. A series of newspaper articles from January 1995, to which the Inquiry has referred me, highlighted the consideration being given to the Hepatitis C look back exercise but also the calls for compensation for those infected [HSOC0016717]. Lady Cumberlege was quoted in some of these articles. On 30 January 1995, Lady Cumberlege had indicated in answer to Oral PQs in the Lords that the Government drew a distinction between HIV and Hepatitis C infection and did not intend to introduce payments for those infected with Hepatitis C. [DHSC0003524_025].
- 7.38. On 27 March 1995, Mike Hall MP wrote to me on behalf of constituents whose son had haemophilia, and voicing his support for the Haemophilia Society's campaign for those infected with Hepatitis C to receive compensation [DHSC0006947_082]. Mr Sackville replied to Mr Hall on 19 May 1995. He explained that,

"We have great sympathy with those patients who may have become infected with hepatitis C through blood transfusions or blood products. Most haemophilia patients were infected with hepatitis C before blood products were treated to destroy viruses. These patients received the best treatment available in the light of medical knowledge at the time. The Health Departments are considering a range of potential initiatives to improve the understanding, treatment and management of hepatitis C. This could include encouragement of research into the condition and guidance to the NHS on best practice where there is a clinical consensus. The Government does not accept, however, that there has been negligence and we have no plans to make payments to such patients. On the more general issue of compensation, the Government has never accepted the case for a no fault scheme of compensation for medical accidents. It is unfair to others and still requires proof of causation which is often difficult to establish. Every individual case where a medical accident has occurred is a personal tragedy for both the individual concerned and their family. If the NHS is proved negligent in a Court, it accepts its liability to pay damages.

It is the Government's view that the most effective use of resources is to seek to improve the understanding, management and treatment of the condition. Only in this way can the impact of the disease on individual patients and their families be effectively minimised.

This Department is supporting an initiative by the Haemophilia Society to undertake a study into the best way to support its members who are infected with the virus.

I hope that this will reassure you that the Government will do all it can to care for those affected" [HSOC0004913].

- 7.39. On 30 March 1995, the issue of financial support was raised at a meeting between Gerald Malone and a number of MPs [WITN5289023]. Mr Malone asked for further advice from Mr Scofield and wanted Mr Sackville's views and those of the Permanent Secretary. Mr Malone appeared at this stage to be in inclining in favour of a financial support scheme.
- 7.40. This then appears to have led to a series of further exchanges on the issue most of which I was copied into. These included the following:
 - (1) A message from Mr Scofield on 30 March (copied among others to my Private Office):

"You will wish to see that M(H) has come out in favour of making payments to haemophiliacs and others infected by HCV. He has yet to convince his Ministerial colleagues.

I understand that Dr Metters has advised Perm Sec to go for a meeting with Minister rather [than] try and cover it in the margins of TOTO [Top of the Office]. This might mean a meeting next week rather than this. Either way I shall move swiftly to get papers round for comment." [DHSC0002610_006]

(2) A paper from Mr Scofield to Gerald Malone (as had been requested) dated 6 April setting out how a payments scheme could be constructed but cautioning that such as scheme was, "... the exact opposite of the

position that the Government generally and Health Ministers in particular have taken to date" (original emphasis) [WITN5289024].

(3) The views of the Permanent Secretary Mr Hart, conveyed to Mr Malone, dated 6 April 1995 [DHSC0042937_121]. The Permanent Secretary stated:

"My recollection is that when the Government conceded payments for those infected with HIV/AIDS via blood products, and then via blood, a very firm line was drawn, by all Ministers, around that scheme. It was, of course, a first step down what could be a very slippery slope towards no-fault compensation and that is why the Treasury and others were so adamant that the line had to be defended. There will therefore be great resistance to any weakening of the line.

Having looked at no-fault compensation, I do think it is a destination to be avoided at almost any price. It would be very expensive, and it would be immensely difficult to devise such a scheme that was acceptable to the parties. Such schemes are I believe no longer well regarded in other countries that have them eg New Zealand.

Any concession towards Hepatitis C victims would be very difficult and we should soon be vulnerable to further demands on behalf of those suffering from other forms of Hepatitis, CJD etc etc, let alone from people suffering non-negligent harm eg in the course of surgery. Mr Scofield has given some thought to this, but we would need to do a lot more work to see whether a defensible and containable scheme could be devised. I have my doubts.

The logical position is that if one has been harmed through negligence, the law is available for redress; if the harm is non-negligent and accidental, then there may be substantial help available from the statutory services (including social security) but there is no obligation on the government to provide specific schemes of assistance. The HIV/AIDS scheme is an exception to what is otherwise a pretty general rule and I think it may prove

easier to differentiate between the HIV/AIDS cases and the rest (though I recognize the argument is not easy) than it is to draw the line somewhere completely different.

I think Ministers will certainly wish to discuss this very fully with officials before reaching a view."

- (4) Minute from Mr Sackville's Private Office to my Private Office dated 11 April 1995. Mr Sackville said that he had seen Mr Scofield's submission of 6 April; that he thought it was important that I was well briefed for a Cabinet discussion; and that he thought that Mr Hart's paper (as set out above) looked "pretty decisive" [MHRA0024538].
- (5) A further minute from Mr Hart to Mr Malone's Office, dated 12 April 1995 [DHSC0042937_119].

"I understand M(H) has been invited to hold a meeting on this next Wednesday when I and a number of other officials involved are on leave.

I do not need to repeat the difficulties that would arise over any decision to concede on payments to those infected with Hepatitis C by blood transfusions or blood products. Those are difficulties of principle as well as practice - and I find them pretty compelling. I recognize, of course, that the political pressures could become too great but I think the prospects of persuading other Departments, especially the Treasury, that we had to move now are not at all good.

I am sure that it would be useful to have a full discussion of the pros and cons before a decision is reached. And, in the meantime, I am sure we must avoid giving any hints to anyone that our line could weaken. That could be fatal."

(6) Minute from Mr Malone to Mr Sackville on 1 May 1995 [WITN5289025].
"I know we have discussed this matter relatively informally but I thought it would be useful to have my views recorded on paper.

I would firmly and enthusiastically support a strategy to resist compensation payments. I think a logical and defensible distinction can be drawn between HIV sufferers and Hepatitis C sufferers.

However, if we were to resist compensation payments, it would be catastrophic to cave in to any subsequent pressure. There are three points to bear in mind:

- A national newspaper is bound to take a campaigning stance with the usual constituency consequences for our Parliamentary colleagues.
- 2. A number of supporters of the campaign are prominent backbenchers (e.g. Sir Geoffrey Johnson-Smith, a member of the 1922 Executive). This has a bearing on point number 3.
- 3. Number 10 must be taken along at all stages and alerted both to the likely vigour of the campaign and to the fact that the PM could be faced with a powerful deputation at what might be a difficult moment (it is quite likely that this would be around Party Conference time or at the time of a possible challenge to his leadership.)

Unless these pressures are clearly understood now, we risk placing SofS in the invidious position of being obliged to back down having initially resisted for all the right reasons. That is why we must consider the political consequences most carefully, before we decide how to react."

(7) I saw this minute and endorsed it with the observation:

"There will always be new examples – I believe we must hold the line – e.g. growth hormone etc. Please ensure senior official talk issue through with Carolyn Fairbairn – Also that territorials views are established" [WITN5289025].

My Private Secretary issued this as a request on 5 May 1995 [WITN5289026]. Carolyn Fairbairn was at the No 10 Policy Unit.

(8) A meeting was planned on 7 June 1995 to be led by Mr Malone to discuss the issue. On 5 June, Mr Pudlo provided an update ahead of that meeting:

"VIEWS OF THE TERRITORIALS

- 2. SCOTLAND The view of officials is that while the "no-compensation" position is becoming increasingly untenable, proposals to link payments to social needs and the degree of harm suffered would be difficult to establish and the (clinical) judgements required would make it costly and complex to administer. A crude estimate suggests costs on the basis of the HIV settlement in the order of £30m. The views of Ministers are currently being sought.
- 3. WALES Legal advisers are of the view that it would be difficult to sustain rejection of claims for compensation on the grounds of a distinction between those infected with HIV and HCV. Such grounds are considered insufficiently robust to resist judicial review.

Given the variable impact of Hepatitis C on individuals, clinical assessment of the effect will be difficult. At HIV rates the estimated cost for Wales is around £21m. If funded out of existing health votes there would be serious difficulties in delivering other health priorities. The views of Ministers are being sought.

4. NORTHERN IRELAND - Officials' view is that it is difficult from point of view of equity to resist comparisons with HIV compensation. But this could mean a substantial drain on health resources. The views of Ministers have not been sought yet. NO 10

Number 10 has not been fully briefed on the issues pending Health Department deliberations. Carolyn Fairbairn will be attending the meeting. one option mentioned by her that does not appear to have been considered so far, is to buy off the risk through private sector insurance. That is to provide all those affected with insurance cover against adverse effects. The pros and cons would depend on the cost of the premium but one

advantage before decisions had to be taken would be to have the benefit of independent risk analysis.

The Prime Minister has been asked by John Marshall MP (Hendon South) to receive a deputation of colleagues to discuss the plight of those infected with Hepatitis C. It is likely that the delegation would press for compensation along the lines of the HIV settlement, in which John Marshall was an active supporter. John Marshall is tabling an ELM calling for consideration of compensation to Haemophiliacs infected with Hepatitis C. No decision on how to respond has been made yet.

Legal Advice

Officials have undertaken an urgent discovery of relevant papers and legal advice on vulnerability to a charge of negligence has been sought. This is not yet available." [DHSC0004428_152]

(9) A meeting of 7 June 1995 attended by both Mr Malone and Mr Sackville as well as Carolyn Fairbairn) [DHSC0003552_155] and [WITN5289027]. Although my Private Office was not copied into the note of the meeting, the conclusion was that:

"...there was a need for ministers to obtain a robust view of the Department's ability to defend any litigation. More work needed to be done on this. However, all those present were agreed that it would be desirable to maintain the status quo and not to extend the principle of no-fault compensation either to those infected with Hepatitis C or CJD. The precedent of payments to those infected with HIV/AIDS through blood and blood products was not helpful in this context but it was agreed that a justifiable distinction could be drawn between HIV/AIDS and other viruses."

(10) On 13 June 1995, revised briefing was provided for No 10 on Hepatitis C copied to our Private Offices: [WITN5289028], [WITN5289029].

- (11) On the same day, 13 June 1995 we had discussed financial support at our Ministers meeting. On 20 June 1995, Mr Sackville provided me with a note on the resulting meeting between officials and the Haemophilia Society [DHSC0004428_049].
- (12) There was a further meeting on 21 June 1995 to discuss the growing pressure for financial support. From a subsequent note between officials (27 June 1995), it is apparent that I had asked for: a summary of the present position; the international position including territorial departments; a fall-back position if we had to concede; further, legal advice on vulnerability [WITN5289030].
- (13)On 3 July 1995, Mr Pudlo provided an update to my Private Office following the 21 June meeting, with an attached paper setting out quite extensively how officials the issues [WITN5289031] saw [WITN5289032]. There is an endorsement on the submission to the effect "P[rivate] O[ffice] rang 5/7 SoS has seen + noted "No further action needed at present"". This was the exact time when Mr Dorrell and I were effectively swapping Secretary of State roles. I therefore cannot be sure whether this note from the Private Office of the Secretary of State was briefly communicating my views as the exiting Secretary of State or the initial views of Mr Dorrell as the arriving Secretary of State. If it is communicating my response to the submission I would undoubtedly have known at this time that I was moving departments and I would not have made a major policy change just as I was exiting; whether to make such a change would be a decision to be made more appropriately by the incoming Secretary of State [DHSC0002549_108].

7.41. In addition to the above developments:

(1) On 15 May 1995 I wrote to the Prime Minister John Major who had written to me on behalf of a constituent requesting his view on compensation for those who had contracted Hepatitis C via infected blood [DHSC0002556 127]. I set out the Department's view of the

provision of compensation to recipients of NHS blood or blood products who contracted Hepatitis C My response was in like terms to Mr Sackville's earlier letter to Mike Hall [DHSC0006861 193].¹⁰

(2) On 18 May 1995, Mr Scofield sent a submission to my Private Secretary in response to an urgent request I had made for advice on how other major countries had reacted to hepatitis C infection through blood and blood products [DHSC0002549_165]. I was told that the information was not readily available but that Mr Scofield had asked Dr Rejman to provide a table showing the position on HIV and Hepatitis C for each country later by the close of play the following day. In the meantime, Mr Scofield advised that:

"No consensus has emerged concerning the way in which those who have been damaged non-negligently should be treated.

So far as we know the UK is the first country to put in hand a general <u>look back exercise</u> to trace, counsel and where appropriate treat those infected.

We have no hard details of other countries who have set up compensation schemes for those infected with Hep C. IRU have asked for details." (original emphasis).

(3) On 19 May 1995 Dr Rejman provided my Private Secretary with the table of comparisons stressing that it was the best information that could currently be obtain, but there are bound to be inaccuracies [WITN5289034]. Five of the countries tabulated had no payment scheme for Hepatitis C; Sweden had a scheme but only for payments after 1990 when a test became available; Austria and the Republic of Ireland had – or were going to have – a payments scheme.

¹⁰ Because the correspondent had also copied his letter to Mr Major directly to me, a response also seems to have been sent on 12 May 1995 by a DH official Mr Levy [WITN5289033]

- 7.42. As will be apparent from the outline chronology I have set out above, I had some direct involvement in discussions regarding the possible provision of compensation or financial support to those who contracted HCV through blood or blood products. While Mr Sackville had the delegated responsibility in this area, I too was involved in the discussions and consideration and it is apparent that I gave personal input, for example:
 - My response of 1 May 1995 indicating that I thought we must hold the line but I wanted to make sure that No 10 Policy Unit and the territorial departments were alerted to the issues. While I had asked that the issues be discussed with Carolyn Fairbairn, I doubt I would have been aware of any personal views of the Prime Minister on this issue. My letter to Mr Major of 15 May 1995 was writing to him in his constituency capacity and that kind of exchange would not, I think, have involved a discussion with him or an exchange of views outside the correspondence. Had Mr Major been concerned with my reply, he would have raised this with me.
 - My request later in May 1995 for information about what other countries had done.
 - My request for further information at the meeting of 21 June 1995.

The fact that I had asked for information on how other major countries had reacted reflects that I was wanted to understand what we could learn from the knowledge and the approach in other jurisdictions. At the 21 June 1995 meeting I had also asked for information on a fall-back position.

7.43. Advice from our officials raised significant concerns about the implications of financial support to those infected with HCV. The strength of those concerns is evident from the Permanent Secretary's interventions of 6 and 12 April 1995. They are also evidenced by the paper provided by Mr Pudlo on 3 July 1995. We were keeping this issue under review and I note in particular that further legal advice was awaited at the time that I left the Department to become Secretary of State for National Heritage. Our position remained against an extension of ex gratia financial support. The Inquiry asks what my personal views were. As I have explained in relation to the earlier consideration of HIV

payments, it would have been inhumane not to want to go further but as Ministers we had to weigh up the countervailing risks, of which the most compelling argument was the precipitous slope of making ex-gratia payments in all cases of NHS treatment causing injury or disease where there was no finding of medical fault.

Section 8: Other issues

- 8.1. To the best of my knowledge and belief, none of my Government roles other than Minster of State for Health and Secretary of State for health caused me to be involved in the subjects set out in the Inquiry's Terms of Reference.
- 8.2. The Inquiry invites me to reflect on how the Department, the Treasury and the Government handled the various issues.
- 8.3. I have referred a number of times to the fact that as Health Ministers it would have been inhumane not to want to go further or faster than we did, but that at the same time we had to weigh up the countervailing impacts on other health priorities in areas of severe unmet need. Any reference to such countervailing impacts (principally the immediate cost and the wider precedent) risks sounding theoretical if not uncaring, whereas for us as Ministers they were serious and compelling. They involved our ability to spend in other vital health areas. Our strategy for improving The Health Of The Nation had to address key areas of poor health outcomes most notably cancer, heart disease and stroke, mental health as well as the wider HIV and AIDS epidemic. Balancing such critical competing demands is the central conundrum and responsibility which Ministers in the large spending Departments face. The concern about the precedent of extending ex gratia payments was genuine and deeply held.
- 8.4. In any close retrospective examination of one policy area, it is a challenge sufficiently to appreciate the wider contemporaneous context and pressures from other priorities and policy areas that were current at the time.
- 8.5. The Inquiry will have noted that at some pivotal times in policy discussions, the most senior advisers in the Department intervened to caution about the precedents that we risked setting. That can be seen in:
 - (1) Chris France and Strachan Heppell minuting their profound concerns about extending the payment schemes to those infected with HIV (December 1992).

- (2) Graham Hart's interventions in April 1995 when Gerald Malone was initially inclined to favour a payments scheme for Hepatitis C.
- 8.6. I do not raise these interventions critically. On the contrary, these were our most senior advisers who were able and impressive, and cared about the delivery of our health objectives for the benefit of all patients. Reflecting on matters now, these interventions reveal the intensely difficult tensions between:
 - (i) Wanting, on a humane and compassionate approach, to do more for the victims of infected blood and blood products;
 - (ii) The fact that we were already pushing at (and in some cases going over) the boundaries of what our most senior officials thought advisable having regard to the immediate costs, and the wider precedents that more payment schemes would set. However difficult it is to raise in the context of this Inquiry and those infected and affected by infected blood / blood products, there were other patients and affected groups who had suffered serious adverse outcomes from medical treatment, for whom the moral obligation argument may be said to have applied with similar if not identical force.
 - (iii) What was achievable in practice. The Treasury is relevant here but not as the caricature of a miserly hindrance to progress by a big spending department. The Treasury had its job to do to control spending in the interests of overall fiscal responsibility and the exchanges with the Treasury have to be seen in that light. At the same time, it can be seen that the Treasury issued their own repeated warnings about the dangers of the moving ringfence in the exceptions made to the stance against no-fault compensation. This was a significant "brake" on extending the payments scheme to blood transfusion patients in 1991 (though one that was overcome by early 1992) and it featured significantly in officials' advice about the counterarguments to an HCV payments scheme.
- 8.7. Reviewing the matters which the Inquiry has raised with me, I identify some areas where we probably could have moved quicker. With some hesitation –

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because I was not involved in the detail and it may be unfair to those who were – I would note that we seem to have taken too long to set up the discretionary payment (what became the Eileen Trust) element of the blood transfusion payment scheme having confirmed the principles of the scheme and the lump sum payments element in April 1992. Might we also have moved more actively towards the settlement of the HIV litigation by making our own offer before November 1990? Whether that would have led to an earlier or different settlement, in the absence of the November 1990 proposals from the plaintiffs' side, is far from clear.

- 8.8. In addition to the above, there are some central questions:
 - Was the HIV settlement sufficient?
 - Should we have funded the MacFarlane and Eileen Trusts more fully?
 - Should we have extended the HIV payments scheme to blood transfusion cases much more quickly, or even at the same time?
 - Should we have found a way to agree an HCV payments scheme of the kind eventually introduced in 2003 mid way through the second Blair administration?

These are all difficult to address even with hindsight. Ultimately, they called for political judgements to be made and there were real issues about what could be achieved in practice at the time. They were difficult and complex judgements. A balance had to be struck on whether payments should be made; on the level of such payments; and in some cases, on when it was achievable to change policy.

8.9. The Inquiry asks if there was ever a specific assessment of the impact of infection with HIV or HCV on the lives of those infected. I am not aware of the Department commissioning a study in those terms but as the Minister of State who had the wider HIV/AIDS remit, we were aware of the devastating impact of HIV. The payments schemes had not been set up to meet the entirety of the needs of those infected since that would have been akin to awarding no fault

compensation. They were funds set up with Government–provided lump sums in order to mitigate financial hardship and, by the later lump sums, provide a measure of support unconnected to individual financial situations. As I have indicated, the agreement to provide a further £5 million to the Macfarlane Trust in 1993 reflected the Government's ongoing commitment to continuing support of this kind. But – as I have explained – we did not see the payments as providing compensation. Nor did we believe, or suggest, that they would give recipients financial independence in the sense that the infected or their families would not need to call on benefits or the wider welfare state. This again was the result of the Ministerial judgements that had to be made about how to balance multiple competing deserving causes against finite health resources.

- 8.10. I am asked if I gave consideration to calls for a public inquiry. I do not recall calls for a public inquiry being a significant feature while I was in post. From the available records rather than from any current recollection, I note that a 'commission of enquiry' was raised by Mr Dobson in his detailed paper of 24 July 1990 in considering options following Mr Justice Ognall's intervention [DHSC0004360 147]. He set out this option in the following terms:
 - " 15. A further approach would be to take up the suggestion of a commission of enquiry. This could be used in one of two ways:
 - (i) the commission could be asked to consider whether the haemophiliacs constituted a sufficient special case to justify a further ex-gratia award; and if so, on what basis (Option C1). This option could well prove more costly in the short-term than any form of out-of-court settlement but it does have the advantage that a form of 'ring-fence' is built in from the start. (There is, of course, some risk that the commission would conclude that both the haemophiliacs and other categories of medical accident should receive compensation.) One disadvantage is that if the commission were to do their job thoroughly there is no certainty that they would be much quicker than allowing the litigation to take its course;
 - (ii) alternatively, an out-of-court settlement could be linked to a commitment to review the general case for a no-fault compensation scheme for medical accidents (C2). This would signal the government's

wish to respond to public sympathy for this particular group of patients, without making unwise changes to policy (or setting the precedent for such changes) on the basis of a single case. The likelihood is that the review would confirm the findings of the Pearson Commission against any form of general no-fault compensation. However, there is a risk that the review itself would be coloured by the favourable treatment given to haemophiliacs — it is unlikely that it would conclude that this treatment was unnecessary — and so that the outcome would be exactly the opposite to that intended. It would also in practice be impossible to limit the review to medical accidents, since other types of accident (e.g. major transport accidents) raise similar problems of the moral responsibility of government to help innocent individuals who are harmed by some public sector agency. For these reasons, any proposal for such a review would have to be cleared with a wide range of interests including the Home Office, DTI and Treasury, all of whom would be likely to be very resistant."

I do not recall what was made of this option at the time but the option that Ken Clarke (with my agreement as Minister of State) agreed upon in July 1990 was to continue to defend the litigation. It is likely that the 'commission of enquiry' option would have seemed unattractive for the reasons set out in Mr Dobson's paper. Once the litigation had been settled, my sense is that the settlement deal was seen as having been the mutually-agreed compromise of the issues that had been raised. I have not seen, for example, a submission coming to me in my time as Secretary of State raising the question of whether a public inquiry should be convened.

8.11. With hindsight, an inquiry commissioned at the time of the HIV litigation may have avoided some of the difficulties experienced by this Inquiry being held so long after the material events, and the concerns raised in Lord Fowler's evidence to which the Inquiry has drawn my attention. Nevertheless, as matters stood in 1990 the option of holding a public inquiry was not attractive because:

(i) it was unlikely to report quickly enough to deal with the immediate calls for greater financial help for those infected;
(ii) there was concern that it may trespass outside of the question of payments to the infected haemophiliacs and

into wider issues of compensation for medical (and even other types of) accidents.

- 8.12. My own experience of commissioning inquiries has been mixed. Earlier in my career I had often found social care and healthcare reviews were generic and similar in the sort of findings and recommendations they made. I was generally cautious and resistant to the use of inquiries as a short term expedient. I did nevertheless commission inquiries in those cases where I considered it appropriate. Christopher Clunis (report by Jean Ritchie QC) and Beverly Allitt (report by Sir Cecil Clothier) were examples.
- 8.13. I agree there are quite exceptional occasions where full public inquiries are justified. In this case the suffering of patients and their families those infected and those affected justifies the serious focus being given to it and I accept that it would have been better for this to have been done sooner.
- 8.14. The Inquiry has referred me to a letter of from a member of the public dated 2 May 1994. She had been infected with Hepatitis C after treatment with intravenous immunoglobulin and what was said to have been in infected batch of the product from the manufacturer Baxter [DHSC0004014_062]. The reply suggests that this correspondence would not have been drawn to my attention but was sent to the relevant Branch for a response from officials [DHSC0004014_063]. The Department did receive a number of individual letters of this kind (as we did on very many other issues). It remains my recollection that, following the settlement of the HIV litigation, we did not face concerted calls for a public inquiry. The main focus was on extending the financial support to (initially) blood transfusion patients, and subsequently for the same to be provided for those infected with HCV.
- 8.15. I am asked what part the Inquiry findings in other countries played in our decision making. From the available papers, while I was in post, 27-32 years ago, the greater focus was on the measures that were being taken in other countries to provide support. I have addressed already occasions when I asked for such comparative information. We received a request for assistance from

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the Canadian Krever Commission in a letter addressed to me on 21 December 1993 [DHSC0004075_185]. Mr Sackville replied on 26 January 1994 offering assistance through the National Blood Authority and Mr Canavan [WITN5289035]. The Commission did not report while I was Secretary of State.

Statement of Truth

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

Signed GRO-C

Dated 9th France 2022