Witness Name: Thomas Sackville
Statement No.: WITN5249001
Exhibits: WITN5249002 – WITN5249056
Dated: 19 July 2022

INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF THOMAS SACKVILLE

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I, **Thomas Geoffrey Sackville**, will say as follows: -

Section 0: Opening Comments

0.1. I have been asked by the Infected Blood Inquiry to provide a witness statement regarding my involvement in the issues covered by the Inquiry's Terms of Reference during my period in office as the Parliamentary Under Secretary of State for Health in the Department of Health ("DH") from 10 April 1992 to 29 November 1995. My full name is Thomas Geoffrey Sackville and my address and date of birth are known to the Inquiry.

General observations

0.2. I would like to make the following general comments before I address the Inquiry's questions.

0.3. I have done my best to answer the Inquiry's questions, despite deteriorating health and the passage of time. However, my recollections of discussions and actions are limited compared to those of other topics for which I had responsibility. I would especially mention NHS IT, the Ambulance Service and the firm policy of opposition to "presumed consent" in organ transplantation.

0.4. This should not be taken as indicating any perception that these were more important than matters concerning infected blood. I was well aware that the harm sustained by sufferers was as bad and deserving of sympathy as those from other medical accidents. It is rather that I felt I had some "ownership" of those policy areas, and could take decisions which would guide government policy.

0.5. I acted under the overall perception that key decisions had been taken by my predecessors, and would continue to be taken by my ministerial superiors and the top officials in the Department; in the case of authorising new expenditure, by the Treasury or even Cabinet.

0.6. I have therefore felt the need to take full advantage of the services of legal advisors offered to me, in guiding me through the relevant documents and assisting me with the drafting of this statement.

0.7. In the statement that follows the section numbers follow the structure of the Inquiry's Rule 9 request to me.

0.8. I have been provided with a relatively limited number of documents by the Inquiry itself. The Government Legal Department as my legal advisers have provided me with a wider range of documents from the disclosure provided to the Inquiry by the current Department. However, the documentary record is not perfect. I may need to amend this statement or add to it if further relevant documents are drawn to my attention. This is particularly important given that some of the Inquiry's questions to me are very broadly phrased.

Section 1: Introduction

Qualifications and Employment History

1.1. I have been asked to set out my relevant professional qualifications and employment history which is as follows:

1970 -1973	I worked for Deltec Banking, New York.
1973 -1974	I worked for Industriefinanz Gmbh, Munich (interbank deposit broker).
1974 -1977	I worked for Grindlays Bank, London.
1978 -1982	I worked for International Bullion and Metal Brokers (importers and distributors of precious metals and industrial safety equipment)
1983 - 1997	I was the MP for Bolton West. • I served as Parliamentary Private Secretary to two Ministers, Barney Hayhoe (1985-1987) then Nicholas Scott (1987-1988) I then served in various ministerial roles from 1988-97: • 1988 Appointed Assistant Government Whip; • 1989 Appointed Government Whip; • Parliamentary Under – Secretary of State for Health (10 April 1992 – 29 November 1995) • Parliamentary Under – Secretary of State for Home Affairs (29 November 1995 – 1 May 1997).

1998 - 2020	• I was Chief Executive of the International Federation of Health Plans (a worldwide health insurance trade association) • I was President of the European Federation of Centres of Research and Information on Sectarianism (a French based European federation of family support groups for cult victims) • I was Chair of Trustees of The Family Survival Trust (a charity whose mission is to look after the family members of a person lost into a cult)

Positions held at the Department of Health

1.2. In my role as Parliamentary Under-Secretary of State for Health (10 April 1992 to 29 November 1995) I was one of five health ministers. The Secretary of State was Virginia Bottomley to July 1995, then Stephen Dorrell. The Minister of State was Dr Brian Mawhinney and then Gerald Malone. The Parliamentary Under-Secretary of State for Health in the Lords was Baroness Cumberlege. The other Parliamentary Under-Secretary of State in the Commons was Tim Yeo who was succeeded in May 1993 by John Bowis. To differentiate between the two Parliamentary Under-Secretaries of State in the Commons, my post was designated in submissions etc., as "PS(H)" while Tim Yeo / John Bowis were "PS(C)".

1.3. As PS(H), I had a wide portfolio of responsibilities. From recollection, I was most active in:

(1) Promoting organ donation, the migration from Donor Cards to the Organ Transplant Donor Register in particular;

(2) Increasing Paramedic training, and encouraging use of emergency ambulance despatch protocols;

(3) NHS IT;

(4) Rationalisation of the hospital network outside London;

(5) Completion of the “Payer/Provider” and Internal Market reorganisation of the NHS in England;

(6) The National Blood Authority;

(7) Birth control and sex education;

(8) Pharmaceutical industry (where delegated by Minister of State);

(9) Media and public appearances (where delegated by Secretary of State) on any departmental topic.

1.4. To the best of my recollection, I was not involved in any relevant Committees or Working Parties.

1.5. When I gave a written statement to the BSE Inquiry (see further below) [MHRA0018946_056]. I was able to include reference to the list of areas of Ministerial responsibilities as it stood at May 1992, in which I had the following portfolio:

> *"acute services (including cancer); waiting lists; transplantation; ambulances; blood; voluntary sector (including s64 grants); crown immunity; NHS IT; capital loans; abortion; family planning; Warnock; private sector; patients' charter; complaints; disciplinary cases; civil defence; DH management (including Next Steps); unconventional finance; income generation; VFM/competitive tendering; confidentiality; superannuation; deregulation; laboratories; NHS estates; and OPCS [Office of Population Censuses and Surveys]."*

1.6. On 15 June 1993, a DH press release listed my ministerial responsibilities. The areas of responsibility included Pharmaceutical Industry; Blood; and Laboratories [WITN5249002].

1.7. I gave the BSE Inquiry the following overview recollection of my time as a junior health minister:

> *"My general recollection of the period April 1992-November 1995 is that it was the busiest three and a half years of my political career. My portfolio of responsibilities included the process of reducing the number of Health Authorities by about half, and the rationalisation of acute services which involved decisions on proposals to close several large hospitals. These were matters which involved considerable public discussion and controversy. In addition, I took particularly seriously my responsibility for the regional ambulance services. I visited, and attempted to keep in contact with each of the 30 or so English ambulance services. I was responsible for the launch of the Private Finance Initiative, and the re-organisation of the Blood Service. More generally, I routinely represented the Secretary of State when she was invited to but unable to attend hospital opening ceremonies and similar public functions. Likewise, I undertook much of the "case work" involving acute services, which involved meeting other members of Parliament, often accompanied by delegations who wished to make representations on health issues relevant to their constituencies".*

Senior Officials within the Department of Health involved in blood products issues

1.8. I am asked which senior officials within the Department were involved in providing advice or information to me about the issues covered by the Inquiry's request. Where I received submissions on particular issues, I have made clear in this statement who the author of those submissions was. I do not otherwise have any independent recollection of the officials who were most involved.

Evidence provided to other inquiries, investigations or criminal/civil litigation, relevant memberships

1.9. I have already referred to my statement to the BSE Inquiry. I also gave oral evidence to that Inquiry on 14 December 1998 (day 93); Virginia Bottomley and Lady Cumberlege gave evidence alongside me [MHRA0018946_019].

Membership of committees, etc

1.10. I do not have membership, either past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference.

Section 2: Safety of the Blood Supply

Arrangements for receiving information and advice

2.1. The Inquiry asks me to set out my knowledge of the arrangements in place during my time at the Department of Health for receiving information and advice about blood and blood products and their safety.

2.2. The Inquiry has not supplied any documents associated with this request, nor focused the request the request in any other way. As such and after such a long time I find this request difficult to address meaningfully.

2.3. Beyond the documents made available to me, I do not have any active memory about what I learnt on this and from whom. Therefore, the written records are the best guide to what I was told, albeit I appreciate that they may not be complete.

Knowledge of risk of infection with Hepatitis C

2.4. I am asked by the Inquiry to comment on what (if anything) I was told about the risks of the transmission of Hepatitis C from blood and blood products when I became Parliamentary Under Secretary of State. I am also asked whether my knowledge of such risks changed during my tenure (and, if so, how and by what means).

2.5. I cannot now recall what I knew about Hepatitis C or when. It is likely that I would have been briefed by individuals within the DH with responsibility for blood and Hepatitis C on various occasions. I cannot now say at what stage during my time in office these briefings would have taken place. I do not recall whether I received any briefing on Hepatitis C when I came into the department, and certainly not any of the detail of what I might have learned subsequently.

2.6. It is relevant to note here that Baroness Cumberlege's portfolio of responsibilities included infectious disease (so HCV) as well as HIV/AIDS.

2.7. The best source of information about what I knew and when is likely to be the information contained in the submissions directed to my Private Office, which are referred to elsewhere in this statement.

2.8. I would like to pay tribute to the officials who worked in the Department; I had maximum faith in their abilities. I believed I was able to rely on what they told me. It is invidious to single out particular individuals when advising and keeping ministers informed was a collective effort, but Strachan Heppell in particular comes to mind. Also, Richard Armstrong in my Private Office. He had very good judgement when it came to deciding what needed to be raised with me.

Section 3: Establishment of the National Blood Authority

3.1. The Inquiry asks about the establishment of the National Blood Authority.

3.2. By the time I had become Parliamentary Under Secretary for Health, there had already been a consultation exercise on the proposed new National Blood Authority. The consultation paper had been published by the Department in September 1991 [HSOC0004153]; [DHSC0006835_043] and responses received. I was not involved at that stage as I was still a Government whip. Prior to the 1992 election, Ministers had already decided in favour of:

(1) the basic principle of the establishment of a NBA;
(2) a slower timetable for its introduction; and
(3) the establishment of a technical working party to consider detailed issues before the NBA's role and responsibilities would be finally determined.

3.3. The documents provided to me include a draft section for the CMO's briefing for incoming Ministers after the 1992 election. The section on the NBA summed up the then current position as follows;

> "*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.*" [DHSC0003591_081]

This is probably the best guide to the sort of overview introduction I would have been given on the issue of formation of the NBA when I took up the PS(H) role. However, I do not now have any independent recollection of what, if anything, I was told about the creation of the NBA at this stage. I was, in general terms, aware of the sensitivity of the issues in the background to the formation of the NBA and the need to avoid stigmatising certain demographic groups.

3.4. I can see from the documentary record that I visited the CBLA on 6 July 1992 but do not directly recall it. I was provided with a background briefing for this visit. This comprised [DHSC0003591_023]:

(1) Covering note from Mr Canavan dated 2 July 1992
(2) Programme for the visit (flag A)
(3) General background briefing (flag B) which also incorporated:
  - Annex A organisation chart for CBLA
  - Annex B CBLA membership
  - Annex C notes on the management personnel expected to be present
  - Annex D a summary of sales and financial information

(4) Briefing on current issues (flag C) – the version that survives appears to be truncated after page 2;
(5) The CBLA's Annual Report[1] (flag D) [NHBT0017149].

3.5. The Current Issues briefing (flag C) had as its introduction, the following explanation:

> *"The main issue which is current is whether BPL should become part of the proposed National Blood Authority or be given independent status outside the NBA. PS(H) will wish to consider the submission on the NBA which will be put forward shortly and await the CBLA Accountability Review before making decisions. The visit will provide the opportunity to discuss the issue but PS(H) will not wish to commit himself one way or the other but can say that he will consider all the arguments in the next few months."*

3.6. On 8 July 1992, my Private Secretary minuted Mr Canavan setting out two matters I wished to have followed-up [DHSC0003591_022]:

> *"Following the visit to the CBLA on Monday 6 July there are two issues that PS(H) wishes to follow-up.*
>
> *<u>NBA</u>*
>
> *PS(H) supports the creation of a National Blood Authority (NBA) and believes that this is something officials should be working to achieve in the near future. However, he has some concerns that the NBA is planned to be simply a policy orientated authority rather than having direct*

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[1] Only the covering page is contained in the documents available to me.

> *responsibility for the management and delivery of blood services (i.e., the regional transfusion centres and BPL). PS(H) would wish to have a paper setting out officials' thinking on the NBA, how it proposes to work, its relations with RTCs/RHAs and the proposed relationship with BPL.*
>
> *Future Management of BPL*
>
> *PS(H) is interested in moving BPL towards a more commercial relationship in competing for business in England and Europe. He is not however, convinced that the time is right for a complete move away from public control, especially as they have yet to demonstrate financial viability. PS(H) would wish officials to pursue suggestions that BPL could become a trust or an Agency (in time moving towards trading fund status): as well as the option of BPL staying within the control of the NBA. PS(H) is more struck by Agency status than becoming a trust in that it will ensure management and the Board of BPL taking a hard-headed look at their business and the actions they need to take to ensure financial viability. He believes Agency status is a better mechanism by which to make them consider these options.*
>
> *One issue which was of particular concern to PS(H), and on which he wishes to have more information, is the funding formula agreed between the CBLA and RTCs for providing plasma to BPL. PS(H) is concerned that this is loaded against BPL and wishes to see a rationale of the current costing. The Minister would also like more information on various charges made by each RTC in providing plasma to BPL and how this differs from the "spot market" price for plasma. If plasma was not provided to BPL would there be savings for the RTCs or would the cost occurring to RTCs in obtaining blood remain the same?"* [DHSC0003591_022]

3.7. While my instinct was to move BPL away from public control as mentioned in the minute, ultimately this was not viable and it remained in public ownership until after my tenure.

3.8. The technical working group reported in late July 1992 [SBTS0000466_008]

3.9. On 24 July 1992 Mr Scofield put a submission to me reporting on the recommendations of the DH/NHS technical working group but also considering the case for going beyond the working group's recommendations and establishing the NBA as the managing authority for the Regional Transfusion Centres. [DHSC0006379_085]. The recommendations (which I was invited to confirm) were that:

(1) The National Blood Authority should be established;

(2) The NBA should be set up along the lines recommended by the Technical Working Group in the first instance but with a firm commitment to move to direct management of the RTCs as soon as possible and no later than twelve months after the NBA is formally established;

(3) BPL should be an integral part of the NBA;

(4) Subject to the results of a cost appraisal, the NBA should be located at a neutral site;

(5) The NBA should be set up as a Special Health Authority; and

(6) The target date for establishing the NBA as an operational unit should be 1 April 1993.

3.10. On the same day, 24 July 1992, Mr Canavan provided me with a submission on the plasma pricing issue (as requested by my PS on 8 July 1992) [DHSC0002439_021]

3.11. My views and decisions on Mr Scofield's submissions were conveyed in a minute from my Private Secretary on 30 July 1992 [DHSC0041257_130]. I gave broad agreement to the recommendations in Mr Scofield's submission. My PS noted that:

> *"PS(H) has seen your submission of 24 July with recommendations on setting up the National Blood Authority (NBA), PS(H) is broadly content with the proposals set out in paragraph 27 of the submission and consequential actions in paragraph 28. He does however have one or two comments on specific points contained in your submission.*
>
> *Para 9, PS(H) is very strongly in favour of NBA having direct management of the RTCs. However, he is unsure whether it is necessary for a specific joint DH/NBA planning and implementation group.*
>
> *With regard to BPL's role within the NBA (para 12) PS(H) has commented:*
>
> > *"I prefer independent status, so long as we have agreement on BPL being charged for plasma; perhaps world spot (price?) – what effect would this have for the rest of the NHS?"*
>
> *PS(H) does recognise that independent status for BPL will be some years off: in the meantime, he would wish to encourage CBLA to seek agency status in the not too distant future.*

> *With regard to the future location of the NBA, PS(H) sees particular reason why the new authority should not be located in Manchester. Finally, PS(H) has asked to be kept informed of the interest being shown by the Office of Fair Trading (OFT) into BPL. He would appreciate some first thoughts from solicitors over the possible implications resulting from an OFT investigation.*
>
> *Apart from these points PS(H) is content for officials to proceed with the actions proposed in para 28 (a-g)."*

3.12. I was in favour of the NBA having direct management of the RTCs because I was convinced by the business argument and believed that this approach would raise standards and increase efficiencies. Later in my career I may have taken a different view as I increasingly became an advocate of more devolved local control.

3.13. On 13 August 1992, Mr Wing (Chairman of the CBLA) wrote to me stating [DHSC0041084_063]:

> *"I have been confidentially informed of your bold and welcome decision concerning the establishment of a National Blood Authority and a nationally managed service. I know my Authority will be most pleased about this decision though I shall defer informing them until I am appropriately advised.*
>
> *I can assure you that CBLA will give every support to ensure success of this initiative."*

3.14. The Department's position on the NBA was summarised in a paper for a meeting between the NHS Management Executive and Regional General Managers on 10 September 1992 [NHBT0002202]. Under the heading "NBA as Manager of the Blood Services", this paper explained as follows:

> *"Ministers have accepted the need for a strategic body for the blood services together with the detailed recommendations made by the Working Group. The Group had been given as one of its assumptions that; the RTCs would continue to be managed by the RHAs and therefore it had to propose forms of relationship between the NBA and RTCs which took account of that assumption. As a result:-*
>
> *1) under the Working Group's proposals accountabilities between the NBA, RHAs and RTCs tended to overlap and there was scope for conflict; line management authority would rest with Regions but RTCs operations*

> *would effectively be controlled by the NBA; thus the RTCs would be trying to serve two masters;*
>
> *2) Similarly there was concern that the NBA would not have sufficient "teeth" to bring about the necessary changes in the RTC network; it would have to rely on backing from Ministers, NHSME and RGMs rather than on statutory authority vested in itself. At the very least this could delay the desired improvements in quality and efficiency. Consultants reporting to the National Directorate in 1991 indicated there could be scope for saving several million pounds a year in the RTCs operating costs. It is in the NHS interest that such savings should be realised as quickly as possible.*
>
> *Ministers therefore believe that the NBA should directly manage the RTCs in order to ensure that national blood supplies are obtained as cost efficiently as possible"*

3.15. The paper went on to explain the two stage approach to the formation of the NBA, with it taking on the strategic authority role first (planned for April 1993), followed by assuming later the full responsibility for managing RTCs (planned for April 1994). The summary of the paper explained that:

> *"The principle of establishing a NBA and its objectives were widely supported in consultation with the NHS last year. The Technical Working Group has made recommendations within its remit to meet the concerns expressed over operational aspects of the NBA. Ministers have accepted those recommendations in the main but are minded to go further and integrate the RTCs into the new Authority. This will give greater assurance to the task of improving the quality and efficiency of blood supplies to the NHS users. It is proposed formally to establish the NBA from 1 April 1993 initially along the lines recommended by the Technical Working Group, but then to integrate the RTCs into the Authority from April 1994."*
>
> *Action*
>
> *RGMs are invited to comment on the proposals."*

3.16. A minute from Mr Scofield to Mr Malone-Lee of 11 September 1992 reported on the views expressed at the meeting of the NHS ME/ RGMs the following day. The minute was not copied to my office but it referred to a discussion between Mr Scofield and my Private Secretary Richard Armstrong [DHSC0020825_043]:

> *"6. A number of RGMs - certainly the most vocal - were basically representing the ambitions of their respective RTCs to become self-governing Trusts. Catherine Hawkins had foreseen that this would be the tack.*

> *7. In the general the RGMs addressed the issue from the perspective of the local RHA/RTC. They didn't tackle the question of improving the service at national level nor of optimising the functions of the NBTS and CBLA including all the complex problems of pricing. Discussion of the internal market was superficial and not enough weight was given to the sensitive nature of the service.*
>
> *8. In my view the blood service does not lend itself to a free market with RTCs fighting each other for donors and sales to local hospitals, nor would most donors accept such handling of their free gift. The rationalisation of the service needs to be managed rather than left to market forces. The position is analogous to the London question where it is generally accepted that special circumstances apply and powerful interested parties are involved.*
>
> *9. I believe that it would be possible to set up the NBA as proposed in the paper but with the agreement that once the rationalisation of National blood services has been completed and a healthy and efficient service has been produced, further consideration will be given to launching the remaining RTCs in the form of NHS Trusts. This decision would be made in the light of experience of purchaser/provider relationships in general and any developments in making other support organisations into Trusts. This commitment to giving the NBTS units as much freedom as possible would parallel the corresponding ministerial commitment that BPL should move to independence as quickly as possible.*
>
> *10. I have spoken to Richard Armstrong PS/PS(H) who had asked for a feedback from the meeting and he felt that Minister was likely to go along with this proposal providing he could be sure that the radical changes had been made first and that Ministers could be satisfied at the time that the Trust solution would maintain and improve the overall service.*
>
> *<u>Handling</u>:*
>
> *11. You will wish to consider whether to report back to PS(H) immediately and offer this compromise solution and then seek to sell it at the meeting with RHA Chairman 23 September, or to await that meeting and then report back when the overall consensus between RGMs and Chairmen has become clear."*

3.17. Flowing from this, on 18 September 1992, I received a further submission from Mr Scofield [DHSC0006379_006]. Mr Scofield wanted to know whether I was prepared to consider Trust status for RTCs albeit at some later date. He also asked whether I was prepared to accept the compromise solution for the management of RTCs, described in the following terms:

> *"...the RTCs to be directly managed by the NBA while the national strategic plan was being drawn up and implemented, but for the NBA to be tasked with identifying alternative delegated management models for the RTCs, including Trust status, once a satisfactory rationalised*

> *National Blood Service has been established. This would parallel the action that the NBA would be required to undertake in preparing BPL for early independence. The timetable and form for the delegated authority would be spelled out in the strategic plan which the NBA would need to draw up as one of its priority tasks"*

3.18. On 23 September 1992, my Private Secretary responded to this submission noting the following as to my views [DHSC0006379_005]:

> *"2. PS(H) is content for the NBA to take direct control of the RTCs. On the question of Trust status, he feels that this should be noted as a vague possibility for the future, but should not be offered as an excuse for the NBA taking direct control, which he feels is absolutely necessary to improve efficiency and to get costs down. His one concern about this approach is that RTCs should not lose their regional flavour and thus threaten their donor base.*
>
> *3. PS(H) is unsure whether RTCs are really suitable to become trusts. He would like to know the average income of each RTC and what the Trust Unit's view is."*

3.19. On 2 October 1992, I received the requested views of the Trust Unit on whether Trust status was suitable for RTCs [WITN5249003]. The conclusion and recommendation of the submission was that:

> *"We have not received further expressions of interest in subsequent waves and it is recommended that SofS reaffirms that Trust status is not the correct management model for Blood Transfusion Services at present. The National Blood Authority does not become operational until the 1 April 1994 and it would not be appropriate for us to consider RTCs for Trust status until after the NBA had wrought changes to the blood transfusion supply service (at the very earliest by September 1994 or 6th wave). It is suggested that this matter is reconsidered then."*

3.20. On 6 October 1992, Mr Canavan sought observations from the Departmental Solicitors, following the request I had made for advice on the possible implications resulting from the OFT investigation [DHSC0041214_046]. It seems that the initial advice from the Solicitor's Division was that this issue was dependent upon a wider issue of whether NHS contracts fell within the ambit of the restrictive trade practices legislation [WITN5249004].

3.21. The CBLA annual accountability review took place on 15 October 1992. I was given a handling brief for this [DHSC0004716_045].

3.22. On 23 October 1992, Mr Canavan provided a submission with information on the variability of performance amongst the RTCs [WITN5249005]. He suggested that, within the limitations of the available data, the indicators were that performance was variable and the NBA will need to get behind the figures to determine the causes and how to make improvements. He noted that the exercise highlighted the shortcomings of the existing arrangements in that the national directorate was not able to insist upon RTCs adhering to national costing and management information systems and some RTCs were reluctant to provide them with any data.

3.23. I then received a further submission from Mr Canavan, dated 26 October 1992, regarding the formal announcement of the creation of the NBA and appointment of the Chairman designate [DHSC0041257_098] [DHSC0041257_100] [DHSC0041257_101] [DHSC0041257_102]. The submission came with information about the five potential candidates for Chairman (copies of which I understand are available to the Inquiry). On 29 October 1992, my Private Office passed on my request for a meeting with the relevant officials to discuss the appointment of the Chairman designate [DHSC0041257_097]. The meeting was held on 3 November. On 5 November, my Private Secretary minuted Mr Malone-Lee following my having spoken to Sir Colin Walker, who ended up as the preferred candidate [DHSC0041257_096].

3.24. I had worked with Sir Colin on a number of issues following my appointment to the Department and had confidence in him. I did not have the same relationship with the leading alternative candidate, Dr Burgess.

3.25. On 5 November 1992 Mr Canavan provided a draft note for me to update the Secretary of State on NBA developments [WITN5249006] [WITN5249007].

3.26. There is a note from my Private Secretary recording matters that were agreed at a meeting with me and relevant officials on 12 November 1992 [WITN5249008]. These were that:

(1) The personality of the Chief Executive of the new NBA would be the key to its success. The successful candidate should probably come from outside the blood industry, have a proven track record in management and a certain amount of charisma. The issue would be discussed with Sir Colin Walker.

(2) I had queried the intention to bring the RTCs under the control of the NBA in 1994 and asked if it could be managed earlier. There was probably no need to mention a specific date in the PQ and press release since these could indicate that we intended to do it "as soon as possible."

(3) The wording of the draft PQ and press release would be changed to emphasise the intention to preserve and better manage the voluntary donation system and improve on the existing high standard of blood supply.

(4) Paul Brown (Parliamentary) would warn No.12 through standard procedures in December about the negative resolution to set up the NBA. There was no need to use the words "subject to Parliamentary approval" in the draft PQ and press release. PS(H) would seek SofS's advice about whether he should write to David Blunkett. I would seek the SofS's advice on whether to write to David Blunkett (who was by this time the Shadow Health Secretary);

(5) Existing CBLA appointments that were due to expire before the NBA was established would be extended until the CBLA was dissolved upon the formation of the NBA.

3.27. On 16 November 1992, I received the updated version of the draft inspired PQ and Press release for the public announcement with changes following the meeting of 12 November 1992 [WITN5249009] [WITN5249010].

3.28. On 24 November 1992, the Department[2] wrote to Dr Gunson, National Director of the NBTS, with an advanced copy of the formal announcement of the establishment of the NBA that I was going to make later that week. [NHBT0002187]. Consistent with my earlier query to officials about the feasibility of bringing the RTCs under the direct management of the NBA more quickly, Dr Gunson was advised in the following terms:

> *"You will notice that no date is given in the Answer for the transfer of the RTCs to the NBA. Minister has now asked us to consider the feasibility of making the transfer earlier than 1 April 1994. We are urgently considering this but in the meantime we need to be non-committal about the date.*
>
> *In briefing staff you may wish to make the points that:*
>
> *- before employment contracts of the staff are transferred to the new Authority the Department will formally consult the representative staff bodies.*
>
> *- many detailed operational issues relating to the NBA have still to be decided. Staff will be kept informed over the coming months."*

3.29. The formal announcement of the establishment of the NBA then went ahead on 27 November 1992 with the inspired PQ answered by me [WITN5249011] and the associated press release [NHBT0006432]. The press release stated as follows:

> *"England is to have a national authority to take charge of all blood supplies. The new authority, to be called the National Blood Authority (NBA), will plan and manage the blood services for England and ensure high standards of safety, quality and cost-efficiency throughout the service.*
>
> *The new arrangements for NHS Blood Services were announced today by Tom Sackville, Parliamentary Secretary for Health. One of the Authority's key objectives will be to maintain and promote blood and blood product supply based on the current system of voluntary donations.*
>
> *Mr Sackville took the opportunity to give blood today at the South Thames Blood Transfusion Service in Tooting and he praised the outstanding British system of voluntary unpaid blood donation.*

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[2] The name of the official writing the letter has been redacted in the version supplied to me by the Inquiry.

> *"Our blood supply is of high quality and among the safest in the world," said Mr Sackville.*
>
> *"But we are constantly trying to improve upon this position and the NBA will achieve this by bringing a national dimension to blood services.*
>
> *"We believe that the new management structure will enable the Blood Service to maintain and improve on those high standards and to improve its operations so the blood freely donated by our volunteer donors can be used most effectively in the interests of patients."*
>
> *Sir Colin Walker, Deputy Chairman Central Blood Laboratory Authority will be the first Chairman of the NBA, which will replace and co-ordinate the work of CBLA and the National Directorate of National Blood Transfusion Services (NBTS).*
>
> *Other key objectives of the NBA will be:-*
>
> > *to implement a cost effective strategy for ensuring an adequate supply of blood and blood products to meet national needs;*
> >
> > *to ensure high standards of safety and quality in the blood supply are maintained throughout the blood services;*
> >
> > *to ensure that blood products meet a consistent standard of safety and quality;*
> >
> > *to ensure the cost efficient operation of the Transfusion Centres and the Bio-Products Laboratory both individually and together as parts of the national service."*

3.30. The notes to editors in the announcement included that:

> *"2. Following a review of the existing arrangements the Department consulted on proposals for a NBA to act as a strategic body for the blood services. This was widely supported in principle and we have been considering the operational details.*
>
> *3. The new Authority will assume management responsibility for the RTCs as soon as arrangements are made to transfer them from the RHAs."*

3.31. Following the announcement of the establishment of the NBA on 27 November, the Department worked towards the 1 April 1993 implementation date. I would not have been involved in the fine detail of that work. I see from the records that an NBA planning group was established, chaired by Sir Colin Walker as the NBA chair designate and his group met on 10 December 1992, 13 January 1993, 10 February 1993 and 18 March 1993, as well as on 7 April 1993 just after the NBA was formally established [DHSC0046902_002]; [DHSC0006359_040]; [DHSC0006359_012]; [DHSC0006359_006]; [DHSC0006359_004]. Mr Canavan and Mr Rutherford were the DH representatives on this planning group.

3.32. I did however receive advice on my query as to whether the direct management responsibility date could be brought forward. This came in the form of a submission from Mr Canavan dated 15 December 1992 [DHSC0004320_011]. Mr Canavan's quite firm advice persuaded me – for the multiple reasons set out in that submission - to retain the planned date of April 1994 and therefore no change was made.

3.33. My response was to ask for Sir Colin's views, and I noted that if Sir Colin was in favour of an earlier transfer of direct management responsibilities, we would achieve that [DHSC0041257_067]. Having decided to set up the NBA, I would have been keen, if practicable, to fast-track direct management to accelerate the further advantages that this further step would bring. Therefore, notwithstanding the reservations apparent from Mr Canavan's advice, I wanted to know what Sir Colin's own views were.

3.34. On 14 January 1993, Mr Canavan updated me on Sir Colin's views [DHSC0041257_048]. Sir Colin, supported by other senior proposed members of the NBA, considered that that an earlier transfer would not be necessary and it would be impractical for the NBA to take over the RTCs in the course of its first year. Sir Colin was also of the view that such a major undertaking needed careful preparation. On that basis, I was persuaded to retain the April 1994 date for the transfer of direct management [DHSC0046977_148], and Sir Colin was informed of this by Mr Canavan on 22 January 1993 [WITN5249012].

3.35. In the same period (December 1992 – January 1993) I was also involved with Sir Colin in discussion about and consideration of the status of the Blood Products Laboratory, and potential collaboration with the private sector. The background to this was in part that Medeva PLC were interested in collaboration with BPL and potentially in purchasing it, were it to be privatised, and I had had a meeting with them in November 1992[3]. Mr Canavan provided a submission to me dated 14 December 1992 ahead of a meeting with Sir Colin the following day [DHSC0006792_041 and DHSC0006792_042]. After our meeting on 15 December[4], I wrote to Sir Colin on 22 December 1992 in the following terms [DHSC0006792_038]:

> *"Up to now, BPL has not been "for sale". However, given that it is a classic non-core activity of the NHS, and the fact that attitudes within Government to involvement with the private sector are changing fast, this is the moment to review the position. In other words, if a respectable buyer comes forward with proposals which fulfil our criteria (e.g. buying NBA plasma) we should look seriously at them and not dismiss them out of hand. Another possibility would be to explore forms of collaboration with the private sector which do not involve a change of ownership or status for the BPL.*
>
> *In terms of time scale, my view was that the longer we wait to consider our options, the more difficult it will become to implement them. If action is to be taken, it should be within the next eighteen months. I will be happy to look at any proposals you wish to put to me, but I must stress the need for caution. First to ensure that nothing undermines either our principle of voluntary donation or the quality of UK blood products. Second, to consider carefully at what stage such a policy shift becomes known more widely: we will have to ensure our position and its presentation are very well thought out by that time."*

There is a hand-written addendum from me on the bottom of this letter which is partially truncated in the version supplied to me. The legible part reads, "*There is still a cautious attitude to this at a political level. I think part of the argument*

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[3] See: [DHSC0006792_052]; [DHSC0006792_053]; [WITN5249013]; [DHSC0006792_048]; [DHSC0006792_044].

[4] In the interim I had been made aware that there may have been some confusion about BPL's status and that a clarification may be beneficial see: [DHSC0006792_039]

must be the long term viability (or lack of it) against some pretty effective private competition".

3.36. Consideration of BPL's status continued in parallel with the work ahead of the NBA being established on 1 April 1993. For example:

(1) On 18 January 1993, I was provided with a draft reply to Medeva [DHSC0006474_014] [DHSC0041084_015] and I wrote to Medeva on 20 January 2003 [DHSC0006792_021] and in confidence, I let Sir Colin have a copy of my letter [DHSC0006792_020];

(2) Virginia Bottomley was provided with briefing on the status of BPL as part of privatisation discussions with the Treasury; my office was copied into these (or certainly the second of the notes): 3 March 1993 [DHSC0006578_052 and DHSC0041151_004] and 11 March 1993 [DHSC0006579_095, DHSC0006579_096 and DHSC0038505_025]. The conclusion in the latter note was:

> *"On balance it would be inappropriate to privatise BPL now. However*
>
> - *we have established the NBA (wef 1 April 93) to take over management of CBLA (including BPL) and the NBTS (wef 1 April 1994)*
> - *this will significantly strengthen the management of blood services in general" (original emphasis)"*

3.37. The NBA came into being on 1 April 1993. The press release said [NHBT0003960]:

> *"The new Authority under the Chairmanship of Sir Colin Walker will be responsible for the strategic planning and management of the blood services in England with the objectives of enhancing their quality and cost efficiency.*
>
> *Mr Sackville said: "These new management arrangements will allow us to build on the achievements of … our current blood services.*
>
> *"Our volunteer donors make a priceless gift of blood and it is the responsibility of the NHS to make the best possible use of this in the interests of patients.*

> *"It is important that the blood services are organised and managed as effectively as possible. The existing services already have an enviable reputation for maintaining the quality and safety of the blood supply but we must strive continually to improve on those high standards.*
>
> *"The NBA will help in this by taking a national overview of the operations of the services and provide strategic direction for their development.*
>
> *"We remain fully committed to our outstanding system of voluntary, unpaid donors and the NBA will help ensure this gift of blood is used to the full."*

The advantages and disadvantages of reform

3.38. The Inquiry asks me to about which factors were most important and about the advantages and disadvantages of the reform.

3.39. As I have indicated, the consultation and decision in principle to establish the NBA had been taken before I took up post. However, I was obviously in favour of the reform. There seemed to me to be major advantages in having more powerful central co-ordination of blood services including the production facility of BPL. The systems and arrangements for blood donation / plasma supply on the one hand and fractionation / blood product manufacture on the other hand, were closely interrelated and likely to be more effectively run by a single national management body than by the three way division of (i) RHAs; (ii) the CBLA, and (iii) the NBTS National Directorate. There had been concern at the wide variation of performance between different regions. As the contemporaneous statements made clear, the main advantage was going to be in a better national overview and strategic direction concentrated in a national body with effective powers being able to implement improvements, drive standards and achieve efficiencies. Accordingly, I was not in favour of the NBA being merely a policy orientated authority rather than having direct responsibility for the management and delivery of blood services. These considerations motivated me to prefer the option of the NBA having management responsibility for the RTCs, and explains why I later enquired as to whether the planned date of the NBA assuming direct management control of the RTCs (April 1994) could be brought forward.

3.40. However, as well as officials advising against this, Sir Colin as the Chairman designate of the NBA considered it prudent to have the full financial year 1993/1994 to plan that further change. At the same time, while we had not wholly ruled out privatisation of BPL, we were not in favour of that course in the short term and had agreed to options being further explored once the NBA was established.

Section 4: Look Back Exercise

Reasons for and timing of the look-back exercise

4.1. I am asked to set out my understanding of the reasons for, and timing of, the Department of Health's announcement on 11 January 1995 that it would proceed with a look-back exercise in relation to HCV. I am also asked whether the announcement on 11 January 1995 was a response to the look-back exercise announced in Scotland on 22 December 1994.

4.2. I should start by explaining that, although I announced the look-back exercise on 11 January 1995 in my capacity as a health minister, [NHBT0005792], the decision to proceed with the exercise and to announce it at that time was based on the recommendations of others, principally the Departmental Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation ("MSBT"), who were much closer to both the policy and scientific reasons for proceeding at that time.

4.3. In seeking to answer the questions, I have been referred to certain documents which would have likely been drawn to my attention at the time (usually as a result of documents being sent to or copied to my Private Office). Given the passage of time, I do not have any specific recollections of the lead up to the announcement. What I say below is therefore based on the documents made available to me for the purposes of preparing this witness statement.

4.4. I can see from the documents provided to me that, on 29 September 1994, the MSBT discussed the recommendations for considering look-back for HCV made by the Standing Advisory Committee on Transfusion Transmitted Infection [WITN5249014**]**. As a minister I would not have seen the minutes of the MSBT's meeting at the time but I may well have received a submission on the key points from officials.

4.5. The MSBT's consideration of an HCV look-back exercise was mentioned in a minute sent from Mr Kelly to Mr Mogford, the Private Secretary to the Secretary of State (copied to my Private Secretary, Mr Hollebon) dated 16 November 1994 [DHSC0041152_216; DHSC0041152_217; DHSC0041152_218; and DHSC0002548_159]. The minute was in response to a request from the Secretary of State for a briefing on the issue of Hepatitis C infection in the context of increasing pressure, not least from the Haemophilia Society and MPs, for the Department to grant ex gratia payments to haemophiliacs who had contracted Hepatitis C as a result of infected blood or blood products. I consider this issue in some detail in section 8 of this witness statement. Whilst I do not wish to speculate, the request was possibly triggered by press reports that were emerging around this time [DHSC0002501_102, DHSC0002501_103 and DHSC0002501_104]. At paragraph 7, the minute recorded that the MSBT had asked a small group of its members to examine and report back on claims made in a paper submitted by the Standing Advisory Committee on Transfusion Transmitted Infection to the MSBT in September 1994 (referred to above). This, the minute stated, would enable a view to be established on the viability and desirability of a look-back exercise.

4.6. As far as I can tell from the documents provided, the MSBT's decision to recommend a look-back exercise was first communicated to my Private secretary, Mr Hollebon, in a minute from Mr Scofield dated 16 December 1994 [DHSC0003544_084]. The minute stated that a formal submission would be made early in the following week.

4.7. I see from the documents that, on 16 December 1994, Mr Hollebon was sent a minute from Ms Sue Greaves in the DH Press Office about a forthcoming Panorama programme about HCV from blood transfusions and a request for an interview with me to discuss, among other things, whether the DH would carry out a look-back exercise [DHSC0002422_162]. The minute referred to a submission that was to be made to me. I have no recollection of personally being asked to participate in the programme. This request would have been dealt with by the Department's press office.

4.8. I can see from the documents that on 20 December 1994 Mr Scofield sent a further minute to Mr Hollebon in my Private Office [DHSC0003544_064]. This minute concerned the proposed response to Panorama's requests. I note that the look-back is referred to at paragraph 5, in which Mr Scofield stated that "*if Ministers agree the recommendations in these papers they will be in a much stronger position to face any questions about hepatitis C*".

4.9. On 22 December 1994, Mr Scofield sent Mr Hollebon in my Private Office (copied to many others) a paper entitled "The Government's response to Hepatitis C" [DHSC0032208_149; DHSC0002501_116; DHSC0003555_228; and DHSC0032208_161]. The paper included a recommendation to undertake a look back programme to identify those at risk. I was asked for my approval of the proposals. It is evident from this submission paper that I was advised that there were a number of reasons for approving the recommendation to carry out a look-back exercise. The reasons advanced were as follows:

(1) First, the DH's lawyers had advised that there may be a duty of care to "*do whatever can reasonably be done to identify, inform, counsel and treat any who may have become infected as a result of NHS treatment*" (paragraph 8 of the paper). Had the look-back exercise not been

undertaken when it was reasonable and feasible to do so, then it could have exposed the Department to legal claims. The submission document also records that the MSBT had also reached the same conclusion as the Department's lawyers.

(2) Secondly, until late 1994 (the paper uses the term "*recently*" in paragraph 11, but it is apparent from the documents provided to me that it was the result of a pilot research study conducted in Scotland which reported in late 1994 that led to the conclusion) it was thought that identifying recipients of blood transfusions who were at risk of having contracted HCV would be technically very difficult. As recorded in the press release dated 11 January 1995, Dr Metters explained that until a pilot research study had shown that procedures had been established which made it possible to trace patients at risk, it had been believed that the exercise would have been technically very difficult [NHBT0005792].

(3) Thirdly, prior to the widespread use of recently-licensed drug Interferon Alpha ("Interferon"), there had been no effective treatment for HCV. Interferon was the first drug to be approved for use in the treatment of HCV. Prior to the licensing of Interferon, the submission paper recorded that it was thought that informing patients of their possible risk would be needlessly distressing because there was no treatment available. This was also explained in Dr Metters' opening statement at the press briefing at which the look-back was announced on 11 January 1995 [WITN5249015] and in the press release of the same date.

4.10. In addition to the change in circumstances regarding feasibility and potential treatment (as a result of which I was being advised that a duty of care to patients might be engaged), the submission dated 22 December 1994 referred to two other issues that might have affected the timing of the announcement. Having reviewed the documents, I do not consider that either would have been a reason contributing to the decision to proceed itself.

4.11. First, the submission paper recorded the increased pressure from MPs, the public and the media to address the known risk of infection. These factors, particularly the parliamentary attention the issue received, would have had some impact on timing. The proposed Panorama programme discussed above was also mentioned; it was proposed to be aired on 9 January 1995.

4.12. In considering the role that media reports and the Panorama programme played, I have seen in the documents provided to me a minute from Mr Hollebon to Mr Mogford dated 4 January 1995 [DHSC0032203_133]. In that minute, Mr Hollebon noted that the pressure applied by the possible Panorama programme had been temporarily eased as it had been rescheduled from 9 January 1995. He went on to say, however, that because of the inevitability of the subject being reported in the press, I had considered it important to make an announcement as soon as possible to "*seize the initiative*".

4.13. While the programme formed part of the context at the time, I do not believe that it had any significant influence on the actual decision to proceed with a look-back exercise. Ultimately the Department was informed by expert opinion and reached a view based on that advice.

4.14. I can see from looking at documents provided to me that a letter from Lord Fraser was sent to me on 22 December 1994. [PRSE0001781]. I note that Lord Fraser's opening paragraph echoed the reasoning of the submission paper in respect of the reasons why a look-back exercise had not been conducted previously. He went on to explain that the feasibility of conducting a look-back exercise had been established via a recent pilot study and that, as a result, the legal advice he had received was such that a wider exercise should be carried out as soon as possible.

4.15. From looking at the documents provided to me both before and after 22 December 1994, it appears that this decision by Scotland accelerated the announcement of the look back exercise. But it was an acceleration of the process; given the expert advice from the MSBT, the look back exercise would have gone ahead in England regardless of the Scottish announcement.

4.16. As noted in Mr Scofield's paper, the advice to me was that for one part of the UK to proceed with a look back on its own would be untenable and that it was vital if the risk to legal challenge is to be minimised to "*maintain maximum commonality between policies throughout the UK*" (paragraph 14). The recommendation made by the MSBT (as recorded in paragraph 28) was that procedures should be put in place to identify those patients at risk and that this should be done on a UK wide basis (the MSBT, in its recommendation of 16 December 1994 [DHSC0003544_084] had stated that "[w]*hatever is done should be done equally and uniformly throughout the UK…*").

4.17. I also note later documents that cast light on the thinking at the time, which was that the look-back programme should be a UK wide exercise.

4.18. In the written statement prepared from me to Panorama dated 23 December 1994 [DHSC0003555_087], it is stated that the MSBT had decided to recommend a look-back process and that this was "*likely to be on a UK wide basis*".

4.19. I have seen in the documents provided a minute from Mr Scofield to Dr Metters dated 3 January 1995 (the document is actually dated 1994 but this is clearly erroneous given its content) [WITN5249016]. Mr Scofield states:

> *"We have to persuade him that there is no loss of momentum in going along with the UK wide approach. This depends upon our ability to demonstrate that we shall be going forward immediately…"*

4.20. In my letter to Lord Fraser dated 4 January 1995 [DHSC0032208_136], I stated:

> *"I want to see the look back exercise started as soon as possible.*
>
> *Now that I have given the go-ahead in England … we have the opportunity to address this issue together using our combined resources and the expertise of our National specialists. …*

> *"I understand your wish to move quickly in Scotland ... I hope however you will recognise the overwhelming advantage of us moving forward on a UK wide basis. Any piecemeal approach, quite apart from giving all the wrong signals and causing confusion to the public, will seriously compromise the Government's defence that we have acted as quickly as possible on the basis of the best advice available uniformly."*

4.21. I have also seen in the documents provided to me a memo from Mr Scofield copied to Mr Hollebon dated 5 January 1995 (again, the document is dated 1994 but this is clearly erroneous given its content) [WITN5249017]. In it, Mr Scofield refers to my letter to Lord Fraser and stated, "*All efforts are being made to get the Scots to come in on a UK-wide programme. Irrespective of their decision we shall announce the look back exercise 11th January.*"

4.22. To complete the narrative, on 9 January 1995, Lord Fraser sent me a letter in which he agreed that there were benefits from a common UK approach [WITN5249018]. I also note the minute from Mr Scofield to Mr Hollebon in my Private Office dated 10 January 1995 which confirmed that Northern Ireland and Wales had also agreed to the UK wide approach [WITN5249020].

4.23. The position in Scotland was more advanced than that in England, which accelerated our announcement of the look-back exercise. However, it was not determinative since the expert advice I received from the MSBT was that there was an overwhelming case for such an exercise in any event. Therefore, I do not agree with the statement at paragraph 31.524 of the Penrose Report that the effect of Lord Fraser's letter to me was that "*in the result, UK policy was changed*" [PRSE0005009]. I was not persuaded by the Scottish decision to push ahead in itself, but rather the contents of the documents and advice I received.

4.24. It was clearly preferable that the exercise be undertaken on a UK-wide basis. I would describe both the parliamentary scrutiny and media attention on the issue (including the Panorama programme) as part of the context and commentary. Neither were material factors in the decision I made to proceed, which followed within days of my receiving the letter from Lord Fraser and the advice set out in the 22 December 1994 paper (with only a short delay over the Christmas period of that year).

4.25. I have also seen in the documents supplied to me a letter sent by Dr Metters to Dr Kendell, the Scottish Chief Medical Officer, dated 14 February 1995 [WITN5249020]. Dr Metters referred to the decision that I had by then made to proceed with the look-back exercise. He stated:

> "*Now that we have got this go ahead … there seems to me no reason for Scotland to go it alone. Indeed, there is every advantage as MSBT recommended in our undertaking this task on a UK-wide basis making the most of our resources and taking advice from National expert collectively. To undertake separate and parallel exercises would not only be wasteful but give all the wrong signals.*"

"Counselling" those at risk of HCV

4.26. I have been asked to explain what was envisaged by the term 'counselling' of those identified as being at risk of HCV. The Inquiry refers me to my Written Answer to a question from Piers Merchant MP on 4 April 1995 [RLIT0000888]. In my answer I said,

> *"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 specialities, 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."*

4.27. I see from the documents that I had read a pamphlet published by the British Liver Trust which was critical of the counselling provisions then in place and I asked for a briefing from officials. Accordingly, on 11 July 1995 I received a briefing from Paul Pudlo [DHSC0003552_115] which stated that "[*t*]*he*

Department has said that it would be open to suggestions from the BLT to improve counselling but officials believe that work has to be done to identify needs…"

4.28. The lines to take in the briefing set out the Department's position on counselling as follows:

> *"Recognise that patients identified as suffering from HCV need appropriate counselling. The Department is currently funding an initiative by [the] Haemophilia Society on [best] way of supporting its members with Hepatitis C – including counselling.*
>
> *For infected patients identified through the Lookback exercise there are three possible sources of counselling; the consultant under whose care the patient received the transfusion; the GP or the BTS [Blood Transfusion Service]…"*

4.29. Some guidance on counselling was set out in the CMO letter dated 3 April 1995 [NHBT0002796_002], in particular Annex B entitled "Guidelines for Counselling Patients". The guidelines referred to the British Liver Trust as a "*source of appropriate information and patient support*". In addition, the guidelines envisaged support at the GP stage followed by referral to a liver specialist where "*further counselling will be given… and treatment options can be discussed in more detail…*"

4.30. I cannot add much to Annex B of the CMO letter or the contents of the briefing I received from Mr Pudlo on 11 July 1995. As set out in the briefing, the Department was open to suggestions from the BLT to improve counselling. There was a certain lack of clarity as to what was meant by "counselling" since there was (and is) a clear difference between medical advice, which might include warnings about the dangers of infection, on the one hand and psychological support on the other.

4.31. I was reassured by the briefing that appropriate forms of counselling were being developed. The Department wanted to ensure that counselling was provided.

In practice, this tended to be handled at the level of the doctor-patient relationship with some input from charities such as the BLT. With hindsight I acknowledge that we may not have delivered on counselling. A lack of adequate resource within the NHS for mental health support arguably remains the case to this day across many health areas.

Section 5: Compensation for those infected by NHS treatment

Payments to the Macfarlane Trust to settle the HIV litigation, 1992

5.1. The Inquiry asks me to describe my knowledge of, and involvement in, the actions of the Department of Health in making payments to the Macfarlane Trust in order to settle the negligence claim brought against it by a number of people infected with HIV, in 1992.

5.2. I understand that the HIV litigation was compromised by the DH and the Plaintiffs before I came into office. I cannot now recall having received a briefing from officials when I came into office about the payments made to the Macfarlane Trust to settle the HIV litigation. The Inquiry also asks me about the basis upon which the payments were calculated and about why litigants were required to sign waivers. Given these matters were resolved before my time, I would of course not have been involved in them and nor would I have had any knowledge of them at the time the events took place.

5.3. In Section 7 below (on the Eileen Trust), I refer to Mr Scofield's submission to Mrs Bottomley dated 13 April 1992 [SCGV0000238_025] and also to Bottomley's response dated 22 April 1992 [WITN5249021]. Mr Scofield's submission stated,

> *"4. 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."*
>
> *[...]*
>
> *"13. 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."*

5.4. Although the submission and Mrs Bottomley's response were copied to my Private Office, I was not involved in the issue of the lump sum payments to the HIV infected blood and tissue recipients. The matter was at that time handled by Mrs Bottomley, who had also been dealing with the issue previously when she was Minister of State for Health (and before becoming Secretary of State following the April 1992 General Election).

5.5. I mention the submission for completeness. The available documents do not otherwise suggest that I received any briefings about the HIV litigation or issues surrounding payments to the Macfarlane Trust, although of course I recognise the documentary record may not be complete.

Government decision not to provide a compensation scheme for those infected as a result of NHS treatment

5.6. I am asked why, during my time in office at the DH, the Government did not provide a compensation scheme (as opposed to a system whereby they made ex gratia payments) for those infected with blood borne viruses as a result of NHS treatment.

5.7. My understanding from my time as a junior minister is that because the Government did not accept it was at fault there was never any tort based compensation. Financial support that was given was always ex gratia. As an aside, in my role after I left Parliament with the International Federation of Health Plans I gained some understanding of New Zealand's "no fault" compensation scheme for medical accidents, known as the ACC. I became aware that New Zealanders were proud of their no-fault compensation scheme, despite its expense. However, I was aware that no other country in the world had set up a similar system.

5.8. In Section 8 below, I refer to a request that I made to officials in July 1992 for a note on the Department's policy on compensation for medical accidents [WITN5249022The response from officials dated 11 August 1992 set out in detail the reasons for the Department's policy [WITN5249023] and [WITN5249024]. I do not think at this remove I can add to what is explained in the paper.

Section 6: Relationship between the Government and the Macfarlane Trust

Names of those responsible in the DH for managing the relationship with the Macfarlane Trust

6.1. I am asked to identify by name those that were responsible in the DH for managing the relationship with the Macfarlane Trust and to set out their areas of responsibility.

6.2. I cannot not now recall any relevant names and am reliant on the documentary record. On the administrative side of DH, the names that come up most frequently in the papers are: Mr Strachan Heppell (HSSG); Mr John Canavan (CA-OPU); and Mr Roger Scofield (CA-OPU). I have also seen Dr Andrzej Rejman (HC(M)) included as a copyee on some Macfarlane Trust submissions. The named officials would be better placed to set out their areas of responsibility.

DH's decision-making and actions in relation to the Macfarlane Trust

6.3. I am asked to describe my involvement in the DH's decision-making and actions in relation to the Macfarlane Trust during my time as Parliamentary Under-Secretary of State.

6.4. The Inquiry refers me to correspondence that pre-dates my time in the Department:

(1) Letter dated 5 March 1992 from the Chairman of the Trustees of the Macfarlane Trust, the Reverend Prebendary Alan Tanner, to the then Secretary of State, Mr William Waldegrave [MACF0000076_049].

(2) Letter dated 13 March 1992 from Mr Waldegrave to Prebendary Tanner [MACF0000072_052].

(3) Letter dated 23 March 1992 from Prebendary Tanner to Mr Waldegrave [MACF0000072_051].

6.5. Looking now at the correspondence, I see that the Government had given assurances that it would continue to review the amounts available to the Trust. Mr Waldegrave's letter to Prebendary Tanner dated 13 March 1992 praised the "*excellent work*" of the Trust and said:

> *"I know that you and colleagues from the Trust recently met with officials from my Department and have sought assurances about future support for the Trust. As you know the Government has given assurances on several occasions that it would continue to keep under review the amounts available to the Trust. I can confirm that a Conservative Government would continue its policy of support for the Trust.*
>
> *I understand you know that the Government did not plan to provide further funding for the Trust for the financial year 1992/93, as the Trust had adequate resources to enable it to maintain spending at present levels for the coming year. However, I am able to give you the assurance that I will look again at the position of funding for the Trust in the autumn of 1992 for the financial year 1993/94."*

6.6. Prebendary Tanner's reply dated 23 March 1992 said:

> *"I know that the Trustees will be greatly comforted by your assurance that you will look again at the position of funding for the Trust, in the autumn of 1992, for the financial year 1993-94. This will allow the Trustees to continue our present allocation policy without making arbitrary cuts in expenditure and in turn reassure those who look to us for support."*

6.7. On 29 May 1992, I wrote to Gerald Malone MP (who later became Minister of State for Health) in reply to his letter to the then Secretary of State, Mrs Virginia Bottomley [DHSC0020843_177]. I said that,

> *"The Government has given assurances on several occasions that it will continue to keep under review the amounts available to the Trust. I understand that at present the Trust has adequate resources for its work of helping to meet the special needs of haemophiliacs with HIV and their families. The Government has recently confirmed to the Trust that it will continue its policy of support."*

6.8. I have been shown minutes of a meeting of the Trustees of the Macfarlane Trust that took place on 18 November 1992 [MACF0000002_036]. At paragraph 92.52, reference is made to a meeting with DH that had taken place that morning. The meeting with the Trustees was attended by DH officials, Mr Heppell and Mr Canavan. I see Mr Heppell expressed confidence that the Government would provide further funds, but the timing (and whether payments would be lump sum or in stages) would be for Ministers to decide. I note the date of the meeting roughly accords with Mr Waldegrave's assurance that DH would look again at the Trust's funding in the autumn of 1992. The minutes record that the Trustees were satisfied with the outcome of the meeting. The available documents do not show that I was made aware of the meeting at the time, nor do they show that the issue of Macfarlane Trust payments was raised with me subsequently during 1992.

6.9. I am reminded by the documents that I was involved in overseeing the award of Sections 64 grants across the Department (see, for example, minute from my Private Secretary dated 1 May 1992 asking officials to put forward proposals for Section 64 grants [WITN5249025]).

6.10. Mr Scofield put a submission to my Private Office dated 2 March 1993 [WITN5249026]. The submission came to me as the minister responsible for Section 64 grants. The submission noted that I had already agreed the branch expenditure plans for the Corporate Affairs Operational Policy Unit (CA-OPU). The branch sought approval to the Macfarlane Trust's application for a Section 64 grant of £158,000 for 1993/94 to cover the Trust's administration costs. Ministerial approval was required because the level of grant sought was above the limit for approval by officials. The submission noted that when the Trust was set up the Government had undertaken to meet its administration costs. I approved the application on 5 March 1993 [DHSC0004236_049]. I understand that Section 64 grants were used to cover the Trust's administration costs in subsequent years (see Baroness Cumberlege's speech in the Lords [RLIT0000886]).

6.11. On 22 February 1993, Mr Brownlee put a submission to the then Minister of State for Health, Dr Brian Mawhinney, copied to my Private Office [DHSC0003124_007]. The submission noted that there was potential underspend of £6 million in DH's Centrally Finances Services budget for 1992/93. Agreement was sought to use the money to meet pressures for 1993/94, including for the Macfarlane Trust.

6.12. The submission set out the following background to the requirements of the Macfarlane Trust:

> *"There is a continuing need for the Trust to meet special needs as more of the infected group become unfit for work; medical advances may have prolonged life but they have done little to alleviate the effects of the advanced stages of illness. The Trust is also committed to supporting children of deceased haemophiliacs and it sees this commitment stretching well into the future because of the considerable number of young children registered with it. The Trust estimates that its reserve will have fallen to £4 million by the end of 1992/93. Falling interest rates and diminishing capital have reduced the extent to which interest can offset the annual expenditure of around £2 million. The Trust says that it will have to cut expenditure drastically in 1993/94 if funds are not topped up. It considers it necessary to keep a reserve to meet the needs of the terminally ill and the immediate needs of the bereaved; and this reserve needs to be able to meet a crisis downturn as there is no reliable prognosis for the health of those with HIV and haemophilia."*

6.13. The submission recommended that,

> *"In view of past assurances, Ministers will wish to avoid a cutback in the Trust's expenditure. A lump sum payment of £5 million now rather than £1 million proposed in my submission of 4 December, will provide the Trust with sufficient resources to meet its commitments for the next 3 to 4 years and could be made on the expectation that no further claims would be received from the Trust for that period. A one off payment of this size is worth more to the Trust than annual payments as they receive interest and can maximise their income and would deal with a significant pressure at the start of the fundamental review of government expenditure."*

6.14. Mr Canavan sent to my Private Office a submission dated 15 March 1993 [DHSC0003152_009]. It noted that Dr Mawhinney had agreed to the £5 million payment. The submission concerned the mechanism for informing the Trust. Officials were concerned that a public announcement would cause difficulties with the campaign for compensation for human growth hormone recipients. I was provided with a draft letter to the Trust, which was less likely to cause publicity and which I signed on 16 March 1993 [MACF0000072_046]. The letter said:

> *"Our expectation is that this sum will provide the Trust with sufficient resources to meet its commitments for the next 3 to 4 years.*
>
> *I take this opportunity to add my own thanks to those previously expressed by William Waldegrave for the excellent work of the Trust over the last five years in providing for the special needs of people with haemophilia who became infected with HIV."*

6.15. On 7 April 1993, Prebendary Tanner replied to me [MACF0000072_045]. He confirmed the £5m had been received and said:

> *"This will give Trustees the confidence that they can continue for the next 3 or 4 years the level of support which has been given to the people in our care without fear that resources will be inadequate to cope with any crisis situation that may arise, it being still very difficult to predict the future course of events.*
>
> *In this light we are particularly gratified by your recognition of the fact that at some time in the future the Trustees may have to approach the Government again for further funds."*

6.16. Prebendary Tanner also expressed his thanks for "the considerate and constructive help we have come to rely on from all levels of your Department."

6.17. I have been referred to a minute from Mr Scofield to officials, Mr Kelly, Mr Burrage and Mr Brownlee, dated 9 March 1995 [DHSC0003162_003]. The minute referred to discussions between officials about possibly making a £2 million or £3 million payment to the Macfarlane Trust in 1995. The minute invited Mr Kelly to prepare a submission for me, which would explain that an application had been made by the Trust and that the DH would "*have to put in some more* *cash pretty soon anyway*". I would not have seen this minute at the time. The available papers do not suggest I was ever sent such a submission.

6.18. For completeness, I add two further points that are apparent from the available documents:

(1) I was usually the minister who signed replies to correspondence concerning the Macfarlane Trust. See, for example, the minute from Mr Burrage to Mr Canavan dated 7 January 1994, which said that I may wish to reply because the correspondence concerned payments to a haemophilia patient infected with HIV [WITN5249027]. I see Baroness Cumberlege also signed some replies. See, for example, the letter to Emma Nicholson MP dated 16 June 1994, in which Baroness Cumberlege noted haemophilia and HIV were part of her Ministerial responsibilities [WITN5249028].

(2) I was involved in approving extensions to the appointments of Macfarlane Trust trustees. See, for example, the submissions that were sent to my Private Office dated 18 February 1993 [DHSC0003416_012], 17 August 1993 [DHSC0003415_014] and 10 March 1994 [WITN5249029].

Letter to Gerald Malone MP, May 1992

6.19. At paragraph 6.7 above, I referred to my letter to Gerald Malone MP dated 29 May 1992 [DHSC0020843_177]. The Inquiry asks me what I meant by stating that *"at present the Trust has adequate resources for its work of helping to meet the special needs of haemophiliacs with HIV and their families".* I am asked to explain the factual and evidential basis upon which this statement was made.

6.20. At this point in time, I do not have any recollection of signing this letter. The ordinary process was that a draft response would be produced by officials.[5] I do

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[5] Here, the available documents show Mr Burrage and Dr Rejman amongst others contributed to the reply [WITN5249030] [WITN5249031]

not believe that at this stage in my career I would have questioned the submissions of the senior officials who would have drafted the letter. At this remove, I do not think that I can add to what is apparent from the letter itself, save to observe that what I said in May 1992 was largely repeating the same point made some two months earlier by Mr Waldegrave. I was not being advised that the funds of the Society, at this stage, were so low as to prevent them continuing to offer the support that they had been providing. I address the top up of funding that followed, below.

Government agreement to provide additional funding to the Macfarlane Trust in 1992/1993

6.21. I am asked a series of questions in relation to the Government's agreement to provide additional funding to the Macfarlane Trust in 1992/93. It seems to me that the Inquiry questions are best answered by reference to the submission dated 22 February 1993, which is referred to at paragraphs 6.11 onwards above.

6.22. Doing my best with the documents that I have seen, it does not seem to me that the Government's view of the needs of haemophiliacs changed from May 1992 to March 1993. Rather, the £5 million "top-up" payment was made because, for the reasons set out in the submission of 22 February 1993 to Mr Malone, the Trust anticipated that its reserves would fall and the Department had given past assurances that it would review the funding position of the Trust for the year 1993/94. The Trust estimated that its reserves would have fallen to £4 million by the end of the 1993 financial year. My understanding of the submission is that the timing of the £5 million payment in April 1993 was such that it meant that the Trust did not have to cut expenditure.

6.23. I cannot add anything to what is said in the submission as to the basis on which the Government determined that £5 million was the appropriate level of funding. My reference to the Trust's "*excellent work*" echoes what was said previously by Mr Waldegrave. The assessment of the Macfarlane Trust's performance would have been a matter for officials in the first instance. I would have been guided by their advice. If it was felt that the £5 million payment was inadequate, or the Trust was not satisfied, then I would have expected to be warned and submissions do not indicate that was the case. Indeed, I have seen a letter from Prebendary Tanner (sent in the context of the Eileen Trust) which said the assurance given by the Government to the Macfarlane Trust had been *"generously fulfilled, and renewed."* [WITN5249032].

Support and assistance scheme for those who contracted HCV as a result of NHS treatment

6.24. The Inquiry asks, during my tenure as Parliamentary Under-Secretary of State, what consideration was given by the Government to setting up a scheme for support and assistance to be provided to those who had contracted HCV or individuals co-infected with HIV and HCV as a result of treatment with NHS blood or blood products. There is considerable overlap here with Section 8 and so I refer the Inquiry to my response to Section 8 set out below.

Section 7: Relationship between the Government and the Eileen Trust

7.1. The Inquiry asks me to describe any involvement which I had in the DH's decision-making and actions in relation to the establishment and operation of the Eileen Trust during my time in office.

7.2. Prior to the April 1992 General Election, other ministers in the Department had been involved in agreeing that there should be a scheme of payments for those infected with HIV through blood or tissue transfer. The decision in principle in relation to this had been made before I became Parliamentary Under Secretary for Health and I was not involved in it.

7.3. Similarly when, shortly after the 1992 election, the finalisation of the scheme and lump sum payments was being agreed, this was dealt with by the Secretary of State Mrs Bottomley who had had prior involvement as Minister of State. However, in February 1993, I was the Minister who was consulted on the discretionary special needs payments element of support for the blood transfusion patients and the establishment of the Eileen Trust.

7.4. I have been referred to a Written Answer from Mr Waldegrave dated 17 February 1992 [DHSC0003625_040]. He said:

> *"I have decided that the special provision already made for those with haemophilia and HIV is to be extended to those who have been infected with HIV as a result of National Health Service blood transfusion or tissue transfer in the United Kingdom."*

7.5. I have also seen a "*CMO briefing for incoming ministers*" dated 23 March 1992 and sent from Dr Rejman to the Deputy Chief Medical Officer, Dr Abrams [DHSC0003591_081]. I see that the briefing included a short note on the extension announced by Mr Waldegrave. Dr Rejman said a major difference in the new scheme was the perceived need to identify causation. Given the passage of time, I cannot now recall any briefing from the CMO or DCMO when I joined the Department on 10 April 1992.

7.6. On 13 April 1992, Mr Scofield put a submission to Mrs Bottomley, copied to my Private Office [SCGV0000238_025]. Officials had finalised details of a payment scheme for the HIV infected blood and tissue recipients. The submission noted that the main principles of the scheme had been agreed previously by Mr Waldegrave. It further said,

> *"Charitable Trust*
>
> *13. 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."*

7.7. Mrs Bottomley agreed the proposed approach on 22 April 1992 [WITN5249021]. Details of the payment scheme were announced on 27 April 1992 [WITN5249033].

7.8. I gave a Written Answer on 21 May 1992 in which I said that the first applications for payment had been received on 12 May 1992 [WITN5249034]. While I answered the Parliamentary Question, that does not mean that I was the minister dealing with the issue. The new scheme was approved by Mrs Bottomley; I was the minister to whom responsibility for answering the Parliamentary Question was delegated. It was a common practice to delegate responsibility for answering Parliamentary Questions to a junior minister, even if they were not directly involved in the particular policy development in question

7.9. About nine months later, officials raised with me the special needs fund element of support for the blood transfusion patients. On 16 February 1993, Mr Canavan put a submission to my Private Office [WITN5249035]. Mr Canavan said:

> *"**<u>Background</u>***

> *1. When announcing lump sum payments for those infected with HIV through blood or tissue transfer, Ministers also undertook to give them access to a special needs fund. This would be similar to the Macfarlane Trust (a charitable trust) set up with a Government grant to meet the special needs of HIV infected haemophiliacs.*
>
> *2. We are seeking PS(H)'s agreement in principle to appointing three Macfarlane trustees to the new trust for blood transfusion cases and to approaching two other candidates to see if they are willing to serve as trustees of the new trust.*
>
> ***Collaboration with the Macfarlane Trust***
>
> *3. The help given to the HIV infected recipients of blood or tissue is regarded as an extension of the help given to the similarly infected haemophiliacs and our policy is to deal even handedly with the two groups.*
>
> *4. Close links between the new trust and the Macfarlane Trust would allow it to draw on the considerable experience of the Macfarlane trustees. It would also help ensure that the same levels of financial support were given to the two groups and so avoid invidious comparisons being drawn. Moreover it would be administratively more efficient as the new trust is likely to have a very small number of applicants (only 76 applicants have applied for the lump sums) and would not warrant its own full time administration."*

7.10. The submission recorded that the Macfarlane Trust had been "*very successful*" in administering to the special needs of the haemophiliacs. The Macfarlane Trust was willing to support the new trust by having common trustees and providing administrative services. The intention was to set up the new trust before the end of the financial year. Mr Canavan sought agreement to appointing three Macfarlane trustees to the new trust and to approaching two other candidates. I agreed to the proposals on 18 February 1993 [DHSC0002731_002].

7.11. On 11 March 1993, Mr Canavan put a further submission to my Private Office [DHSC0002745_002]. Mr Canavan sought agreement to inviting four named candidates (one of whom was Prebendary Tanner) to serve as trustees. He also proposed registering the new trust under the name the "Eileen Trust". I agreed the proposals on 12 March 1993 [DHSC0002742_004].

7.12. On 31 March 1993, Mr Canavan put two submissions to my Private Office concerning the Eileen Trust. The first submission said that the Trust was formally established on 29 March and a payment of £0.5 million had been made to it [DHSC0002753_014 and DHSC0002755_006].[6] In terms of how to announce that the Eileen Trust was now in existence, the submission advised:

> *"3. There is a risk that an announcement at this time will encourage those campaigning on behalf of human growth hormone recipients but PS(H) may feel it is necessary to place on the Parliamentary record that the Trust has been established. In due course DSS will be laying Regulations to disregard payments from the Trust for the purposes of means tested benefits. We are not proposing a press release since the Department will be writing to those who have established entitlement under the lump sum payment Scheme and who may become beneficiaries of the Eileen Trust."*

7.13. On 2 April 1993, I confirmed I did not want an inspired PQ [DHSC0002753_008].

7.14. Mr Canavan's second submission was about Prebendary Tanner's concern that providing administrative support for the Eileen Trust might jeopardise its primary function of meeting the needs of haemophiliacs with HIV [DHSC0002756_002]. In preparing this statement, I have not seen the letter from Prebendary Tanner dated 22 March 1993, which is referred to in Mr Canavan's submission. Agreement had been reached that while the Macfarlane Trust were providing the administration for the Eileen Trust, the Secretary of State would seek nominations from the Macfarlane Trust for three of the five Eileen Trust trustees and the Macfarlane Trust had the right to terminate the arrangement. I wrote to Prebendary Tanner on 2 April 1993 to confirm the arrangement reached with officials [DHSC0002769_012].

7.15. On 28 May 1993, Mr Canavan put a submission to my Private Office that sought agreement to making an approach to three candidates with a view to

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[6] Mr Scofield's submission to my Private Office dated 18 February 1993 suggested that the Eileen Trust's administrative costs were met by a Section 64 grant from the DH [WITN5249036].

appointment of one of them as the fifth trustee [DHSC0002771_015; DHSC0002771_011]. I agreed the list of candidates on 7 June 1993 [DHSC0002770_006]. A further submission followed on 14 June 1993 and which sought agreement to the appointment of one of the candidates [DHSC0002769_007; DHSC0002769_008; DHSC0002769_009].

7.16. On 29 September 1993, Mr Canavan put a submission to my Private Office [WITN5249032]. Mr Canavan attached a letter dated 30 July 1993 from Prebendary Tanner to Mr Heppell, which referred to the assurance given by Government to consider the further needs of the Macfarlane Trust. Prebendary Tanner's letter said:

> *"Whilst not seeking an excuse for extravagance, the Trustees of the Eileen Trust would find it much easier to develop policies given the reassurance of a similar kind of promise [...]*
>
> *Although the Eileen Trust fund is comparable in pro-rata terms it is nevertheless a little more vulnerable in view of its size. To operate on income alone would be considerably inhibiting to a well-balanced policy, and the Trustees will be faced with the same dilemma faced as the Macfarlane Trustees as to what extent they dare to deplete the capital to meet current expenditure.*
>
> *In exercising this judgement it would be a relief to know that our further needs might be again considered in (say) three years' time."* [WITN5249032]

7.17. Mr Canavan's submission advised that:

> *"In our reply we must be careful not to commit ourselves to making future payments, as this would need clearance by Treasury. We do not recommend an approach to Treasury at this sensitive time in terms of PES, particularly as they have not been well disposed towards payments to HIV infected patients for a number of years. On the other hand we need to give the Trust an answer fairly quickly and we recommend that the reply from officials should make clear that, without commitment, we would be prepared to look again at funding of the Trust in three years' time."*

7.18. On 5 October 1993, my Private Office confirmed to Mr Canavan that I had seen his note and that I was content for officials to write to the Eileen Trust in the terms of Mr Canavan's draft letter.

7.19. The available documents do not suggest that I subsequently had any direct involvement in issues around the Eileen Trust.

Section 8: Government response to those infected with HCV as a result of NHS treatment

Financial assistance for those infected with HCV – background and justifications for policy

8.1. I have been asked by the Inquiry to describe my knowledge of, and involvement with, the Department of Health's policy during this period of declining to provide any financial assistance to persons infected with Hepatitis C (and their family members) as a result of blood products or blood transfusions within the NHS.

8.2. First, I set out some of the relevant background to this issue.

8.3. In July 1992, a ministerial away day took place at Chevening in which the issue of compensation for medical accidents was discussed. A minute of 21 July 1992 from Mr Armstrong in my Private Office records my request for a note on the Department's current policy and the arguments over no fault compensation [WITN5249022].

8.4. The note was produced on 11 August 1992 [WITN5249023]. It set out that a victim of an injury caused by medical treatment had recourse only to the court where they would be required to prove negligence on the part of the NHS in order to be awarded compensation.

8.5. As set out in the note, the government had consistently resisted no fault compensation schemes because, in summary:

(1) If the requirement to prove negligence in court were to be dropped, the number of claims would increase dramatically and with it the cost to the public, reducing the funds which would otherwise have been available to the wider NHS budget;

(2) The government's policy was that negligence in healthcare should not, in principle, be treated differently from negligence in any other area of life;

(3) Doctors ought to have the opportunity to defend their conduct and reputation in court;

(4) No fault compensation could reduce the deterrent effect to malpractice of the threat of prosecution for negligence;

(5) Causation would still require proof and the courts were the forum best suited to reaching a determination of the cause of any injury by examining the relevant facts;

(6) Such a scheme could be seen as unfair to those disabled as a result of disease who would not be compensated;

(7) Free health and social care services were available to all disabled people regardless of the cause of their disability.

8.6. The note drew attention to the costs of any such scheme, estimated in New Zealand (in relation to accidents generally) at around 1.4% of the country's entire gross national product. An estimate of the cost of adopting an equivalent approach to the scheme found in Sweden in the UK was between £300m and £400m annually.

8.7. Following settlement of litigation in relation to HIV-infected haemophiliacs in the Spring of 1991 and public pressure for similar treatment for HIV-infected blood and tissue recipients, the government agreed that blood and tissue recipients were in the same special category as haemophiliacs since both groups were infected with HIV as a result of NHS treatment. See further the discussion in Section 7.

8.8. The government's clear and established policy in relation to those infected with Hepatitis C, a policy which I inherited, had been that any claims for compensation should be pursued through the courts for the reasons I outlined above.

8.9. On 30 October 1992 I wrote to Elliot Morley MP [WITN5249037] in respect of one of his constituents who claimed to have contracted Hepatitis C as a result of a blood transfusion they received before 1985.

8.10. I explained, in line with the policy outlined above, that the scheme of payments for those infected with HIV through blood or tissue transfer was an extension of the settlement scheme for haemophiliacs who contracted HIV through using infected blood products. There were no plans to extend the scheme to those who may have been infected with Hepatitis C.

8.11. Questions were raised in Parliament on this issue, for example [WITN5249038] which records a question directed to the Secretary of State on 3 February 1993 from Alfred Morris MP, who asked "*what representations she has had in regard to compensating people with haemophilia who have contracted hepatitis in the course of treatment under the NHS…*"

8.12. I set out the government's policy in my written replies to questions from MPs such as my response to David Porter MP on 2 September 1993 [WITN5249039].

8.13. On 18 January 1994 I received a minute from Dr Rejman and Mr Canavan [WITN5249040] in respect of blood screening for rare viral infection and Anti-HBc. The minute was not specific to Hepatitis C and therefore the context in which the minute discussed the availability of testing and its cost benefit analysis of the same was different (because by this stage regular testing was in place for Hepatitis C). Noting the position on compensation, namely that (with the exception of HIV cases) the only recourse for victims of infected blood or blood products was through the courts, ministers' views were sought as to whether the principle of ex-gratia payments should be further considered.

8.14. Following the above minute and a meeting with Dr Metters, Dr Rejman and Mr Canavan, I approved the advice of the MSBT that the routine testing of blood and blood products for Anti-HBc should not yet be introduced because testing was not yet effective enough, as recorded in the minute of 4 February 1994 [DHSC0042296_061]. I did not approve the principle of ex-gratia payments, noting the arguments against such a special arrangement set out in the 18 January 1994 paper.

8.15. On 28 June 1994 I received further correspondence from David Porter MP, who asked me whether there was any prospect of the Department reconsidering its decision not to offer one off settlement payments to Hepatitis sufferers to match those made to haemophiliacs who contracted HIV through infected blood products. I acknowledged the letter on 13 July 1994 [WITN5249041] and asked my Private Office for advice on the issue, noting ([WITN5249042]) *"a tricky one: if HIV, why not Hepatitis… please could I have advice and a line to take…"*

8.16. On 15 July 1994 I received a minute from Mr Kelly attaching advice and a line to take ([WITN5249043]) which advised me that "*[o]ur concern has been to ring-fence the payments to HIV-infected haemophiliacs, and those infected with HIV through blood transfusion. There has always been the danger that these payments might encourage claims from other groups damaged by medical accidents. 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.*"

8.17. Special provision had been made in respect of those with haemophilia and HIV. It was noted that:

> *"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 a result of their hereditary haemophilia…*
>
> *Hepatitis C is much less severe than HIV, 50% may progress to chronic hepatitis with varying degrees of ill health and mortality. Some of these*

> *will respond to interferon treatment. It is not transmitted sexually as easily as HIV. Hepatitis C does not have the same social consequences of ostracism that has HIV…"*

8.18. In accordance with the above, the Department's line to take as provided to me was "*We have no plans to extend the settlement scheme for haemophilia patients with HIV to those who may have been infected with hepatitis*".

8.19. In November 1994, an article was due to appear in the Independent newspaper, prompted by the Haemophilia Society, about haemophiliacs infected with Hepatitis C through blood products before heat treatment was introduced in 1985 and blood transfusion recipients infected between 1989 and 1991 (when routine screening of donations was introduced). [WITN5249044].

8.20. I asked for a briefing on the proposed article and on 15 November 1994 I received a background note and updated line to take from Mr Hollebon [DHSC0002501_102; DHSC0002501_103; DHSC0002501_104].

8.21. The Department's concern remained to ring-fence the payments to HIV-infected haemophiliacs and those infected with HIV through blood transfusion from other categories of medical accidents. The line to take provided to me was as follows:

> *"We accepted that the haemophilia patients who, tragically, contracted HIV through infected blood products were a very special case.*
>
> *We have great sympathy with those who may have been infected with hepatitis C through NHS treatment. We have no plans to extend the settlement scheme for haemophilia patients with HIV to patients who may have been infected with hepatitis C. These patients will have received the best treatment available in the light of medical knowledge at the time".*

8.22. A briefing for the Prime Minister (copied to my Private Office) setting out the position and line to take on 16 November 1994 [DHSC0003527_008; DHSC0003527_009; DHSC0014961_040; HSOC0021550] included the following:

> *"The Haemophilia Society, in a statement issued this morning in response to the alarmist press reports, recognise that only a small proportion of sufferers have had severe problems. We are working closely with the Haemophilia Society and others to do everything we can to improve our knowledge of the condition and the full extent of the problem. The Haemophilia Society in their statement indicate that they have no plans to seek compensation from the government".*

8.23. The Secretary of State Virginia Bottomley had also asked for full briefing and legal opinion on Hepatitis C infection [DHSC0041152_216; DHSC0041152_217; DHSC0041152_218; and DHSC0002548_159]. As I have addressed in paragraph 4.5, above, this request was against the background of increasing pressure to grant ex gratia payments to those infected with Hepatitis C through blood and blood products and press reports that were emerging around this time.

8.24. On 6 December 1994, I responded to a parliamentary question from Joe Benton MP [WITN5249045]. In accordance with the Department's policy, I said that "*we have great sympathy for those who may have become infected with hepatitis C from contaminated blood products, but have no plans to make payments to patients who may have been infected with hepatitis C as a result of National Health Service treatment.*"

8.25. I see from the documents that Mr Scofield circulated a minute on 9 December 1994 [WITN5249046], noting that "*there has been increased interest in hepatitis C recently and we can expect the campaign for compensation for those infected through NHS treatment to be stepped up over the next few months…*". The Permanent Secretary had "*held a meeting on 25 November [1994] to review the Department's advice to Ministers in respect to claims for compensation for those infected with Hepatitis C following blood transfusions or treatment with blood products…*" Mr Scofield's minute set out a number of action points which could be taken by the Department short of making ex gratia payments. These were explained in the following terms:

> *"i) undertaking whatever research may be appropriate to determine the aetiology of the disease and its treatment/management.*

> *ii) drawing up and publishing good practice guidance on treatment and ensuring that all affected have proper access to treatment facilities.*
>
> *iii) determining whether there are ways of identifying those who have been infected (eg. by using "look back" procedures) so that they may be notified and any prophylactic action taken or treatment given…*
>
> *iv) supporting any self-help initiatives…"*

8.26. On 23 November 1994, Ann Winterton MP wrote to Gerald Malone (Minister of State for Health) in respect of potential compensation for patients who had been infected with Hepatitis C as a result of NHS treatment. Her letter was referred to me for a reply and a draft prepared for me by Mr Scofield on 13 January 1995 [WITN5249047], including the following text in line with the Department's policy:

> *"We have great sympathy with those who may have become 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…*
>
> *…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 court, it accepts its liability to pay damages…."*

8.27. On 30 January 1995 Baroness Cumberlege gave a parliamentary written answer [NHBT0005768_002] in respect of the government's plans for a compensation scheme for haemophiliacs who had Hepatitis C following infection from contaminated blood products similar to that for those infected with HIV. Baroness Cumberlege said, in an answer which I also approved "*we have great sympathy for those affected, but have no plans to make special payments*".

8.28. There follows in the same document a briefing note for House of Lords ministers answering supplementary questions in respect of the comparisons increasingly being drawn between the position of those infected with HIV through NHS treatment and those infected by Hepatitis C. In accordance with the

Department's policy, the note set out that HIV victims were a special case, principally because "*those affected were all expected to die very shortly and were subject to significant social problems, including ostracism*".

8.29. The "*special circumstances*" were, in contrast to the circumstances of Hepatitis C patients, as follows:

(1) The nature of the HIV infection (which was invariably fatal);

(2) The significant lifestyle implications of HIV; and

(3) In the case of the infected haemophilia patients the problems of HIV were superimposed on the health, social and financial disadvantages they already suffered as a result of their hereditary haemophilia.

8.30. The above points were reflected in my letter to Winston Churchill MP on 31 January 1995 [HSOC0004917] in which I explained "*Hepatitis C is different and does not attract similar problems*".

8.31. In addition, and as reflected in the House of Lords briefing note, the government was concerned by the potential costs of a Hepatitis C scheme. It was estimated, based on a population of circa. 6,000 individuals paid between £41,500 and £80,500 each (with an average payment of £60,000), a comparable cost with the HIV scheme, that the cost to the taxpayer could be in the region of £360m.

8.32. On 14 March 1995, the Haemophilia Society launched its campaign for financial compensation for haemophiliacs who had been infected with Hepatitis C through receiving contaminated blood [DHSC0003595_111].

8.33. The campaign generated further publicity and correspondence to my parliamentary colleagues from constituents. My letter to Douglas Hogg QC MP dated 19 May 1995 [WITN5249048] reflects one such case. I explained that, in respect of Hepatitis C patients, the government did *"not accept… 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…"*

8.34. On 23 March 1995 I received through my Private Office an updated line to take and background note on the Hepatitis C issue in respect of EDM 864 [DHSC0006230_026 and DHSC0006230_027]. It set out the following reasons why the government was opposed to a no-fault compensation scheme:

(1) Proof of causation was still needed;

(2) It would be unfair to those whose conditions resulted from disease (or birth) rather than accidents;

(3) The costs would impact upon the NHS funds available for patient care;

(4) Health care negligence was not considered different from negligence in any other walk of life where claims for compensation were resolved through the courts; and

(5) The present system had a deterrent effect on medical malpractice.

8.35. As to the differences with HIV:

(1) HIV victims suffered health, social and financial disadvantages not suffered by those with Hepatitis C; and

(2) Many people infected with Hepatitis C:

> *"…may enjoy a long period without any symptoms appearing. 50% of sufferers may progress to chronic hepatitis with varying degrees of good and ill health. Perhaps 20% of infected patients will develop cirrhosis, a progressive destruction of the liver, that may take 20 or 30 years. The majority of those years will be trouble free in terms of ill health and only a small percentage will actually die of liver disease."*

8.36. On 30 March 1995, the Minister of State, Gerald Malone, held a meeting with John Marshall MP, Sir Geoffrey Johnson Smith MP and Sir Terence Higgins

MP. As recorded in a minute from Mr Malone's APS to Mr Scofield on the same date [DHSC0002548_009], it was agreed that:

> *"…there was a need for the Department to give careful consideration to the issues raised:*
>
> - *that those suffering from life-threatening complications (eg cirrhosis of the liver and liver cancer) caused by Hepatitis C contracted through blood transfusions and blood products might be granted 'ex gratia' payments (such payments have been granted to those who contracted the HIV virus in this way).*
> - *it would not be sensible to provide assistance to all those who have contracted the Hepatitis C virus since not all of those infected develop life-threatening complications.*
> - *Consideration would need to be given to potential 'triggers' for Government assistance".*

Mr Malone requested my views and the views of the Permanent Secretary.

8.37. Mr Malone is recorded in the papers as apparently having been in favour of making payments to haemophiliacs and others infected by Hepatitis C but had yet to convince the wider Department and ministerial colleagues [WITN5249049].

8.38. Mr Malone requested that a potential plan should be formulated for a scheme. Mr Scofield's paper was accordingly produced on 6 April 1995 [MHRA0025171] and noted at the outset that such a scheme was "*the exact opposite of the position that the Government generally and Health Ministers in particular have taken to date*".

8.39. The paper set out the reasons for the government's position in similar terms to the 23 March 1995 paper, with the added reason that "*in those countries which have such a scheme, the amounts payable are very small in comparison to what a case would win in the courts…*"

8.40. The summary paper set out the potential basis for a scheme in accordance with the campaign by the Haemophilia Society and noted "*if Ministers consider that* *the case for a payments scheme is admissible… then there is a case for taking a pro-active approach now…*"

8.41. On 6 April 1995 the Department's Permanent Secretary, Sir Graham Hart, circulated a minute [DHSC0042937_121] expressing views firmly against no-fault compensation. He said as follows:

> *"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 recognise 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."* (Emphasis added)

8.42. In my response to the above [DHSC0042937_120], recognising the concerns expressed by the Permanent Secretary, I noted that Sir Graham's paper "*looks pretty decisive*" and commented that "*it will be important that [the] Secretary of State is well briefed for a Cabinet discussion*". I must stress that there was no lack of sympathy for Hepatitis C sufferers but my colleagues and I were acutely aware of the limited resources available to the NHS and the likely strong opposition by the Treasury to any scheme of ex gratia payments.

8.43. A meeting of the Department's ministers was scheduled to discuss the position in April 1995, in advance of which Sir Graham minuted the ministers' Private Offices on 12 April 1995 [DHSC0042937_119]. Sir Graham wrote:

> *"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. These are difficulties of principle as well as practice – and I find them pretty compelling. I recognise 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."*

8.44. On 1 May 1995 Mr Malone wrote to me and explained that he had changed his mind [WITN5249050]. His note records that "*we [had] discussed this matter relatively informally*". I have no recollection of that discussion but the document sets out Mr Malone's complete change of view as follows:

> *"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:*
>
> 1. *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 (eg 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 [the Secretary of State] 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."*

8.45. Mrs Bottomley added her comments to the views of Mr Malone by way of a handwritten note on the document as follows (as recorded in a typed minute of 5 May 1995 from her Private Office to Mr Malone's Private Office [WITN5249051]

> *"...there will always be new examples where no fault compensation becomes an issue and believes that we must hold a consistent line. Other areas where comparison may already be drawn include thalidomide and haemophiliacs with HIV/AIDS, SofS is concerned that growth hormone may bring a similar campaign.*
>
> *SofS has asked that:*
>
> *we establish the views of the territorials, and;*
>
> *the senior official[s] talk [to] Carolyn Fairbairn from No 10 through the issues."*

8.46. These documents record that it was Mrs Bottomley's decision to maintain the Department's policy and that she agreed with the advice of the Permanent Secretary. From my memory of working with Mr Malone, my view is that he did not fully understand the ramifications of the views he expressed in March 1995. It was, after all, not an area of policy within his remit. It was one of my areas of policy responsibility rather than his. I suspect that he was seeking to be helpful to senior colleagues and did not fully understand the implications of the view he expressed. It therefore does not surprise me that, on further examination of the issues, he reversed his view.

8.47. Mr Scofield minuted Dr Metters referring to correspondence between Mr Malone and ministerial colleagues on 9 May 1995 [DHSC0006327_007]. In accordance with the request by the Secretary of State, Mr Scofield had written to Carolyn Fairbairn (a senior 10 Downing Street official) and the territorial offices for their views.

8.48. Following a request by the Secretary of State for information in respect of the way in which other EU countries dealt with payments in respect of HIV and Hepatitis C, Dr Rejman circulated a summary document [DHSC0006600_081 and DHSC0006600_082] on 19 May 1995.

8.49. On 7 June 1995 I attended a meeting of ministerial colleagues and officials in respect of Hepatitis C [WITN5249052] and [DHSC0042937_103]. The meeting discussed the question of whether the Department would be able to defend a claim in negligence brought on behalf of those infected with Hepatitis C as a result of infected blood or blood products. It was agreed to maintain the status quo and meanwhile obtain legal advice on this question.

8.50. The preliminary view of the Solicitor's Division (Charles Blake) was as follows [DHSC0003552_154]:

> *"In my opinion the difficulties of testing, the unreliable results obtained in 1990 and the other problems mentioned suggest that there was no negligence in not introducing the testing at that time. As to the timing of the later introduction of the tests it is arguable that there was some needless delay. I suspect that if we were sued an expert could be found to say that we reacted too slowly.*
>
> *The difficulty in this area is that whether or not we broke the duty of care owed is a matter of fact rather than of law. Experts can always be found to contradict each other. But my preliminary view… is that we would have some prospects of defending a negligence suit".*

8.51. The Department's position remained unchanged, as set out in our response to EDM 1219 [DHSC0006774_060] and the draft briefing to the Prime Minister of 9 June 1995 [DHSC0006600_080]. This expressed sympathy to those infected with Hepatitis C and stated that the Department "*was 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*". However, it restated that there were no plans to compensate those infected with Hepatitis C.

8.52. At a ministers' meeting on 13 June 1995, it was decided that I would speak to officials about the Haemophilia Society's initiative for those infected with

Hepatitis C [DHSC0006600_041]. Officials met with the Society on 16 June 1995 and a report was sent to the Secretary of State, Mrs Bottomley [DHSC0004428_049].

8.53. I asked for the latest legal advice on Hepatitis C compensation to be provided to me by 20 June 1994 [WITN5249053]. This led to the advice of Nigel Pleming QC and Steven Kovats of 39 Essex Street Chambers being produced, to which I refer below.

8.54. On 4 July 1995 the Secretary of State received a letter from Cynog Dafis MP and Dai Lloyd MP [DHSC0020743_011] in which they asked the government to reconsider its decision not to give financial assistance to those haemophiliacs infected with Hepatitis C as a result of NHS treatment with contaminated blood products.

8.55. In my draft response I referred my remarks in the Adjournment Debate of 11 July 1995 and explained [DHSC0002467_259]:

> *" ... it has to be acknowledged that hepatitis c is different to HIV. Patients infected with HIV were all expected to die very shortly. They were subjected to significant social problems, including varying degrees of ostracism. Many people with hepatitis C live normal lives for decades..."*

8.56. I would like to emphasise here that the Department appreciated the significant impact of its policy to the Hepatitis C infected and affected when it was being developed during my tenure.

8.57. The policy that was implemented was the result of considered research (for example, as referred to above the Department considered the policies of a number of other European countries as to compensation for the contraction of Hepatitis C – see the letter from Dr Rejman dated 19 May 1995 [DHSC0006600_081 and DHSC0006600_082]).

8.58. The Department had great sympathy for those infected with Hepatitis C as a result of blood products provided to them, but concluded that a no-fault compensation scheme was not appropriate for the reasons I have outlined.

8.59. In the House of Commons debate of 11 July 1995, to which the Inquiry has referred me, I explained the reasons underpinning this policy. The following passage [RLIT0000887] summarised those reasons:

> "*… some people would argue that although individuals were infected in different ways, they are entitled to payments--even though no fault on the part of the NHS was proved.* ***The Government have never accepted the case for a no-fault scheme of compensation for medical accidents.*** *There are sound reasons.* ***Proof of causation would still be needed.*** *It may be just as difficult to establish that medical treatment has caused injury as to prove that someone has been negligent. It also has to be demonstrated that the outcome was not a foreseeable and reasonable result of treatment.*
>
> ***It would be unfair to others if individuals whose plight was the result of a medical accident would be compensated, whereas those whose condition stemmed, for instance, from disease from birth would not. Health negligence is not considered fundamentally different from negligence in other walks of life, where claims for compensation are resolved through the courts.***
>
> *The experience of other countries that have tried to follow the compensation path has strengthened the Government's view.* ***The costs of the New Zealand scheme have proved extremely high--some 1 per cent. of gross domestic product, which is equivalent to £6 billion in the United Kingdom.*** *In addition to practical difficulties, that scheme effectively denies access to the courts.*
>
> *I understand that payments under Sweden's no-fault compensation scheme are much lower, but the authorities have found it necessary to make additional payments to individuals infected with HIV.*
>
> *I am not aware of any country in Europe that has made payments to patients with haemophilia infected with hepatitis C through blood products. Every individual case in which a medical accident has occurred is a personal tragedy for the individual and his or her family.*
>
> ***If the NHS is proved negligent in a court, of course the service accepts its liability to pay damages. It remains the Government's view that the most effective use of available resources is to seek to improve the understanding, management and treatment of the condition.*** *Only in that way can the disease's impact on individual patients and their families be effectively minimised*" (Emphasis added).

8.60. On 12 July 1995, the Department received legal advice from Nigel Pleming QC and Steven Kovats of 39 Essex Street Chambers on the issue of compensation for those haemophiliacs infected with Hepatitis C [DHSC0017297].

8.61. The advice focused on whether blood was a 'product' within the terms of the Consumer Protection Act 1987 and European law generally, following from the Haemophilia Society's request for compensation.

8.62. The advice was that blood was to be viewed, at least in some circumstances, as a product, but that it was necessary to look at the facts of each case to determine whether the transaction was a supply of goods or services. The Department's policy meanwhile was unchanged.

8.63. I am asked by the Inquiry to explain the relevance of and weight attached to the Department's stated justifications for its policy.

8.64. The fact of the lack of proven negligence by the NHS, including foreseeability of injury and causation, as well as the concern that establishing a 'no-fault' compensation scheme would be unfair to other victims of medical accidents, are closely linked. While I cannot recall my thinking at the time, I believe that the potential unfairness to other NHS patients was the most significant factor, since it was felt that they would lose out as a result of the inevitable reallocation of funds within the finite resources of the NHS budget.

8.65. These were all essential considerations with substantial weight. Blood and blood products were provided to patients on the reasonable understanding that they were safe. It was felt that the NHS had the best scientific evidence available at the time. To compensate patients who had received Hepatitis C infected blood products (and/or their families) in these circumstances would be contrary to the uncontroversial and long-accepted principle in English law that a person who has allegedly suffered loss as a result of negligent medical treatment must prove their claim in court.

8.66. The fact that treatment was understood as having been provided "in good faith" was part and parcel of this reasoning. In essence, treatment was provided in accordance with the best medical knowledge available at the relevant time and the policy was that no-fault compensation payments should not be made to those who had, albeit very unfortunately, become infected with Hepatitis C. Where appropriate the courts offered the best means of resolution.

8.67. As to causation, the Department considered that an ex-gratia scheme for hepatitis C infection would also be problematic because potential beneficiaries would still need to establish that their infection had been caused by blood or blood products and this would be more complex than had been the case for the HIV schemes. In addition, there were concerns that a no-fault scheme could conceivably encourage doctors to be less cautious, as outlined in the note dated 23 March 1995 for EDM 864 [DHSC0006230_026 and DHSC0006230_027].

8.68. I have also been asked specifically to address the relevance and weight of the cost and unworkability of a no-fault scheme, referring to figures recorded in New Zealand and Sweden.

8.69. This was closely linked to the concerns I have described above. Essentially, it would not have been practically feasible to introduce a policy that provided compensation to patients without proof of negligence. Information obtained as to the operation of a compensation scheme in Sweden was not the decisive factor in the formation of the Department's policy, but it did demonstrate the practical difficulties of seeking to compensate large numbers of patients for a range of losses out of a single limited fund, as set out in the briefing notes for the Minister for Health's Meeting with MPs on Hepatitis C Compensation dated 28 March 1995 [WITN5249054].

8.70. The Swedish government, which ordinarily operated a fixed payment scheme, had been forced to supplement its usual fund for those infected with HIV from blood products due to the particular circumstances of those patients. This showed that substantial complexities would be likely to arise as to the assessment and funding of a no-fault award for those infected by blood products.

8.71. As to costs, the Department had obvious (and understandable) concerns about the opening of "floodgates". Again, figures from New Zealand were not the sole decisive factor in the formation of the Department's policy, but they demonstrated that a no-fault scheme could become extremely expensive. This would also impact upon the amounts available for patient care, as outlined in the background note dated 23 March 1995 for EDM 864 [DHSC0006230_026 and DHSC0006230_027].

8.72. In addition, although not related to costs, as I outlined in the House of Commons debate of 11 July 1995, a no-fault scheme such as that in operation in New Zealand would cause a disadvantage to patients in that they would not also have the opportunity to bring their case in court and to recover potentially more than the sum offered to them under the scheme.

Distinction between persons infected with HCV and HIV for purposes of "no fault" compensation

8.73. The Inquiry has asked me to explain why the Department distinguished between persons infected with HIV and Hepatitis C for the purposes of 'no fault' compensation. I am asked to address a number of specific factors in my answer.

8.74. This passage of the speech given by me in the House of Commons debate of 11 July 1995 [RLIT0000887] provides a clear explanation of the reasons for the distinction between HIV and Hepatitis C patients, as follows:

> *"The debate reminds us that, alongside the great benefits to patients, medical procedures rarely come without some risk. It is important to remember that it is not always possible fully to appreciate the risk at the time or to avoid suspected or known risks. In the case of each individual*

patient, a balance must be struck between the benefit to be gained versus any possible risk. Let us look at the facts of hepatitis C. Most haemophilia patients infected with hepatitis C were so infected before blood products were treated to destroy viruses in 1985. That was well before the first hepatitis C tests were available in 1989. Those patients received the best treatment available in the light of medical knowledge at the time. When those patients were infected, little was known about hepatitis C, or non-A, non-B hepatitis as it was then known, and even today a lot more information is needed.

The House will be well aware that, notwithstanding the subject of the debate, the availability of factor VIII concentrate has brought great benefits to patients with haemophilia. Previously, only about 5 per cent. of patients with severe haemophilia reached the age of 40, whereas by 1980 the life expectancy was very close to that of normal males. There was less need for long periods of hospitalisation and boys had a better chance of achieving a reasonable education. Additionally, the convenience of patients being able to keep concentrate in a domestic fridge and treat themselves at the first sign of a bleed meant a considerable reduction in long-term disability.

Before there was any test for non-A, non-B hepatitis, the only way to safeguard blood was to limit those from whom blood was taken by a system of self-deferral. It excluded, among others, those known to be suffering from hepatitis or any other liver disease; drug misusers; and men who were sexually active with other men.

No one should underestimate the effects of hepatitis C. The point that I am making, and this is at the heart of the debate, is that, contrary to views that have already been expressed in another place, patients who tragically contracted HIV through NHS treatment were in a different category. Their exceptional circumstances caused us to make special provision for them.

Many people infected with hepatitis C, as has already been said by my hon. Friend, may live for a long period without any symptoms appearing. However, 50 per cent. of sufferers may progress to chronic hepatitis with varying degrees of good or ill health. Perhaps 20 per cent. of infected patients will develop cirrhosis, a progressive destruction of the liver that may take 20 to 30 years. The majority of those years will be trouble-free in terms of ill health and, as I have mentioned, only a small proportion will die of liver disease, but every death is a tragedy for the family concerned.

In the case of those who contracted HIV through NHS treatment, special payments were made and trusts established to help sufferers or their families in cases of hardship. Those arrangements were put in place in recognition of the very special circumstances of those who contracted HIV. Those affected were all expected to die very shortly, although it has since become clear that, fortunately, that is not always the case. It meant that there might also be significant numbers of young children who had lost one parent or perhaps both if the disease had been transmitted also to their partner.

> *Sufferers were also subjected to stigmatism and a whole range of other social problems. There were cases of doors daubed with graffiti, lost jobs and children not allowed to mix with other children at school--in short, people were denied any normal family life. I would in no way wish to minimise the physical suffering of those who have been infected with hepatitis C through blood or blood products--the suffering which may result or the worry which they or their family may experience--but each case has to be examined on its merits. I have to recognise that those who have contracted hepatitis C are not also subject to all the additional problems experienced by HIV sufferers, who were accepted as being a very special case. Many people infected with hepatitis C may live for a long period without any symptoms appearing or may never experience any…"*

8.75. One of the main reasons for the distinction, as is clear from the extract above, was that Hepatitis C patients generally had a very significantly better clinical condition and prognosis as compared with those of HIV patients.

8.76. In general, they lived longer and developed symptoms at a considerably slower rate. Treatments were also becoming available for Hepatitis C. By contrast, HIV patients would generally experience significant symptoms and, very sadly, would be likely to die more quickly. There was no treatment for them at the time. Therefore, it was felt fair and appropriate to offer ex gratia payments to HIV sufferers: they had a clear requirement for such payments to meet evident additional clinical and care needs, and they did not have the time to bring a claim to its resolution in the courts.

8.77. The shorter life expectancy of patients infected with HIV had additional complications. Many of those patients would die young, with young dependent children. There was therefore a strong case that funding was justified and appropriate, in order to support dependents after the death of the patient.

8.78. On 27 September 1995 I wrote to Veronica Hardstaff MEP [BNOR0000296], in particular referring to the differences in life expectancy between HIV and Hepatitis C in the following terms, echoing the points I raised in my speech to the House of Commons:

> *"At the time the HIV settlement was made, haemophilia patients with HIV were expected to die shortly. Fortunately, with progress in treatment, the numbers who have survived are greater than we expected. However, out of the 1,238 haemophilia patients infected with HIV more than half (641) have progressed to AIDS and died.*
>
> *With regard to hepatitis C, it is believed that the vast majority of haemophilia patients treated with blood products prior to 1985 are infected with the virus, that is a total of about 4,000 (including the 1,238 who are HIV positive). Our latest figures from the UK Haemophilia Directors Association show that 48 of those patients have died from liver disease up to December 1993, of whom at least 22 were HIV positive; it is known that co-infection with HIV leads to more serious clinical problems with hepatitis C.*
>
> *The long period of time during which haemophilia patients with hepatitis C are able to lead normal lives is also reflected in the ages at which those with HIV have died in comparison with those with hepatitis C. A significant proportion of those with HIV have died whilst still young and with dependent children and have, therefore, lost many years of potential life. 129 living haemophilia patients with HIV have dependent children and 153 of the patients who have died had dependent children. Patients with hepatitis C and clinical symptoms, on the other hand, in particular those not co-infected with HIV, have tended to be older and so are less likely to have dependent children."*

8.79. Hepatitis C positive patients were also not thought to be subject to the same social stigma as those who were HIV positive. The disadvantages to HIV sufferers in this regard were undeniable and it was appropriate to reflect that through compensation, bearing in mind not only the impact on personal lives, but also on financial matters such as increased insurance premiums.

Government position on most effective use of resources for HCV

8.80. The Inquiry has asked me to explain the rationale for the Government's position that "*the most effective use of available resources is to seek to improve the understanding, management and treatment*" of Hepatitis C.

8.81. This quotation is taken from the Hansard debate of 11 July 1995 and a letter from Stephen Dorrell MP (then Secretary of State for Health) to Sir Edward Heath MP dated 31 July 1995 [HSOC0019856_002].

8.82. On 18 July 1995, the Haemophilia Society wrote to the Department (specifically Mr Pudlo) [WITN5249055] on precisely this question. Referring to my recent ministerial correspondence with its members in which I had explained the government's position, the Society asked what measures were being taken to improve the understanding, management and treatment of Hepatitis C.

8.83. Mr Pudlo's note to me referred to my undertaking in Parliament to look into the question of ensuring that such patients obtain the treatment they needed. My response to Mr Pudlo was "*it is important to stay on good terms with the Society*" [DHSC0002474_005].

8.84. Mr Pudlo met with Graham Barker of the Haemophilia Society on 9 August 1995 [WITN5249056] and responded to the Society's letter on 16 November 1995 [DHSC0041361_045]

8.85. I set out the Department's work on treatment in subsequent parliamentary correspondence. In a letter to John Marshall MP dated 26 July 1995 [HSOC0005118], I referred to Interferon treatment. I explained that it was not a panacea for Hepatitis C patients but that it had been shown to have real benefits for a proportion of sufferers and that it was important that those who could benefit received it, with individual decisions as to treatment of course being a question of clinical judgment in all the circumstances.

8.86. The Department did not hold money centrally or allocate resources to support specific treatments for particular segments of the population. However, I agreed with Mr Marshall that if there were problems of availability of the drug for haemophiliacs the Department could seek to assist and I committed to seeing what I could do to help.

8.87. I therefore instructed departmental officials to work with the Haemophilia Society and the directors of Haemophilia Centres to obtain relevant information.

8.88. I referred above to my response to Cynog Dafis MP and Dai Lloyd MP of 26 July 1995 [HSOC0016742], to which the Inquiry also refers. In that response I related the fact that the Department was considering "*a range of potential initiatives to improve the understanding, treatment and management*" of Hepatitis C. This included the encouragement of research into the condition and guidance to the NHS on best practice where there was a clinical consensus.

8.89. I repeated the government's position in respect of compensation, that is that the case for a no-fault scheme for victims of medical accidents was not accepted. Given that policy and the government's opposition to such a compensation scheme for all the reasons I have outlined, it was the Department's position and my own view that the most effective use of the finite public resources available to the NHS would be to direct funds to the research into and understanding and management of Hepatitis C.

8.90. It was the Department's role to strategically manage the resources available to the NHS in accordance with our policy. In doing so in respect of Hepatitis C we wished to work with the experts and representatives, including the Haemophilia Society, to improve the condition of those infected and affected by Hepatitis C.

8.91. For this reason, as I explained in my letter to Mr Dafis and Mr Lloyd, the Department made available a grant of £91,000 in the financial year 1995/1996 in support of an initiative by the Haemophilia Society to study the best means in which to support its infected members. Further funding was promised for the years 1996/1997 and 1997/1998. The outcome of the Society's report would inform the future policy of the Department with regard to those affected by Hepatitis C.

8.92. Ultimately, the rationale for the government's position on resource allocation was the need for the Department to focus its limited funds most effectively to best address the problems encountered by Hepatitis C sufferers, in accordance with the advice of officials and experts. Ex gratia payments to one group would have meant a reduction in the funds available elsewhere and for all the reasons I have set out in this statement this was not an approach supported by the government.

Steps taken to improve the understanding, management and treatment of HCV

8.93. I am also asked what other steps were taken the improve the understanding, management and treatment of Hepatitis C during my tenure as Parliamentary Under-Secretary of State for the Department.

8.94. In particular, I am asked to explain what consideration was given to, and what steps were taken by, the Government in relation to a) the funding of research into Hepatitis C and its effects and b) guidance from the Department and the Chief Medical Officer to the NHS on best practice based for treating those with Hepatitis C.

8.95. I do not directly recall the other measures taken by the Department in this regard and therefore am entirely reliant on the documents collated by the Inquiry and my legal representatives.

8.96. Mr Pudlo minuted Dr Rejman following the former's meeting with the Haemophilia Society on 9 August 1995 [WITN5249056]. The focus of the note was the problem of haemophiliacs with Hepatitis C gaining access to Interferon treatment. Anecdotally it appeared that the limitations on access were financial and that the issue was being confused by the various funding mechanisms in place.

8.97. The Department wished to work with the Haemophilia Society to survey local Haemophilia Centres to ascertain the scope and extent of the problem of access to treatment. Of course as I outlined above Interferon was a relatively new treatment and therefore some initial issues were to be expected in facilitating access to it across the UK for all those in need.

8.98. Mr Pudlo's minute also referred to the Haemophilia Society's view that the Department should endorse and distribute a Chief Medical Officer's letter on "*Guidelines on the Diagnosis and Management of Chronic Liver Disease in Haemophilia*" by the UKHCDO Working Party on Chronic Liver Disease in Haemophilia. There was a question as to the scientific and clinical status and efficacy of the guidance and therefore Mr Pudlo suggested circulating a Senior Medical Officer letter on a "*you may wish to be aware*" basis.

8.99. To conclude on this issue, throughout my period in office and until the change of government in 1997, the Department's policy on ex gratia payments to Hepatitis C sufferers remained the established policy which I inherited. Indeed, the Labour government which took office in 1997 did not change the policy in its first term and it was not until 2003 that there was a change in position.

8.100. My own influence as a junior minister was relatively limited. As I have set out, the decision to maintain the policy during my tenure was taken by the Secretary of State on the strong advice of officials (including in particular the Permanent Secretary).

8.101. I have no further comments to make on the matters within the Inquiry's terms of reference. However, I would like to repeat that I have the greatest sympathy personally for those who suffered from Hepatitis C as a result of NHS treatment at any time.

Statement of Truth

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

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

Dated 14/7/22 ....