Witness Name: Charles Lister
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INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF CHARLES LISTER OBE

CONTENTS

SECOND WRITTEN STATEMENT OF CHARLES LISTER OBE

I, **CHARLES LISTER**, will say as follows: -

PRELIMINARY

0.1. I am providing this statement in response to a request dated 3 November 2020, under Rule 9 of the Inquiry Rules.

0.2. This is the second witness statement I have provided to the Inquiry. As the Inquiry is aware, I have already provided a first written statement dated 1 March 2020, which deals with my role as a Trustee/Director and Deputy Chair at the Caxton Foundation. I gave evidence to the Inquiry on 25 and 26 March 2021 in relation to that role.

0.3. This second statement addresses the other sections of the Rule 9 request dated 3 November 2020, concerning the aspects of my work at the Department of Health (DH) relevant to the issues to be determined by the Inquiry.

SECTION 1: INTRODUCTION

1.1. My full name is Charles Edward Lister. My date of birth and home address are known to the Inquiry.

1.2. I am asked for a narrative description of the overall functions of my responsibilities in my DH roles on HIV/AIDS and in the blood policy unit.

1.3. I have referred throughout this statement to DH records which have been made available to me following electronic searches of the scanned versions of the Department's hard copy records which have been disclosed to the Inquiry. I understand that the electronic records, which came to be increasingly used from the early 2000s onwards, have not yet been reviewed unless they were also retained in hard copy. I may need to add to or amend this statement to address further records (including the electronic records) that may become available.

HIV/AIDS role (May 1995 – October 1998)

1.4. From **May 1995 to October 1998** I was the team leader responsible for HIV/AIDS sexual health promotion. This involved working with the then Health Education Authority and charities such as the Terrence Higgins Trust on new health promotion initiatives for which I was the budget holder. Most of the focus was on advice for gay men. But, following the growing incidence of HIV/AIDS among sub-Saharan African communities in England, I also worked closely with groups such as the Uganda AIDS Action Fund to develop and fund programmes for those communities.

1.5. Other roles that I can recall included administration of grants for health and local authorities and acting as the UK representative on the EC Management Committee for the Programme on AIDS which took decision on funding for HIV/AIDS initiatives across the EU.

1.6. My general policy responsibilities on HIV/AIDS meant that I was in touch with a wide range of experts in the field and service providers, including clinicians, the National AIDS Trust, the Terrence Higgins Trusts (as mentioned), GMFA (Gay Men Fighting AIDS) and the London Lighthouse. I therefore developed a good understanding of HIV, its impact on individuals and the development of treatments. However, at this stage I did not have a role in relation to the transmission of HIV through contaminated blood.

Blood Policy Team (October 1998 – May 2003)

1.7. I made a lateral move to Head of Blood Policy - **from October 1998 to May 2003**. This involved a wide range of responsibilities which increased during my time in the role, including:

- Development of government policy on the safety and supply of blood and blood products to the NHS.
- Sponsorship of the National Blood Authority (NBA) including business planning, ensuring Ministerial objectives were met, appointments to the Board, negotiations with the NHS on blood pricing etc.
- The Better Blood Transfusion initiative.
- Development of measures to reduce the risk of vCJD and HCV transmission through blood, including funding of measures introduced by the National Blood Service (NBS) and the provision of recombinant clotting factors for people with haemophilia.
- Ensuring sufficiency of supplies of key blood products for UK patients, including sourcing of blood plasma supply from the US.
- Negotiating and implementing a new EU Blood Directive on standards and quality of blood.
- Drafting responses for Ministers on calls for compensation and a public inquiry into the contamination of blood with HCV.
- Sponsorship of the Alliance House charities (AHOs). This meant that I was the liaison between the AHOs and the Department, making sure that the funding got delivered and dealing with any policy issues (including DH funding and appointment of DH sponsored trustees). This was of

course long before I became involved with the Caxton Foundation. During this period, the Alliance House charities involved were the Macfarlane Trust and the Eileen Trust.

1.8. I am asked who I reported to and who reported to me. I will confine this part of my response to my role in the Blood Policy Team as the work I did on HIV/AIDS health promotion is not, I believe, of direct relevance to the Inquiry.

1.9. When I joined the Blood Policy Team in October 1998, it was part of the Department's Health Services Directorate (HSD1). I reported to Dr Mike McGovern who was a haematologist. David Hewlett was the Branch Head. Dr Sheila Adam headed the Directorate. Ron Kerr was the Senior Departmental Sponsor for the National Blood Authority (NBA), supported by me.

1.10. As a result of a DH restructuring, responsibility for blood moved in July 2001 from the Health Services Directorate to the Public Health Directorate (PH) headed by Dr Pat Troop (Deputy Chief Medical Officer). From then on, I reported to Dr Vicki King (PH6.6). Dr Mary O'Mahony was the Branch Head (PH6).

1.11. When I took over leadership of the Blood Policy Team, we were understaffed for the issues we needed to deal with. These issues only grew in number and complexity. Although I succeeded in making the case for additional staff and support over the period, there was always a delay in obtaining these extra resources so, as pressures grew, difficult decisions sometimes had to be made in prioritising work.

1.12. In October 1998, I had two members of staff reporting to me - Gwen Skinner (HEO) and Ann Willins (EO). Around the time of the move to PH, my team consisted of Jill Taylor (SEO) (Jill was working for me by September 2000), Robert Finch (HEO and Margaret Ghlaimi (EO). Robert was asked to join the Minister's private office during 2002 and was replaced by Zubeda Seedat.

1.13. During 2002, Olivier Evans (then a European Fast Streamer) joined us specifically to help with the implementation of the EU Blood Directive. We also drafted in additional people as and when needed for specific projects and obtained support for some work from other parts of PH6. For example, Gerry Robb (HEO), and later Linda Lazaras, helped with the running of MSBT (the Advisory Committee on Microbiological Safety of Blood and Tissues).

1.14. The move to PH coincided with the events and aftermath of September 11th 2001, in which the Public Health Directorate was deeply engaged. This meant that Mary O'Mahoney and Pat Troop were unable to devote much time to issues around blood. Also, Mike McGovern did not move with us meaning that we lacked access to the expertise of an in-house haematologist. After some delay, Dr Amal Rushdy joined the team in 2002 and was involved in issuing new guidance on Better Blood Transfusion, one of the issues that Dr McGovern had worked on previously.

1.15. Pat Troop initially took on the role of Senior Departmental Sponsor for the NBA but was unable to continue the role much after September 11th 2001. The position was taken up by Professor Lindsey Davies, at the time a Regional Director of Public Health. There was a little delay before this happened but I can't recall how long. Professor Davies also chaired the National Commissioning Group on Blood, which my team ran, to negotiate the pricing of blood charged by NBS to the NHS. Lindsey Davies and I communicated well, and I found her immensely supportive.

1.16. The pressures on my team were recognised internally and externally. On 4 November 2002, Martin Gorham, the Chief Executive of the National Blood Authority, wrote to Nigel Crisp, Chief Executive of DH, to raise concerns about the impact these were having in delaying work, which the Authority wished to take forward, e.g. on capital projects and issues relating to blood testing. Martin opened the letter **[DHSC0034270]** by stating that the timing of his writing was *"…"…stimulated by the knowledge that Charles Lister, our key contact, is looking for a well-merited career progression move…"…."*.

1.17. After relating some of the issues described above, Martin Gorham went on say that,

> *"...Charles Lister has therefore had to be the main link and has provided excellent support. But he has become completely overwhelmed by the amount of business that needs to be conducted. This has been exacerbated by the increase in the scale and number of issues on which the NBS currently requires substantial DoH input. You are aware of Project Red; this has occupied Charles more or less fulltime for several months. In the meantime, essential capital proposals (tactical and strategic redevelopment of blood centres and the replacement of the NBS core IT system for example) are being delayed. Nor has the DoH been able to respond in a timely fashion to policy advice we require on the future of all hepatitis C testing and on issues relating the detection of vCJD through blood testing. At another level they have been unable to make the arrangements to replace the non-executive medical Board member (Prof. Sir Keith Peters) who resigned at the end of March having given us well over three months' notice!"*

1.18. Project Red was the name given to the acquisition by the Department of the US Company, Life Resources Incorporated, to secure safe supplies of blood plasma for fractionation by the Bio Products Laboratory.

1.19. I would certainly not have described myself as overwhelmed at the time (I think this was a deliberate overstatement by Martin Gorham). But as mentioned above, we did have to prioritise the issues we dealt with and there were sometimes differences in view between DH and the NBA on the issues on which they should be focussing. The DH view of the NBA at this stage is summarised in a briefing I wrote for the Minister, Hazel Blears, for a meeting with Martin Gorham on 5 December 2002 **[DHSC0042275_114]**

1.20. I recall that I drafted the response for Nigel Crisp to send to Martin Gorham, which was sent on 3 March 2003 **[DHSC0034263].** This was delayed enabling us to address Martin's concerns directly. Key points in the response included:

- The importance of regular meetings between NBA and the sponsor branch (PH6) to keep each other abreast of current issues and to establish mutually agreed priorities. *"I am therefore pleased to see that these are now being arranged. These improved communications should prevent the concerns you have raised escalating into crises."*

- Much had happened over the past year to strengthen the blood team and this process continues. *"I think it is therefore stretching a point to say that Charles Lister is lacking support."*

- 2002 saw a number of major achievements on blood. *"As well as Project Red and the work on Better Blood Transfusion, the blood team, supported by a fast stream entrant, negotiated an EC Blood Directive that the UK Blood Services and the NHS can live with. They also steered through a number of successful spending review bids, including increased capital and revenue funding for the NBS. Lindsey Davies also obtained agreement to substantial increases in blood prices in 2003-04 to support NBS initiatives, through her chairmanship of the National Commissioning Group on Blood."*

The National Blood Authority

1.21. Before I answer the Inquiry's specific questions, it may help if I say a little about the history of the National Blood Authority (NBA) which was going through a period of major change and upheaval at the time I joined the Blood Team.

1.22. The NBA was a Special Health Authority established in 1993. Previously, collection of blood had been the responsibility of Regional Health Authorities. Between 1993 and 2000, the NBA went through a process of reorganisation from a regional to a national service. The handling of this process by the NBA

in Liverpool and Manchester caused serious political fallout and loss of confidence in the Authority. This in turn led to the dismissal of the Chair of the Authority by the Secretary of State in 1998 and the appointment of a replacement. This was followed swiftly by a change in Chief Executive. Martin Gorham, the new NBA CEO, took up his appointment in October 1998, around the same times as I joined the Blood Team.

1.23. The NBA was responsible for the management of:

- The National Blood Service (NBS) responsible for the collection of blood from donors and its processing, testing and supply to hospitals in England & Wales.
- The Bio Products Laboratory (BPL) which made therapeutic products from blood plasma, such as Factor VIII and Immunoglobulin, for the NHS in England & Wales.
- The British Bone Marrow Donor Registry, a database of typed bone marrow donors in England, Scotland and Northern Ireland.
- The NHS Cord Blood Bank.
- The International Blood Group Reference Laboratory (IBGRL) which provided a reference service and issued diagnostic materials.

1.24. The names NBA and NBS were often used interchangeably, including within the Department, but technically the NBS was a subset of the NBA.

1.25. A report on the NBS by the National Audit Office, published in December 2000 acknowledged that good progress had been made towards providing an effective national service at the same time as coping with the emergence of vCJD. The report picked up the need for NBS to improve the experience of blood donors, in particular the need to reduce waiting times. The need to improve donor experience was also addressed by the Public Accounts Committee in 2001.

Personal Circumstances

1.26. I had a period of 4-5 weeks serious illness in late 1998/early 1999, including nearly two weeks in hospital. I can't now recall the dates but it means that there was a short period at the start of my role in the Blood Team when I was entirely absent and later periods, up to around May 1999 when I had various outpatient appointments.

SECTION 2: INVOLVEMENT IN TRUSTS AND SCHEMES / CONSIDERATION OF PAYMENT SCHEME / COMPENSATION FOR THOSE SUFFERING FROM HEPATITIS C

MACFARLANE AND EILEEN TRUSTS

2.1. I am asked about my recollection of the circumstances in which the trusts and schemes were established and any involvement I had in this. The Macfarlane and Eileen Trusts were both created well before I started my role in the Blood Policy Team in October 1998. Consequently I had no involvement at all in the establishment of those schemes.

SKIPTON FUND

2.2. As I have already set out, I left the Blood Policy Team in May 2003. The Skipton Fund was established in 2004, following the announcement of the scheme on 29 August 2003 by the Secretary of State for Health, John Reid. I was not therefore involved in establishing the Skipton Fund itself as that post-dated my involvement.

CONSIDERATION OF A PAYMENT SCHEME / COMPENSATION FOR THOSE SUFFERING FROM HEPATITIS C FROM INFECTED BLOOD

2.3. I was not involved in the establishment of the Skipton Fund. However, during my time within the Blood Policy Team the pressure grew for financial support or compensation to be extended to those who had been infected with HCV via blood products, blood transfusions or tissue / organ transplants. Accordingly, consideration of whether there should be a payment scheme for those infected with HCV from infected blood was a recurring theme and it may assist the Inquiry if I seek to summarise my involvement in this. Rather than provide a commentary on every document on this topic, I have sought below to summarise the main developments during my time in the Blood Policy Team.

The Government's Position On An HCV Payment Scheme / Compensation When I Joined The Blood Policy Team

2.4. When I joined the Blood Policy Team in October 1998, the Haemophilia Society already had a well-established and long running campaign in support of their proposal that a payment scheme similar to the Macfarlane Trust for haemophiliacs infected with HIV should be set up for those haemophiliacs infected with HCV through blood products.

2.5. The Government's policy was against a payment scheme of this kind. Some months before I started in post, Frank Dobson, the Secretary of State for Health, had set this out in a letter to the Haemophilia Society dated 28 July 1998 **[DHSC0016534].** Having referred to the lengthy and careful consideration given to the Haemophilia Society's proposal, the Secretary of State explained that,

> *"The Government has proceeded on the basis that compensation or other financial help to particular patients or groups of patients is only paid out where the NHS or individuals working in it have been at fault. The needs of people whose condition results from Inadvertent harm Is met from benefits available to the population in general. I am sorry to have to tell you the after considering all aspects of this matter we have decided that we should not make an exception to the general rule in the case of haemophiliacs infected with hepatitis C.*
>
> *Your Society takes the view that haemophiliacs infected with hepatitis C are a special case because the infection comes on top of a pre-existing serious long term medical condition. However the same considerations apply to other individual patients and groups of patients, whether inadvertently infected with another Illness or harmed as a result of another medical or surgical procedure who can only obtain compensation if there has been negligence.*

You have also argued that as the Government provides financial help to haemophiliacs infected with HIV this scheme should be extended to cover people with hepatitis C.

However we take the view that the circumstances of the people infected with HIV were different. The stigma surrounding HIV at the time the decision was taken, the fact that it was generally considered a sexually transmitted disease and that Haemophiliacs could have inadvertently infected their partners were all important considerations which do not apply to Hepatitis C.

...

This has been a difficult decision to make and we have looked at a number of alternative approaches but I'm sorry to say that none of them seemed the right thing to do."

2.6. The Secretary of State gave the same information to Parliament that day, 28 July 1998 in a written answer to a PQ from Mr Coaker **[DHSC0006176_137].**

2.7. Following Frank Dobson's letter of 28 July 1998, the Haemophilia Society renewed their campaign for a special payment scheme challenging the justifications given by the Secretary of State through PQs in both Houses and correspondence to MPs. In broad terms, this was the position on the HCV compensation issue when I joined the team.

Overview Of HCV Payment Scheme Issues During My Time In The Blood Policy Unit

2.8. During my time within the team, the Department's position remained one of opposition to an HCV payments scheme. However, there were developments that can clearly be seen as factors that led to significantly increased pressure on the Government's stance and were pre-cursers to the ultimate decision to set up the Skipton Fund. These included:

- The High Court Judgment in the HCV group litigation;
- The very effective campaign run by the Haemophilia Society and other campaign groups.
- The Scottish Executive moving towards, and eventually announcing, its own payment scheme.

2.9. The countervailing considerations that led to the Department continuing to resist calls for an HCV payments scheme were not new and were essentially those that had been set out by Mr Dobson:

(1) A payment scheme for haemophiliacs with HCV (even one short of the levels of compensation that would be payable by the Courts) raised policy considerations about no fault compensation. It was the Department's established policy that compensation or financial help is only given when the NHS, or individuals working in it, were at fault. There was concern that any deviation from this could open the floodgates making it impossible to resist calls for other groups adversely affected by NHS treatment;

(2) An exception had been made for the Macfarlane Trust, a special payments scheme for haemophiliacs infected with HIV. The reason these individuals were considered to be a unique group was said to be on the basis of: the stigma surrounding HIV at the time the decision was taken; the life expectancy of haemophiliacs with HIV at the time which was dramatically reduced; and the fact that partners of individuals who had been infected could also be infected. The Department's position was that these factors did not apply to those

who had been infected with HCV through blood and blood products. At the time, I think it is fair to say that HIV was still considered by the Department to be a considerably more serious virus than HCV. However our understanding of the very debilitating nature of HCV infection including its adverse interaction with HIV treatment for those co-infected, continued to evolve.

Events in late 1998 and 1999

2.10. In November 1998, my team advised in favour of Lady Hayman (Parliamentary Under Secretary of State in the Lords) meeting the Haemophilia Society **[WITN4505003].** This advice noted the Society's renewed campaign for a special payment scheme. The Department was seeking to support the Society's Youth Information and Support Project (which had been promised by Mr Dobson), while conscious that the Society remained firmly committed to challenging the basis upon which a payments scheme had been rejected.

2.11. Examples of the Parliamentary Questions being tabled around this time include those raised by:

- Sir Geoffrey Johnson Smith in the Commons (see written answers 30 April 1999 **[WITN4505004];** and
- Lord Morris (who was of course President of Haemophilia Society at this time) in the House of Lords
    - 24 May 1999: **[HSOC0023993]**
    - 15 June 1999: **[WITN4505004A],** when the following was said:

"Lord Morris of Manchester asked Her Majesty's Government: Further to the Answer by the Baroness Hayman on 24 May (H.L. Deb., cols. 631-632), where it was officially stated that the social stigma of HIV, and the danger of infecting partners, were important considerations in the grant by the then government of special payments to National Health Service patients infected with HIV during treatment.[HL2723]

The Parliamentary Under-Secretary of State, Department of Health (Baroness Hayman): My right honourable friend the Secretary of

State for Health gave the view of this Government when he wrote to the Haemophilia Society on 28 July 1998. He said, with regard to the decision not to introduce a special payment scheme for people with haemophilia infected with hepatitis C through National Health Service treatment, that the circumstances of the people infected with HIV were different. He added that the stigma surrounding HIV at the time the decision was taken, the fact that it was generally considered a sexually transmitted disease and that haemophiliacs could have inadvertently infected their partners were all important considerations which do not apply to hepatitis C."

2.12. Lord Morris followed the questions above with another PQ tabled on 28 June 1999 **[HSOC0008580],** and a letter of 29 June 1999 **[DHSC0041305_141]**, forwarding one from the Haemophilia Society **[HSOC0014601].**

2.13. I drafted a suggested reply to Lord Morris, which I sent to Lady Hayman on 9 July 1999 **[WITN4505005].** The draft letter reaffirmed the existing policy on special payments and stated that *"the special payments which were made in the case of HIV infection were exceptional."* **[DHSC0041305_138]** I would have provided a draft response in this form because, despite significant personal sympathy for those infected, my understanding was that, as a matter of policy, ministers remained persuaded of the need to resist the calls for a payment scheme. At the end of this section of my statement, I have added my reflections on the line that was being taken.

2.14. It appears from the available records that Lady Hayman raised queries about the background to this issue and asked Dr Sheila Adam for her views.

2.15. In response, Dr Adam prepared a draft submission to Lady Hayman dated 15 July 1999 **[DHSC0041305_130].** Both Gwen Skinner and I gave input into this before it was finalised.

2.16. Gwen Skinner advised on the rationale behind the decision to make an exception for individuals who had contracted HIV, see her email dated 16 July 1999 **[WITN4505006]:**

"In the 1980s, when the HIV decision was made, HIV was rapidly fatal. Hep C is not. The difference between HIV and all the other "harm" circumstances of a range of groups is that HIV meant imminent death. All the others mean impairment of quality of life. The key thing - life - is still present and the challenge is to devise means of overcoming the new difficulties.

It is difficult that the 1987 statements attribute the HIV decision to the fact of another serious disease superimposed on the pre-existing haemophilia. I have spoken informally to Roger Moore who was the G7 at the time. He said that the decision to introduce the scheme was an emotional one, made on the spur of the moment after a moving presentation to the then SofS by two young haemophiliacs. Before that moment there had been no intention whatsoever to agree to a scheme. RM described the decision as irrational."

2.17. I reviewed a draft of Dr Adam's submission providing comment on it **[DHSC0041305_128].** I noted that:

"Part of the difficulty with defending the distinction between HIV and HCV is that the decision to give financial assistance to haemophiliacs with HIV was arguably not very logical in the first place. It was very much a decision bound up with contemporary feelings about HIV although this was not reflected in the public statements made at the time (Gwen Skinner's note below sheds some light on this). However, from today's perspective, there are enormous difficulties in making a distinction between haemophiliacs and others inadvertently harmed by NHS treatment. Another example that come to mind, which you may wish to use, is MMR vaccine. There is therefore a strong argument for continuing to say that haemophiliacs and HIV were a special case and for drawing the line there. Otherwise the only logical step is to move towards a system of no fault compensation.

To complicate matters, a group of people infected with HCV through blood are currently taking legal action against the NBA. We have no information on the litigants but some are likely to have haemophilia. The case is being brought under the Consumer Protection Act, arguing that the blood which caused the infection was a defective product within the meaning of the Act and that, as the US and other European countries introduced HCV testing 18 months before the UK, the 'state of the art' defence does not apply for those infected in this period. The legal advice received by the NBA from the lawyers acting for the NHS Litigation Authority (NHSLA) is that, for those infected after May 1991, there is likely to be a finding of liability under the Act. The NHSLA are therefore urging an out of court settlement and we will be recommending to Ministers, in a submission to go up shortly, that the NBA accept the Authority's advice.

This raises the question of whether we can justify a financial settlement on the litigants but continue to refuse financial assistance to non-litigants (many haemophiliacs with HIV will also have HCV but will have signed an undertaking when they received their financial settlement not to take legal action on HIV or HCV). However, the option which avoids this difficulty is not to offer a blanket settlement but to limit it to those in the group who would be likely to succeed if the case went to court."

2.18. Dr Adam's final submission was sent to Lady Hayman on 21 July 1999 **[DHSC0041305_123].** It highlighted that the distinction between HCV and HIV was difficult to explain logically and was tied up with contemporary feelings about HIV in 1987. However, any shift in policy on haemophiliacs with HCV would have far reaching consequences in relation to other examples of the NHS inadvertently harming people. In reply, Lady Hayman indicated on 22 July that she wished to take Dr Adam up on her suggestion of a meeting with her, Dr McGovern and me **[DHSC0041305_121].** Related issues arose in the advice I gave Lady

Hayman the next day, 23 July 1999, in relation to a request for a meeting with the Manor House Group **[DHSC0014990_029].**

2.19. Lord Hunt took over as the Minister in the Lords after Lady Hayman left the Department on 29 July 1999. On 3 September 1999, I provided Lord Hunt with briefing for the planned meeting with officials on 7 September to discuss HCV financial assistance, which had been originally promised to Lady Hayman **[DHSC0041304_045 and SCGV0000169_007].** It was envisaged that I would attend the meeting along with Dr Sheila Adam, Dr Mike McGovern and Gwen Skinner. The briefing set out that Ministers had made a clear decision not to create a special payments scheme for haemophiliacs with HCV but that there was continued unhappiness and lobbying from the Haemophilia Society and some MPs in relation to this.

2.20. My 3 September 1999 briefing also provided background information on the HCV litigation and the 'Scottish situation'.

2.21. On the HCV litigation, I noted that any decision to settle the HCV litigation out of court would be seized on by the Haemophilia Society in support of their campaign as revealing an inconsistency of approach, although we could argue that there was a clear distinction to be drawn.

2.22. On the Scottish situation, I noted that Susan Deacon MSP, the Minister for Health and Community Care in the Scottish Parliament, had announced in early August that she would review the position on HCV compensation in Scotland, prompted by concerns that heat treated products were not fully HCV inactivated in Scotland until later than in England. Susan Deacon had made it clear to her officials that she was not prepared to give in on the issue of financial assistance for haemophiliacs with HCV unless she thought that there was a case to answer. However, her public statement had raised expectations within the haemophilia community and amongst campaigners that the Scottish Government may be shifting its ground. We had agreed with Scottish officials

that no public statement would be issued until Ministers had had a chance to consider the implications.

2.23. I understand that a record of the meeting of 7 September 1999 has not been located in the electronic disclosure. However, there was an exchange of emails between Dr McGovern and me in the days following the meeting, regarding the timing of Lord Hunt meeting the Haemophilia Society, the interplay with the expected timetable for Scottish developments, and the need for joined up UK policy **[WITN4505007] [DHSC0006801_089].**

2.24. I can see from the available records that we were also asked to provide an updated line to take on this issue for the Prime Minister on 23 November 1999 **[WITN4505008 and MHRA0024551].**

Events in 2000

2.25. I have already noted that my 3 September 1999 submission had alerted Lord Hunt to the situation in Scotland. I drafted a further submission to Lord Hunt, dated 13 March 2000, **[DHSC0041330_023].** This mainly addressed a review of UK blood products manufacturing and how it should be taken forward. However, I advised that a meeting with Susan Deacon could also include a discussion of the Scottish fact finding investigation into heat treatment of blood products in Scotland in the mid-1980s (involving why their products had not initially been heat treated so as to attain the same inactivation of HCV as in England). We were mindful that Susan Deacon would be publishing that report and making a statement on the compensation issue.

2.26. On 27 March 2000, Gwen Skinner put a submission to Lord Hunt, the main focus of which was to respond to his request for information on the scope for doing more for people with haemophilia infected with HCV, focussing on counselling provision **[DHSC0004033_003].** Annex A to that submission contained information on outline costing for a hardship fund. It flagged the

difficulty that such a fund (if based on the amount disbursed by the Macfarlane Trust in single grants and winter payments) would cost about £15 million over 10 years but would likely be unacceptable and there would be continuing demands for parity with the HIV scheme.

2.27. On 30 March 2000, there was a debate in the Lords on HCV infection through blood products raised by Lord Morris, with Lord Hunt responding for the Government **[HSOC0011775].** I provided briefing for this **[DHSC0004033_037, DHSC0004033_038 and WITN4505009]**. Lord Hunt set out the Government's reasons for resisting a payments scheme and emphasised the action being taken on HCV more widely.

2.28. I have referred above to the HCV litigation which was ongoing at this time, and the consideration being given to settlement of that litigation. While the HCV litigation is a subject area in itself (which the Inquiry has not asked me questions about), I have already noted that it was acknowledged to have an obvious potential on the wider calls for financial assistance to those infected with HCV through blood products.

2.29. I had prepared a submission for Lord Hunt, the final version of which was dated 13 April 2000, advising on an out of court settlement of the HCV litigation **[WITN4505010].** The submission sought Lord Hunt's views on the proposals made to the NBA by the NHS Litigation Authority (NHSLA), for an out of court settlement. It also considered the wider implications of such a settlement, including, at §16(i) the Department's stance on compensation for haemophiliacs with HCV:

> *"From a purely legal standpoint, the issue is straightforward. There is a clear separation between settling litigation on the basis that a significant number (if not all) cases will be lost if it goes to trial and making payments to non-litigants where there is no evidence of liability. The main plank of our argument against compensating the haemophiliacs — that the NHS does not pay compensation in cases of non-negligent harm — therefore still stands. It will, however, be necessary to resist the inevitable claims*

of inequity from the Haemophilia Society, especially as the 400 or so haemophiliacs still alive with HIV also have HCV and signed an undertaking when they received their financial settlement not to take legal action on HIV or HCV. However, the same issue would arise if damages were awarded in court."

2.30. The advice was that the arguments in favour of the NBA agreeing to an out of court settlement seemed to us as officials to be overwhelming; although regardless of the outcome, the litigation was bound to be linked to the campaign for financial assistance for haemophiliacs with HCV.

2.31. On 10 May 2000, I wrote to Lord Hunt enclosing a draft letter for him to send to Susan Deacon, Minister for Health & Community Care in the Scottish Executive. This was in response to her request to discuss the proposed settlement of the litigation against the NBA. Scotland had similar litigation pending and we agreed that we needed to develop a common approach with Scotland, and also in respect of their report into the events surrounding heat treatment of blood products for HCV in Scotland. **[DHSC0046972_070].** A meeting was due on 18 May 2000 with Lord Hunt to discuss the proposed settlement.

2.32. On 30 June 2000 Lord Hunt provided a note to Gisela Stuart (Parliamentary Under Secretary in the Commons) and Alan Milburn as Secretary of State, recommending settlement of the HCV litigation **[DHSC5297720].** This would have been based on a draft prepared by officials including my team. At §2 Lord Hunt recognised the presentational difficulties in seeking to settle this litigation given that ministers were refusing financial assistance to haemophiliacs. At §9 and §10 Lord Hunt addressed the distinction between the decision to try to reach a settlement in the NBA Litigation and the refusal to establish a payments scheme.

"9. … I want to ensure that there is a clear and defendable distinction between settlement of this litigation and our continued, and justified, refusal to compensate haemophiliacs infected with HCV through blood products on the basis of non negligent harm.

10. The main plank of our argument for refusing payment to haemophiliacs has been that heat treatment to eliminate HCV from blood products was introduced as soon as the technology was available. This is not true for the introduction of the screening test for HCV, and a financial settlement can be justified on that basis. However, we would start to run into difficulties if we include in the settlement those claimants infected before the screening test became commercially available."

Lord Hunt went on to address the extent to which the settlement options might impact on the maintenance of this distinction.

2.33. On 24 October 2000, Sandra Falconer from the Scottish Health Department wrote to me **[WITN4505011]** enclosing a copy of the Scottish fact finding exercise. The letter stated that Susan Deacon had accepted the conclusions of the report that the Scottish National Blood Transfusions service were around 18 months behind England in producing a heat treated product that eliminated HCV and that there were understandable technical reasons why this was the case. The letter stated:

"The Minister considers it an important general principle that the NHS should not pay compensation for non-negligent harm; she acknowledges that medical treatment often necessarily involves a balance of risks. She would like to repeat her expressions of sympathy to haemophiliacs infected through blood products, as indeed to all people who have suffered inadvertent harm through medical treatment."

At this stage, therefore, it appeared that the Scottish Executive was seeking to maintain the (common UK) position against a payment scheme for those infected with HCV.

2.34. Within the Department, Lord Hunt was focussing at this stage on what might be provided in terms of a package of care for those infected with HCV – see my

minute of 24 October 2000 querying whether it was envisaged that this would be restricted to those infected though blood products **[DHSC0020784_029]** and the reply from his Private Office **[DHSC0020784_029]**. See also my submission to Lord Hunt (jointly with Jane Verity) of 26 October 2000 **[DHSC0020784_008]** with draft minute for him to send **[WITN4505012]**, and later briefing for the unstarred question from The Earl Howe on 1 November 2000 **[DHSC0004183_009]; [WITN4505013].**

2.35. However, at around this time, another factor came into play relevant to the calls for an HCV payment scheme which was the Government's response to the BSE Inquiry report's recommendation on financial support for those infected with vCJD. The Inquiry report was published on 26 October 2000. At the time, the Government also announced that it intended to put in place financial arrangements to benefit sufferers of vCJD and that the preferred option was to establish a compensation scheme. There was concern about comparisons being made between the decision to make payments to individuals with vCJD and the refusal to set up a payment scheme for those with HCV. This placed pressure on the Government to provide an explanation as to why individuals with vCJD were being treated differently to haemophiliacs with HCV.

2.36. On 31 October 2000, with input from Alan Harvey, I updated the lines to take in respect of Earl Howe's question on why compensation for haemophiliacs with HCV was different from vCJD **[WITN4505014]**. The payments to individuals and families affected by vCJD were explained as being made as a result of exceptional circumstances with an inevitably fatal, incurable disease (as to the rationale for the distinction with HCV see further my later submission to Mr Hutton of 12 November 2001, referred to at §2.55 below). See also my input into a response from the Secretary of State Alun Milburn to Baroness Jay, Leader of the House of Lords, on 20 November 2000 **[SCGV0000173_040 and WITN4505015].**

2.37. On 15 December 2000, Jill Taylor in my team provided further briefing to Lord Hunt in advance of a meeting with the Manor House Group on 18 December

2000. Haemophilia and HCV. Compensation was one of the main items on which background notes were supplied **[WITN4505016].**

Events in 2001

2.38. In early 2001, there was a further intensification of the campaign for financial assistance. This can be seen from developments such as Eddie O'Hara's and Lord Morris' request to meet with the Prime Minister, upon which Jill Taylor advised on 3 January 2001 **[WITN4505017].** Alongside this kind of campaigning, in 2001, the Haemophilia Society developed its earlier delivery of lilies to Downing Street into the 'Carpet of Lilies' campaign. This centred around three issues, one of which was compensation for all haemophiliacs who contracted HCV through contaminated blood products.

2.39. As the Inquiry is aware, an out of court settlement was reached with the claimants who had been infected with HCV after 1 April 1991. However, ultimately, it was not possible to negotiate the settlement of all the claims and on 26 March 2001, Burton J. held that the NBA was liable under the Consumer Protection Act 1987 in respect of those claimants infected after 1 March 1988. As the claims were brought under the CPA 1987, no haemophiliacs were in the class action because most, if not all, were infected with HCV prior to 1 March 1988 when the CPA came into effect. This was due to the introduction of heat treatment for blood products eliminating HCV infection through that route.

2.40. The Government's decision not to provide ex-gratia payments for people with haemophilia and HCV as a result of their treatment with blood and blood products stemmed from the longstanding policy that compensation or other financial help to patients is only given when the NHS or individuals working in it are at fault. However, the Judgment made a finding of strict liability under the CPA; if a product (in this instance blood and blood products) was found to be defective then the producer is liable, regardless of whether there has been negligence. The Judgment resulted in payments of compensation for non-negligent harm, contrary to the established policy of successive governments.

It increased the "moral" pressure upon the Government. I recall, for example, that in April 2001, the Manor House Group and Haemophilia Action UK staged a protest march demanding compensation. This started at Trafalgar Square and stopped at Downing St, Richmond House and Parliament. I met them outside Richmond House at Lord Hunt's request. There was also an adjournment debate in the House of Lords with renewed calls for a payments scheme among the issues raised **[HSOC0009296 pages 34-42].**

2.41. In May 2001, the Haemophilia Society wrote to its members/ subscribers with details of the first phase of the 'Carpet of Lilies' campaign which ran from May to September **[HSOC0006033].** Members were encouraged to contact their prospective parliamentary candidate and elected MPs to lobby for support for the campaign's three goals.

2.42. Alongside member action, Parliamentary pressure was also intensified. Examples of this are the PQs from Lord Morris on 23 April and 10 May 2001 **[WITN4505018], [DHSC0020742_115]; [DHSC0020742_102]** and the Early Day Motion from Dr Brian Iddon, to which I return below.

2.43. Following the High Court judgement in the HCV litigation, Yvette Cooper, asked for a position paper on haemophiliacs infected with HCV. On 2 July 2001, Briony Enser (who was briefly a member of my team on a 'fill-in' basis) sent the requested submission **[DHSC0041379_177].** She noted that the timing was urgent because of the considerable Parliamentary concern, and summarised the position as follows:

- *"until the mid 1980s, when heat treatment of blood products became possible, most haemophiliacs were infected with HIV or hepatitis C, sometimes both, through contaminated blood products supplied by the NHS;*
- *in the late 80s, those haemophiliacs with HIV were awarded ex-gratia payments and the Macfarlane Trust was set up to provide continued support;*

- *for the past l0 years haemophiliacs with hepatitis C have campaigned for compensation on the same basis as those with HIV. Ministers argued that the payments to haemophiliacs with HIV were exceptional, as in the late 80s everyone with HIV was expected to die (victims of hepatitis C were not);*
- *since Ministers last reviewed their position, the High Court has awarded no fault compensation under the Consumer Protection Act 1987 (CPA) to a group of people infected with hepatitis C by blood transfusion (a hepatitis C screening test was not introduced in the UK until 1991). No haemophiliacs were in the group action because most, if not all, were infected before the CPA came into force;*
- *although this judgement only places a legal obligation on Government to make payments to those awarded damages by the Courts, it introduces further questions of inequity and increases the moral pressure to do so."*

2.44. In the discussion section, the submission addressed the general rule against 'no fault compensation' noting that the Judgement in the HCV litigation was a departure from this (because strict liability was applied) as were the exceptional cases made both for both the HIV and vCJD special payment schemes. It noted the inequitable outcome whereby the Judgement provided financial support for those in a limited 'qualifying window' for which many, including most infected haemophiliacs would not qualify.

2.45. The submission then set out five options for action (which were expanded in an options paper **[WITN4505019]:**

"i. Do nothing (This, like all the options, entails compliance with the letter of the CPA Judgement and the legal precedents that it sets)

ii. Public Inquiry, lump sum and hardship fund for all haemophiliacs infected with Hep C by blood

iii. Lump sum and hardship fund for all haemophiliacs infected with Hep C by blood and low key Inquiry,

iv. Lump sum and hardship fund for all or some haemophiliacs infected with Hep C by blood

v. Hardship fund for haemophiliacs infected with Hep C by blood and who have severe liver disease."

2.46. If Minsters decided to consider making payments to haemophiliacs with HCV, Option V was recommended on the basis that it would: re-establish the Government's position on no fault compensation (i.e. exceptional cases only); provide an equitable outcome for haemophiliacs who will not benefit from the judgment; defuse the campaign on behalf of all haemophiliacs; and entailed relatively modest costs (see §18 of the submission).

2.47. At this time, developments in the various areas were overlapping. The Early Day Motion in support of the Carpet of Lilies campaign was coming up before Yvette Cooper had had a chance to give full consideration to Briony Enser's submission. I advised on 4 July 2001 that while the response to the EDM may remain "no compensation no inquiry", it may be best to say that the Government was reviewing this **[WITN4505020]**. In accordance with this, Yvette Cooper agreed an amendment to the line to take indicating that the *"Ministers are, however, reviewing the case for compensation in the light of recent representations by members of both Houses as well as the Haemophilia Society and other lobby groups".* **[WITN4505021; WITN4505022]**

2.48. At the same time, the Scottish Executive was about to announce that it would look to settle its own HCV litigation claims (following our decision not to appeal the 'English judgment') but was resisting calls for wider compensation. However they decided to postpone the announcement to give time for discussions between Scottish and English Ministers **[WITN4505023] [WITN4505024].** I noted that a further issue arising was the group of those infected with HCV who

would have been entitled to recover damages but had not joined the group action.

2.49. On 19 July 2001, I sent a further submission to Yvette Cooper **[DHSC0006983_129 and WITN4505025]**. This was in response to three questions she had raised, one of which was:

"If we were to make some sort of symbolic gesture, what could that be? What would a money package look like? What kind of sums are we talking?"

2.50. I provided costings on a possible scheme on the basis of affordability and acceptability. Any scheme was likely to be extremely expensive and I tried to balance affordability against acceptability to the Haemophilia Society, so that the scheme was adequate to persuade the Haemophilia Society to drop their campaign.

"8. A package which we can be fairly confident the Haemophilia Society would find acceptable is at Annex A. This gives a range of cash payment to all infected haemophiliacs based on the extent of their illness. It is very similar in structure to a scheme put in place by the Canadian Government. We have calculated the total cost at £37m with the bulk of this falling in year 1. This could be reduced to £20m by restricting payments to those with cirrhosis and end stage liver disease and those who have already died. This group would equate with the haemophilia/HIV group who, at the time the awards were made, were all expected to die. However, such a scheme would be harder for the Haemophilia Society to sell to their members because not everyone will benefit.

9. A cheaper alternative still - in the short term - would be to make no cash payments but to set up a hardship fund run by the Macfarlane Trust (who administer the HIV scheme). This could take the form of monthly payments to haemophiliacs with HCV who are at an advanced stage of illness to meet additional needs such as heating. This could be done by

announcing a grant of say £10 million to the Trust to run the scheme. However, such a scheme is likely to have a prolonged life - the HIV scheme has now been running for over 12 years - and is likely to require additional funding in the future. The HIV scheme currently costs the Department £2.5m a year.

10. If, additionally, payments were made to non-haemophiliacs this would push the cost up considerably. At the very least, the scheme would have to be extended to the 550 or so infected transfusion recipients identified by the NBS. Very roughly, this would add a further 25% to the cost of the scheme.

11. It should be added that no money has been identified that would allow us to make payments to haemophiliacs. If a scheme were to be introduced immediately or within the next 18 months, money would have been found from within existing Directorate/Divisional SR funding envelopes. A longer term solution would be to be include a bid in SR2002 but this would tie our hands until 2003/04."

2.51. This submission also sought to address another of Yvette Cooper's questions which was *"By giving haemophiliacs money, what other groups would then want compensation? Would the floodgates open to several more groups of people? And if so who".*

2.52. On this aspect, my submission noted as follows:

"2. If you give money to haemophiliacs with HCV, the immediate group wanting compensation would be non-haemophiliacs infected with HCV by blood transfusion. 669 patients in this group have been identified from a look back exercise conducted by the National Blood Service. Of these, 113 received damages through the High Court leaving 556 unrecompensed.

3. These numbers may be manageable within any scheme. More worryingly, it is estimated that there are between 4,000 and 5,000 other patients still living who were infected with HCV through blood transfusion who cannot be traced. These people may or may not know that they are infected and a proportion of them could well come forward if a compensation scheme is announced. It is likely that the existence of a scheme would encourage people who have had a blood transfusion to seek a HCV test. For the vast majority there will be no documentary evidence to prove that blood transfusion was the cause of their infection. However we would probably be obliged, if we had a scheme, to award damages on the basis of probable cause.

4. It would be difficult to compensate the haemophiliacs without making payments to this group also. An identical situation arose in the late 80s when the payments made to haemophiliacs infected with HIV through blood were extended to non-haemophiliacs. However, in the event, a relatively small number of non-haemophiliacs came forward.

5. Other groups currently seeking compensation are:

- *RAGE (Radiotherapy Action Group) — patients who have suffered permanent damage as a result of breast cancer but failed to win damages in the courts. Ministers have maintained the line that no scheme will be introduced for this group but that Trusts must pay compensation where harm has been caused by clinical treatment and negligence can be established;*
- *Bristol Royal Infirmary Inquiry Cases --No compensation has been offered by the Department. Parents will be taking action through the courts;*
- *Retained Organs —Parents are taking action through the courts.*
- *Myodil Action Group -- seeking compensation for alleged injury following use of Myodil, a diagnostic agent. It has been established that there is no basis for a negligence claim against*

the Department or MCA and, on that basis, compensation has been refused by the Department.

- *MMR Vaccine -- there is no evidence to date that children have been injured through use of MMR but, if this were proven, claimants could be eligible to claim through the vaccine damage payments scheme.*

6. *Despite the existence of these groups, it would be possible to justify payments to haemophiliacs as exceptional given that Hepatitis C related illness, which can lead to cirrhosis and liver cancer is a devastating, debilitating disease. Around 200 haemophiliacs have died as a result of this infection and at least as many again are likely to die in future."*

2.53. On 12 September 2001, John Hutton (Minister of State) held a meeting on HCV compensation. His Private Office sent a summary of the meeting to Vicki King, Yvette Cooper's Private Office and me **[WITN4505026]** Mr Hutton did not think that compensation was an option. Instead he wanted to look into providing a social care support package for haemophiliacs with HCV on the lines of the one developed for people with vCJD, e.g. exempting haemophiliacs from the charge regime. The Minister wanted to look at the Parliamentary Questions and POHs (i.e. ministerial correspondence) and we were to check and send the standard line in light of the meeting. From later submissions, it can be seen that I was also tasked with investigating compensation for people who contracted HCV through blood who did not take their cases to court but would be eligible under the High Court's CPA judgment **[DHSC0004601_021].**

2.54. On 2 October 2001 the Scottish Parliament's Health Committee (SPHC) published its report. The report called upon the Scottish Executive to implement financial support and other appropriate practical support for all NHS patients who were infected with HCV as a result of blood transfusions provided by the NHS in Scotland or involving blood products produced by the Scottish National Blood Transfusion Service **[WITN4505027].** This was regardless of whether negligence has been proven and it was recommended this should come into

operation within 12 months. The report recommended that the level of financial assistance awarded should be determined on the basis of need, having regard to the physical or psychological loss individually suffered and should include support for practical difficulties such as the inability to obtain an affordable mortgage or life assurance. I can see from the available papers that this was something which the Scottish Health Ministers wished to raise at discussions with DH Ministers planned for 22 October 2001 **[DHSC0004363_062].**

2.55. On 8 November 2001, I was chased by John Hutton's Private Office for the submission on an HCV care package and compensation for people who contracted HCV through blood who did not take their cases to court but would be eligible under the High Court's CPA judgment. I have addressed in paragraph 1.16, above, the pressures we were working under. I then put the submission up to Mr Hutton on 12 November 2001 **[DHSC0004601_021].**

2.56. In relation to the ex-gratia payments to individuals infected with HCV, who did not take their cases to court as part of the CPA litigation but who would have been eligible to compensation under the High Court ruling, I did not recommend making payments to them, in summary:

"• it would set a precedent for settling litigation against the NHS in other areas;
• it would take the Government a step closer to no fault compensation and prejudge the outcome of the CMO's Advisory Group on Clinical Negligence;
• it would inflame the situation with the haemophiliacs and weaken the Government's arguments for resisting their campaign for compensation."

I went on to note, however, that the position faced by people infected with HCV through blood transfusion (who could only win damages they were entitled to by going to court but found themselves time barred) lent support to the argument for some kind of limited no fault compensation scheme. And I suggested that Ministers may wish to draw this to the attention of the Advisory

Group on Clinical Negligence as an example to consider as part of their deliberations.

2.57. In relation to a care package for haemophiliacs with HCV, I contrasted the position with payments to individuals with vCJD where a fund was needed because of the speed at which vCJD progresses. This meant the existing care systems could not always cope. In addition, the vCJD payments were practicable as only 10 patients were alive with vCJD. This therefore made the package easy to administer. I noted, in contrast, that there were questions whether the vCJD care package model could work, due to the much larger number of HCV infected haemophiliacs and whether it was necessary due to the relatively slow progression of the disease.

2.58. I went on to consider the 'rudiments of a [care] package' and periods when those infected with HCV may particularly need care. However, Haemophilia Centre Directors had not reported failures of local services in care support when it was needed, and patients complained of financial hardship rather than lack of health and social services support. I noted that in areas where support might be provided, the Department's HCV Steering Group was considering them for all people with HCV. I suggested waiting for their report in January before taking any further action as considering these issues just for haemophiliacs could lead to accusations of a two-tier system.

2.59. In the meantime, I suggested revisiting the £2 million bid in the SR2002 to support implementation of the HCV strategy with a view to increasing the number of specialist nurses/ counsellors; considering what further initiatives the Department could fund through the Haemophilia Society; and providing a letter to send to DWP Ministers to raise the issue of haemophilia/ HCV awareness among DWP medical examiners.

2.60. I asked if the Minister was content:

- *"to hold the policy line that no payments will be made in respect of hepatitis C infection through blood and blood products except where awarded by the Courts;*
- *to refer the hepatitis C litigation case to the CMO's Advisory Group on Clinical Negligence as an example when they consider no fault compensation;*
- *for officials to take the actions set out at para 18 above;*
- *to leave wider consideration of the social care needs of people with hepatitis C to the Hepatitis C Steering Group and the subsequent consultation paper?"*

2.61. John Hutton agreed to all of these recommendations **[SCGV0000247_039].** This was followed by an adjournment debate on 15 November 2001 **[DHSC0032036_047].** At the end of that debate, Mr Hutton said this:

"The issue of compensation was raised. I, personally, found that the most difficult decision of all. We have listened carefully to arguments for a special payments scheme for people with haemophilia and hepatitis C similar to that in place for HIV. After a long and difficult consideration, we came to the same conclusion as the previous Government, that such a scheme should not be established. That was not a view we came to lightly. I assure my hon. Friend the Member for Bolton, South-East that every one of my colleagues who considered the issue and met individuals affected by this tragedy found it a difficult decision to make. As I said earlier, as soon as technology became available to render blood products safe, it was introduced. The policy of successive Governments has been that compensation, or other financial help to patients, is paid only when the NHS or individuals working in it are at fault. I do not believe that the NHS has been at fault in this case.

…

The issue of compensation has been widely debated in the House. I know that some hon. Members take a different view, which I respect, but it is not the view that the Government have come to. However, we intend to develop options for reforming the system for dealing with clinical

negligence claims. As my right hon. Friend the Secretary of State for Health announced on 10 July, we will produce a White Paper on that subject early next year. The chief medical officer is chairing an expert advisory committee to explore the issues and options, one of which is whether no-fault compensation for NHS patients may be appropriate in future"

Events in 2002

2.62. On the 7 January 2002, I wrote to Yvette Cooper's office informing them of a forthcoming debate in the Scottish Parliament on the SPHC report **[DHSC0041379_116].** Scottish Ministers had decided to reject the recommendations in the report that no fault compensation should be paid to people infected with HCV through blood and blood products. However, the matter was subject to a vote in the Scottish Parliament. I had been informed by Scottish officials that Malcolm Chisholm, the Scottish Minister for Health, was concerned that they would lose the vote. I advised that if this happened Scottish Ministers would probably have to go at least some way towards accepting the Committee's recommendation, which would weaken our tough stance on the issue.

2.63. On the same day, Jill Taylor from my team advised Yvette Cooper regarding a request from the Manor House Group at which compensation was obviously likely to be raised. **[WITN4505028].**

2.64. In February 2002, Scotland set up an expert review group on financial support arrangements. It was to consider the broader circumstances of a system of financial and other support that could be available to those who had been harmed by NHS treatment in Scotland but where there is unlikely to be liability on behalf of NHS Scotland. One of its other remits, was to also consider the situation of patients who have contracted HIV and/or HCV from blood transfusions or treatment with blood products **[HSOC0023748_013].**

2.65. On 8 May 2002, I provided briefing to Yvette Cooper prior to a meeting with her the next day to discuss haemophilia and HCV handling issues **[DHSC0041379_025, WITN4505029, WITN4505030 and WITN4505031]**. These included the Haemophilia Society's request for a meeting to present new proposals for financial compensation for haemophiliacs with HCV, and the request from Michael Connarty MP to see the papers considered by Mr Dobson when he reviewed the compensation issue in 1997 / 1998. The Haemophilia Society had devised a model payment scheme, based on one introduced in Canada, setting out more precisely the type of financial settlement they would find acceptable. They had requested a meeting before the summer recess to present it. I advised that given Ministers had repeatedly stated that there was no financial settlement for these patients, there was nothing to be gained by such a meeting. However, for presentational reasons, I recommended meeting with them to show a willingness to listen, "*There are advantages in showing a willingness to listen bearing in mind that neither the Haemophilia Society nor the All Party Group have great expectations of Ministers changing their minds on this issue.*"

2.66. On Mr Connarty's request for Mr Dobson's papers (consideration that pre-dated my involvement) I noted the following:

"11. This request was made by Michael Connarty when you met him recently. He made it under the assumption that a detailed analysis would have been undertaken by the Department. The papers show this not to have been the case. The debate was focussed around concerns that such a scheme would open the flood gates to further claims. If papers are released they will show that Frank Dobson was minded to support a scheme limited to haemophiliacs with HCV but was persuaded from this by officials and Margaret Jay. A chronology is attached at Annex C [(*sic*) it was actually Annex B]

12. Given the sensitivity of releasing this information, which in any case would require the consent of Frank Dobson and Baroness Jay, you may wish to consider writing to Michael Connarty explaining that the decision

was taken after a discussion on the principles and wider implications of offering a scheme rather than on the basis of a detailed analysis of costings etc."

2.67. My briefing also noted at §10 the shift in thinking by Scottish Ministers following pressure from the Scottish Parliament. Scottish Ministers were now looking for a way of providing haemophiliacs with HCV with some kind of financial package and could no longer be guaranteed to adopt the same position as us on the compensation issue. I recommended that Yvette Cooper might discuss the current position with Malcolm Chisholm.

2.68. Yvette Cooper met the Manor House Group and other campaigners on 15 May 2002 **[WITN4505032]**. Compensation was one of the issues discussed with the Minister re-stating the position that compensation would not be paid on a no fault basis. Shortly after this meeting, Hazel Blears moved posts within the Department to succeed Yvette Cooper as the Parliamentary Under Secretary of State for Public Health.

2.69. It was, accordingly, Hazel Blears who met the Haemophilia Society and Michael Connarty MP, the Chair of the All Party Parliamentary Group on Haemophilia on 12 June 2002. The Society were presenting the Minister with their proposal for a compensation package for haemophiliacs infected with HCV (the All Party Group on Haemophilia also supported the case for compensation).

2.70. On 10 June 2002, Jill Taylor from my team provided a briefing for the Minister ahead of that meeting **[DHSC5307583]**. We had received the Society's report on 31 May and a copy had been sent to the Department's Economic and Operational Research branch for their views. At that stage, it had not been possible to analyse it in any depth. The report was based on an estimate of 3,641 people with haemophilia and HCV, as of 1 January 1993, and the cost of payments was £522.6 million over ten years. The proposal was for payments to be made according to the stage of the individual's liver disease and included

allowances for dependants, family members, loss of earnings, inconvenience of drug therapy, expenses and costs towards care.

2.71. Jill Taylor provided the current Government line on Compensation (Annex B) which remained:

"This Government and its predecessor have held that compensation is only paid to patients when the NHS has been at fault and that an exception to this rule is not justified in the case of haemophiliacs infected with hepatitis C.

We deeply regret that so many people with haemophilia were infected with hepatitis C through blood products. But the fact is that as soon as a technology became available to make blood products free from hepatitis C the NHS introduced it. There is therefore no justification for compensation based on legal liability for people with haemophilia and hepatitis C."

2.72. The briefing noted the intense political pressure on Scottish Ministers to come up with a financial compensation scheme that would cover the patients who had contracted HCV from blood and blood products but which would not create enormous problems elsewhere. This would make it harder for the Government and the rest of the UK to continue to resist introducing their own compensation scheme. I recognised that the decisions taken in Scotland on this might create further pressure on the Government to devise a settlement for haemophiliacs and others. Jill Taylor's succinct summary of the immediate handling options was that there were two options:

"a. to adhere to the line that compensation is not payable to haemophiliacs infected with hepatitis C; or

b. agree to consider the Report and respond to the Society in writing."

2.73. Hazel Blears agreed that the Department would look into the report in detail and respond in due course.

2.74. On 29 July (with an update on 31 July) 2002, I emailed Hazel Blears' private office, advising that the preliminary report of the expert group set up by the Scottish Health Ministers will recommend the establishment of a financial assistance scheme similar to the HIV scheme **[DHSC0042275_132].** The group was impressed with the principles that underlie the Macfarlane and Eileen Trusts and was interested in a scheme operating on broadly similar principles for those infected with HCV through blood and blood products. The final recommendations were deferred by the Group's Chairman, Lord Ross, so that they could consider the cost implications.

2.75. Scottish officials were to put the group's recommendations to Malcolm Chisholm. I noted that he was in a difficult position politically with the prospect of defeat in the Scottish Parliament if he maintained his "no compensation" stance. Whilst it was a devolved issue, it would be difficult for us to have different positions. My email noted that *"In the past, the understanding has been that any policy changes on this issue would be taken on a UK basis. That position can no longer be guaranteed."* **[DHSC0042275_132].**

2.76. Hazel Blears discussed this with the Secretary of State, Alan Milburn, who I recorded as being *"unequivocal in his opposition to a compensation scheme"* in my email to Hazel Blears' private office on 6 September 2002 **[WITN4505033].** I asked if it was sufficient for the Scots to say: *"The Department of Health in England has advised that it has no intention on initiating any scheme for compensating this group"* or if we wanted a stronger statement? A handwritten endorsement shows that Mr Milburn was content with that line.

2.77. On 22 October 2002, there was an adjournment debate in the Commons, with Richard Spring MP raising the case of his constituent Dominique Porché **[HSOC0011088].** Hazel Blears responded, including on the issue of compensation.

> *"Haemophiliacs Infected with hepatitis C have been campaigning for compensation for a number of years. They have put forward a proposal for a scheme that amounts to about £500 million over 10 years. That*

was submitted early this year by the Haemophilia Society. We are currently giving the proposal our detailed consideration. There has also been a call for financial assistance in Scotland for all people infected with hepatitis C through blood. That has been discussed by the Scottish Parliament Health and Community Care Committee. The Scottish Executive is currently considering its response to that.

The Government have listened carefully to all the arguments in favour of a compensation scheme. I am aware of the personal tragedy that is caused to those who find themselves in these circumstances. However, the fact remains that in the NHS compensation is usually given only when either the NHS or those working in it have been at fault. That is where there has been some negligence and the damage can be attributed to it. That is not the case with hepatitis C infection. We therefore do not believe that an exception can be made to the general rule in the case of people infected with hepatitis C. The same conclusion was reached by the previous Government. They examined the issue in the mid-1990s and decided that it was not possible to depart from the general principle.

As the hon. Gentleman has said, a number of blood transfusion recipients with hepatitis C were successful in winning damages in the High Court through a judgment in March 2001. It was a landmark judgment made under the Consumer Protection Act 1987. Those who were awarded damages were infected between March 1988, the date when the Act came into force, and the start of screening for hepatitis C In September 1991. The hon. Gentleman will appreciate that that is quite a small window of the people who were infected between the date that the legislation came into force, which is strict liability, product liability legislation, and the date when it could reasonably be held that the NHS should have, and did, introducing screening of blood donors. Those people who fell into that category were entitled to compensation.

The Consumer Protection Act implements the 1985 European Directive on product liability, As I have said, it is a piece of strict liability legislation. That means that there is no requirement of proof of fault, unlike the ordinary law of negligence. It is about defective products. The judge ruled that hepatitis C-infected blood was a defective product and that, irrespective of fault, there was product liability. That is why it appears that the claimants who fell within the window to which I have referred were treated differently in that they received compensation. There is a good legal reason why they became eligible for compensation.

The outcome of the case does not alter our position on the general rules of compensation. Damages were awarded on a no fault basis, and at present we do not have such a basis of compensation. Although Governments have occasionally made ex-gracia payments to patients--for example, in the case of haemophiliacs with HIV and the families of people with variant CJD - these have been in truly exceptional circumstances that do not apply to hepatitis C. When HIV first emerged as a disease, it was almost undoubtedly the case that people would die quickly in dreadful circumstances as a result. Even to date there is no accepted treatment as there is in the case of some of those suffering from hepatitis C.

My understanding is that the hon. Gentleman's constituent was infected after the Consumer Protection Act came into force, but he was not part of the group action and is now barred from seeking damages under the limitation period in the Act. It contains a provision stating that legal proceedings must be initiated with a solicitor within 10 years of the infection. I entirely understand the frustration felt by anyone who has missed out on an opportunity to take legal action for damages. The hon. Gentleman's constituent is not the only person in that position of whom we are aware, but it would set a most unfortunate precedent in other litigation where there are "time bars" if the Government were to accept that as a reason for awarding financial compensation, because it would

be entirely outwith the legal framework that applies to our decision making in such matters. I recognise how hard that seems to individuals facing difficulties or family tragedies, but it is important that we maintain the integrity of the system and the rules by which we are bound."

2.78. On 25 October 2002, Hazel Blears responded to a further letter from Lord Morris on the compensation issues **[WITN4505034]**. The majority of the letter addressed the comparison with the Vaccines Damage Act, but the Minister also stated that she would respond to the Society shortly on their report on proposed financial assistance.

2.79. On 4 November 2002, Malcolm Chisholm called Mr Milburn. A chronology which I prepared the following year for a PQ **[WITN4505035]** summarised what occurred as follows:

"Malcolm Chisholm phones SofS to inform him that:

- *the Expert Group were about to publish a preliminary report calling for financial and other practical support for all people infected with HCV through blood, blood products and tissues.*
- *Scottish Ministers felt they had to offer something, probably payments to people once they become seriously ill and that an announcement would be made on 6 November.*

SofS said that he thought this would be a grave mistake and that once the principle that we'd established had been breached, then we were on a slippery slope to payments running into the millions across the UK. He said he thought Malcolm Chisholm needed to tough it out.

Malcolm Chisholm said that the advice he had was that this was a devolved matter for the Scots, however he wasn't sure this was right.

SofS subsequently asked officials to find some way of showing that the Scots don't have the devolved power to go it alone on this, and thereby prevent them going ahead with any kind of announcement on 6 November"

2.80. On 5 November 2002 I put a submission to Alan Milburn on the Scottish Compensation proposals **[WITN4505036].** The Secretary of State had asked for advice following his discussion with Malcolm Chisholm and, as noted above, wanted officials to pursue the devolution argument. The first part of my submission was an update on the position in Scotland. On 30 October 2002, the Scottish Cabinet had considered the recommendations from Scotland's Expert Group on Financial and Other Support. They had not accepted the recommendations as drafted but wanted to provide some form of financial support. They had not yet decided what that would be or the global amount of money to be set aside for such a scheme. However, they wanted the ongoing benefits provided by the scheme to be disregarded for social security purposes. The Scottish Cabinet was concerned to establish that any difficulties with such payments being disregarded for social security purposes could be overcome. They were also concerned to establish that the UK Government agreed that such a scheme fell within devolved powers. I provided an annex dealing with the implications if the Scots established such a scheme.

2.81. I then turned to the devolution issue. We had received legal advice suggesting that a scheme which made payments to individuals who were incapacitated or suffering hardship through illness could arguably be a social security, not a health issue. It depended upon the principal purpose of the scheme. If it was to relieve financial hardship and therefore not a health related issue, it arguably would mean that the scheme did not fall within Scotland's devolved powers. I advised that this should be raised with Jack McConnell, the First Minister for Scotland, and Alan Milburn should request that Scotland did not give any public indication that they were exploring a financial package until this issue had been resolved.

2.82. On 6 November 2002, the Scottish Executive provided a news release welcoming the preliminary report of the Expert Group on Financial and Other Support [**SCGV0000192_005**]. Malcolm Chisholm did not commit to the report's recommendation that the Executive should provide financial support for patients

who were infected with HCV by the NHS in Scotland through blood, blood products or tissue. He said:

> *"...there are complex medical, legal and financial considerations to take into account. What we need to do now is think carefully about who needs help, what is the best way to design a scheme and structure payments sea that the individuals involved benefit fully, while taking account of the costs of any payment scheme in the light of other health priorities.*
>
> *"We want to avoid a position where we provide financial support which leads to social security payments being withdrawn or reduced which could very easily happen in many cases. Therefore we are looking at the interface with the social security system to see if we can devise a scheme that fits this as well as possible. We are in discussion with colleagues at the Department of Work and Pensions about this."*

2.83. The Scottish report did not immediately alter the Department's position that there was not a case for compensation for those infected with HCV through blood or blood products, although it added to the factors that were building further pressure on this issue. This was evident from, for example, the further oral question laid by Lord Morris in the Lords on 21 November 2002 **[HSOC0011089] [DHSC0006216_137]**

2.84. On 23 December 2002, Jill Taylor emailed the Private Office of Hazel Blears concerning a meeting on financial services for HCV sufferers. There appears to have been a communication slip with a letter from Malcolm Chisholm having been initially overlooked. We were keen for Hazel Blears to attend the meeting in part because, if a financial scheme was not to be offered, this area was the only initiative available to have positive impact for HCV sufferers. **[DHSC6696471].**

Events in 2003

2.85. On 13 January 2003, the issue of compensation arose again in supplementary questions following a PQ tabled by Lord Morris **[HSOC0015042]**:

"Lord Addington: My Lords, will the Government please explain to the House the difference in the circumstances of the relatives of people who have died as a result of contracting HIV through no cause of their own, and those of someone who has died of cancer of the liver caused by hepatitis C?

Lord Hunt of Kings Heath: My Lords, these are very difficult judgments. I do not think that anyone who has gone into this matter—in the previous government or the current government—has found making a decision in this area at all easy. At the end of the day, after careful review, we came to the conclusion that we could not make an exception to the compensation rule.

Lord Rix: My Lords, does that mean that there is a lack of conviction about the cost or about the treatment?

Lord Hunt of Kings Heath: My Lords, I do not believe that those are the issues that are paramount in considering this matter. There has long been a general rule that compensation is given by the National Health Service only when the service itself or individuals working in it are at fault. In this case, there has been no fault."

2.86. On 29 January 2003, I emailed Hazel Blears' private office alerting her to the fact that Malcolm Chisholm had made a statement that day to the Scottish Parliament Health Committee concerning the type of scheme he would like introduced if the devolution and social security issues were resolved **[DHSC0046315_070]**. He now proposed a financial assistance scheme for those infected with HCV through blood and blood products that would make payments of £20,000 to all those living with the virus, with a further payment of £25,000 to those who had developed cirrhosis. I advised that if we were to adopt the same policy in England, the cost would be considerable, I estimated the total costs in England to be £150 million, with around £90 million of it payable in the first year, and the remainder payable over a number of years. I gave the

current media line which was: *"The report published on 6 November 2002 by the Scottish Expert Group on Financial and other Support was commissioned by the Scottish Executive. Its recommendations, and the subsequent statements made by Scottish Executive Ministers, relate only to people who contracted HCV from blood or blood products provided by NHS Scotland. Although we have enormous sympathy with people who were infected with HCV through blood, the Government's position remains that a special financial assistance package for this group is not justified."* I suggested a possible supplementary line, *""A strategy to achieve effective prevention, testing and treatment services for all hepatitis C sufferers has been published for consultation. An action plan to implement this strategy will be produced in the next few months."*

2.87. There was, inevitably, reporting of the emerging difference between the Scottish and DH positions and I alerted Hazel Blears' Office to this, noting that the reporting had suggested that DH was expected to obstruct payments **[WITN4505037].**

2.88. On 4 February 2003, I updated the Secretary of State's Office to provide a requested update and clarification **[DHSC5320610]**. I noted that the Office of the Solicitor to the Advocate General for Scotland has sought the opinion of the Law Officers on 30 January. I noted that little could be done until we received the Law Officers' opinion. I further noted that we were continuing to work closely with the DWP, Office of the Deputy Prime Minister, Scotland Office and (as far as possible) the Scottish Executive.

2.89. On 13 February 2003, I emailed asking how Hazel Blears would like us to proceed on liaison with the All Party Group / Haemophilia Society on the HCV compensation issue **[DHSC0042275_127].** Michael Connarty wanted a meeting with their technical advisers and DH officials to discuss their proposed compensation package. I advised that we could arrange a further meeting. However, as Ministers were firmly opposed to a payment scheme, it might give the impression that there was a possibility of Ministers agreeing to a scheme. I

suggested the alternative of Ms Blears writing to the Haemophilia Society confirming that the Society's proposals had been carefully considered but there were no grounds to justify them or any other form of financial assistance.

2.90. On 26 February 2003, this issue arose again in the Lords with Lord Hunt advising Lord Morris that the Haemophilia Society's report was still being considered. **[WITN4505038]**

2.91. On 12 March 2003, I sought a steer from Hazel Blears' Private Office on the outstanding correspondence from Michael Connarty including the approach to the Haemophilia Society's proposed financial payments scheme **[DHSC5320611].** I was concerned that a long time had passed since the proposals had been put and that a response should be provided even though the Law Officers' advice on the Scottish devolution point was not yet available. I noted that:

> *"DWP tell me that it may still be 2-3 weeks before we have an answer from the Law Officers. There is a general understanding with DWP Ministers that the Law Officers are not to be hurried. This should ensure that a decision does not have to be taken before the Scottish Elections (we are about 3 weeks away from the purdah. period).*
>
> *I understand that when you last discussed handling with PS(PH), she was inclined, to wait for the Law Officers opinion before replying to the outstanding correspondence from Michael Connnarty. Given the expected delay, and the age of the Connarty letters, could you put this back to her please. If you recall, our advice was to reply to MC saying firmly that there is no prospect of any form of special payments scheme being agreed for haemophiliacs in England. We would therefore not be taking up MC's offer of a meeting to discuss the Haemophilia Society's proposals in more detail, although we are very grateful for all the work they have done etc.*

I am assuming that, even if Scotland do have the power to make payments, this will not affect our 'no payments' stance in England - although it will put us under increased pressure. Apart from anything else, there is no funding for this over the next three years. I am therefore very much in favour of coming clean with Michael Connarty and the Haemophilia Society as soon as possible. It is already 9 months since the Society first presented its scheme to Ministers."

2.92. I received a response on 31 March 2003 confirming that Hazel Blears was happy to write to Michael Connarty and the Haemophilia Society and to be firm on the issue **[WITN4505039].** She wanted to show that we had properly considered the Haemophilia Society's report and felt that Alan Milburn needed to be aware.

2.93. On 9 April 2003, Jill Taylor followed this up with a further submission to Hazel Blears. She addressed the financial details of both the Haemophilia Society proposal and the estimated cost of an English equivalent to the recommended Scottish scheme **[DHSC5320619].** The conclusion of her submission was that:

"9. *The sum proposed in the Society's report is £522.26m over 10 years, however even if we were to accept a reduced payment scheme based on the lines of the [Scottish Executive] proposal (if accepted), the position remains that there is no further funding available over the next three years. There is also a major concern that any compensation made to haemophiliacs with hepatitis C could open the floodgates for other groups who are current seeking compensation.*

10. SofS has consistently held the compensation is not payable to haemophiliacs infected with hepatitis C and that an exception cannot be made to the general rule that compensation or financial help is only given when the NHS or individuals working in it have been at fault."

The submission attached draft letters to Michael Connarty MP and Karin Pappenheim making clear that the Government did not support the proposed scheme.

2.94. Hazel Blears asked for both letters to be redrafted so that the tone was more compassionate (see the minute from her Private Office of 14 April 2003 **[DHSC5320617]).** It seems that re-drafted letters were prepared (see **[DHSC5320618])** but, so far as I can tell, they do not appear to have been cleared before I left post in May 2003.

2.95. The position when I left the blood policy role in May 2003 is summarised in my handover note: **[DHSC0041246_045]**

"The current position is that Ministers here are sticking strongly to the no compensation line but Scottish Ministers have weakened. Political pressure in Scotland forced them to set up an expert group which recommended a fairly generous compensation scheme. After the expert group reported, Malcolm Chisholm, the Scottish Health Minister, went public with a lesser offer of cash. SofS asked us to see if a way could be found to stop this. The result was a legal challenge saying that any payment scheme to haemophiliacs would be a social security scheme and therefore outside Scotland's devolved powers. This issue is currently with the law officers for a determination and we are expecting them to give a view very soon. If they decide in Scotland's favour, DWP will then need to decide whether to disregard such payments for social security purposes (as is the case with the Macfarlane Trust scheme)."

Reflections on the issue of a payment scheme for those infected with HCV through contaminated blood

2.96. During my time on the Blood Policy Team, and before, the view within government on the issue of compensation was consistently that the NHS had acted reasonably in the measures taken to make blood products free from HCV. There was therefore no legal liability to justify a compensation scheme and a concern that introducing one would open the way to no fault compensation. This view was shared by Ministers and officials and seemed to be supported by

the evidence. I do not recall questioning it. This would not of course have prevented a decision to introduce some form of financial support short of compensation, as happened later.

2.97. As this statement shows, I had opportunities to put the case to Ministers for some form of financial support, for example my submission to Yvette Cooper in July 2001 and subsequent discussions with John Hutton. However, Ministers, including the Secretary of State, maintained a very clear 'no compensation' policy throughout my time.

2.98. In writing this statement, I have asked myself whether I could have presented a more compelling case to Ministers for some kind of financial settlement and have questioned how much in this I was affected by a collective mindset. My answer 20 years on is that I honestly don't know but doubt whether I could have done much more at the time. Despite my sympathy with the victims of this tragedy, my focus as a DH official was largely on maintaining the arguments against compensation in support of the policy position taken clearly by Ministers. It took decisions in Scotland to move things on politically.

SECTION 3: VARIANT CJD (vCJD)

3.1. I am asked to address what decisions and actions I took in relation to variant CJD and in particular:

(a) The dealings I had with the United Kingdom Haemophilia Centre Doctors' Organisation (UKHCDO) in this regard.

(b) The dealings I had with blood products licencing authorities in this regard.

(c) The dealings I had with the Chief Medical Officer in this regard.

3.2. I have not at this stage been provided by the Inquiry with any particular documents it wishes me to address on this subject area. Given the large volume of material that I would have seen that touched on vCJD, I have sought to set out below the major developments or documents which illustrate the sort of engagement that I had, drawn from electronic searches for keywords around vCJD within the DH records. I have included references to minutes and submissions sent by those more senior, particularly my Grade 5 manager, Dr McGovern, and colleagues in other parts of the Department e.g. in the CJD Unit, as it helps to illustrate the flow of events. I will of course address any further documents in which the Inquiry may be interested if they are provided to me.

vCJD – OVERVIEW OF KEY ISSUES

3.3. Dealing with the emergence of vCJD and the potential risks impacted a wide range of blood policy issues. This makes for a complex chronology, so it may be helpful to the Inquiry if I start by drawing out some of the main aspects. Needless to say, these issues were under consideration long before I joined the Blood Policy Team and continued long after.

3.4. I came to the Blood Policy Team role in October 1998, with reasonable background knowledge of Transmissible Spongiform Encephalopathies because of my earlier role in the Health Aspects of Environment and Food

(Administrative) branch (1992-1995) where my work areas had included BSE and CJD surveillance. I had been the DH Secretary to the Spongiform Encephalopathy Advisory Committee (SEAC) from 1993-1995 at a time when concerns about the public health risks from BSE were growing.

3.5. From the first identification of vCJD, UK policy was based on the presumption that infection might be transmissible via blood transfusion, and steps were taken to reduce the risks. The approach was therefore highly precautionary. However, these risk reduction methods had to be balanced against the risk of reducing the amount of blood available to the NHS for life-saving operations.

3.6. A number of decisions by the Department and its expert groups were based on risk assessments commissioned from Det Norsk Veritas (DNV) and from the Department's own Operational Researchers, Andre Hare and Peter Bennet. I was involved in the commissioning process along with colleagues in the CJD team.

3.7. When I took up post in the Blood Policy Team in October 1998, the decisions had already been taken on two key precautionary measures. First, that UK plasma should be removed from use for fractionated blood products to reduce the risk of transmission. To avoid a crisis of supply, this change needed to be phased in. Secondly, leucodepletion was to be introduced to reduce the risk from whole blood; it had been directed that this should be achieved by the end of October 1999. Leucodepletion involved removal of almost all white cells, or leucocytes from blood for transfusion. There remained no diagnostic test for CJD in any of its forms.

3.8. In parallel with this, the CMO's Better Blood Transfusion initiative was aimed at reducing the usage of blood and encouraging clinicians to consider alternatives. vCJD was one of the drivers behind this initiative.

3.9. A major issue during my time on blood policy was the sourcing of Fresh Frozen Plasma (FFP) used for children and certain groups of adults needing frequent

transfusions. In 1998, the NBS had advised the Department that imported plasma for FFP could not be obtained for the 100,000 to 150,000 patients every year who required this component. In June 2000, the Advisory Committee on Microbiological Safety of Blood and Tissues (MSBT) commissioned a risk assessment of FFP and vCJD in conjunction with a further international search for possible alternatives to UK FFP.

3.10. After further discussions at MSBT during 2001 and 2002, Ministers agreed in August 2002 that the NBS would import FFP from the US for neonates and children born after 1 January 1996 and that it would be virally inactivated using Methylene Blue treatment. The significance of the date was that children born after 1995 would not have been exposed to BSE through the food chain.

3.11. The Bio Products Laboratory initially sourced US plasma for fractionated blood products through contracts with independent suppliers. However, by mid-2001, they faced serious risks around continued supply. This led to a decision by the Government to purchase the privately owned US plasma collection company, Life Resource Incorporated (LRI) to secure a safe, long-term supply of plasma. The purchase was completed by the end of 2002. I was heavily involved in this process from start to finish, including initial advice to Ministers, project management, negotiations on the purchase and setting up appropriate governance arrangements afterwards. By this stage, the decision had been taken to fund recombinant clotting factors for all people with haemophilia, so the driver for the purchase of LRI was about ensuring the supply of intravenous immunoglobulin for people with primary immune deficiency.

3.12. During this same period, I was a member of the expert committee in Brussels negotiating the draft EU Blood Directive. This was the first EU Directive addressing public health issues. This did not impact directly on UK risk reduction on vCJD, although there were concerns during the latter part of the negotiations that provisions might prevent the UK from importing US plasma.

3.13. A further development was the establishment of the Transfusion Medicine Epidemiological Review (TMER), by the National CJD Surveillance Unit led by Professor Bob Will and the UK Blood Services to determine whether there was any evidence that CJD, including vCJD, was transmissible via blood transfusion. This led to the identification of people with vCJD who had been blood donors, raising the question of what to say to recipients of those donations, including those who came forward to give blood

3.14. In addition, two people with vCJD were identified who had donated to BPL plasma pools before the switch to US plasma. As a result, a number of people with haemophilia were told about this potential exposure by their clinicians.

3.15. These issues were considered during my time by the CJD Incidents Panel. A good summary of the position on these issues at the time I left the Blood Policy Team is included in my handover note to my successor **[WITN4505040]**.

3.16. Another risk reduction measure under discussion, at least from late 2000, was the exclusion of transfusion recipients from giving blood. However, a decision to do this was not taken until 2005.

CHRONOLOGY

vCJD developments in 1998

3.17. Documents from October 1998, illustrate the sort of work that was ongoing on vCJD when I took up my post. On 20 October 1998, Dr McGovern minuted Nick Wingfield in the EOR team about vCJD prevalence studies in haemophiliacs that had been proposed by Dr Lee and Dr Ludlam **[DHSC0041249_011],** and there was a vCJD progress meeting on 27 October 1998 organised by Andre Hare from the Department's Operational Research Directorate who led on vCJD risk assessment throughout my time in this role **[WITN4505041; WITN4505042].**

3.18. Dealing with the emergence of vCJD and the potential risks obviously impacted a wide range of blood policy issues. Blood prices was one such area. The costs of collecting, testing, processing and distributing blood in England were recouped by the NBA on a "cost=price" basis from NHS hospitals. From April 1999, the NBA moved for the first time from regional to national pricing based on a standard commissioning agreement for the main blood components. This coincided with steep increases in the price of blood because of vCJD risk reduction measures, particularly leucodepletion (£65m pa) and the importation of fresh frozen plasma (£23m pa). **[WITN4505043].**

3.19. On 30 October 1998, I emailed Richard Douglas and Robert Newton in the Finance and Performance Division with a draft submission to Baroness Hayman on the impact of forthcoming blood price increases. My draft submission had sought a Ministerial indication on whether the price increases should be fully passed on to NHS Trusts from April 1999 or phased in more gradually. However, no doubt reflecting the input from my colleagues in finance, the final submission (dated 3 November 1998) made clear that phasing in the price increases was not an option as it would involve subsidising the NBA (which had not been budgeted for and in any event would end up being funded by the Health Authority budgets so they would be no better off) **[WITN4505044].**

3.20. The next day, 4 November 1998, the Secretary of State's private office communicated Mr Dobson's view that the costs associated with vCJD should not be passed on to the NHS. He wished us to explore top-slicing of funds at the allocation stage which would then be passed directly to the NBA **[DHSC0043857_181]**. I do not recall the outcome of this and have not been provided with any DH documents that jog my memory, save that a later background note to a suggested PQ answer, indicates that from April 1999,

> *"the cost of these measures - £50m for lecodepletion and £23.5m for plasma importation - are being recouped by the National Blood Service through blood prices charged to NHS Trusts ..."* **[DHSC0041341_203]**

3.21. On 12 November 1998, Dr Jefferys of the Medicines Control Agency provided a submission to Baroness Hayman addressing a media article which had questioned the safety of immunoglobulin used for prophylaxis against Hepatitis A and anti-D immunoglobulin **[WITN4505045].** My team and Dr McGovern were copied into the submission. Both products were being moved across to production from non-UK plasma, with the products being available from late 1998/99 for normal immunoglobulin and a few months later for anti-D immunoglobulin.

3.22. On 13 November 1998, the DCMO Dr Metters responded to a query which had been raised by the CMO (Sir Liam Donaldson) following an article by Dr Dealler, concerning fresh frozen plasma (FFP) **[DHSC0038638_018]**. Dr Metters indicated that SEAC could look again at fresh frozen plasma but that the latest discussion at the MSBT was that FFP was clinically needed for some patients and that it was not justified to withdraw it completely. The question was being reviewed at every MSBT meeting.

3.23. The same day, the CMO's private secretary minuted a wide range of officials to summarise position statements that were required on a range of topics connected to vCJD **[WITN4505046].** These had been commissioned by the Secretary of State, Mr Dobson, and added to by the CMO. Blood and vCJD was one of the topic areas. Dr McGovern replied to this on 16 November **[DHSC0004790_103],** noting as follows:

> ***"The move to produce blood products from imported plasma:***
> *All sites for the collection of plasma abroad have now been approved by the Medicines Control Agency. Currently Bio Products Laboratory (BPL-Elstree) and the Protein Fractionation Centre (PFC-Edinburgh) are processing blood products. Both plants will be in a position to provide blood products made from normal plasma e.g. Factor VIII Factor IX and intravenous immunoglobulin by January 1999 and those made from hyperimmune plasma e.g. Anti- D by July 1999. Both groups are meeting with the MCA later this week to plan the introduction of the*

newly sourced blood products and the necessary variations to the licences.

Leucodepletion of the blood supply:
Progress is good and the move to 100% leucodepletion will be completed by October 1999 as planned. In the run up to October 1999 certain centres will be ahead of others and will act as pilots from which expertise and experience will be forthcoming. There are no anticipated snags."

3.24. On 15 November 1998, I was copied into a minute from John Guest to Peter Coates which addressed whether PFI testing should be required for the projects to improve the production facilities at Bristol and the implementation of leucodepletion **[DHSC0043857_164].**

3.25. On 16 November 1998, Dr McGovern minuted the CMO's Private Secretary in response to the query that had been raised on the state of readiness report for winter 98/99 **[DHSC0038638_015].** The query had been whether the contingency plans took into account the potential effect on blood stocks of 'scare stories' in relation to nvCJD and the need for leucodepletion. Dr McGovern explained in his 'bottom line', that:

"nvCJD scares have not been specifically factored into the contingency plans. They do not appear to have had any impact on blood donation or the blood supply. The range of publicity and donor management plans should be sufficient to support the blood supply in the face of another vCJD scare."

New variant CJD (nvCJD) was the term used initially when this new phenotype of Creutzfeldt-Jakob disease was first described in 1996. This was later changed to variant CJD (vCJD).

3.26. On 30 November 1998, Dr McGovern put a submission to Baroness Hayman on Recombinant Factor IX. I have addressed this paragraph 4.14, below in

addressing recombinant products, although of course the risk of vCJD was relevant to the introduction of recombinant products. **[WITN4505047]**

3.27. On 10 December 1998, Dr McGovern wrote to Ms McAnulty of the UK Central Council for Nursing, Midwifery and Health Visiting **[DHSC0041225_082]**. He made clear that the Department had supported the development of the RCOG guidelines to extend using Anti-D to prevent alloimmunization during pregnancy and postpartum, but that the advice was the guidelines should not be extended until such time as a non UK sourced supply of Anti-D can be provided and maintained.

3.28. On 14 December 1998, Mr Savery (Director of Finance and Administration, National Blood Authority) approached me regarding the facility to transfer up to 5% of capital cash limits to review, in view of the high volatility of BPL sales and the general uncertainty relating to the vCJD situation. **[DHSC0041801_009].**

3.29. On 15 December 1998, Dr McGovern put a submission to Baroness Hayman and the Secretary of State concerning a US Food and Drugs Administration meeting which was due to take place the following day, and which Dr Metters was due to attend. The meeting was going to consider measures to prevent those who had been resident in the UK (or possibly Europe) from donating blood in the US and possible withdrawal criteria for blood and plasma products. **[DHSC0042287_003]**. Dr McGovern also provided Dr Metters with a briefing for this meeting **[DHSC0004790_090].**

vCJD developments in 1999

3.30. On 12 January 1999, Glyn Austin (Pubic Health Branch PH1) minuted the Secretary of State's Private Secretary to advise that: (i) SEAC had met on 11 January 1999 and discussed the potential use of pentosane as a prophylactic against vCJD. It was noted that once the Committee had finalised their advice to Ministers, Ministers were to be consulted on the handling; (ii) SEAC had also discussed the latest version of the Det Norske Veritas report on the 'Assessment of the Risk of Exposure to vCJD infectivity in Blood and Blood

Products'. It was an earlier version of this report that had led to SEAC's earlier recommendation for the extension of leucodepletion. Once the report was finalised, Ministerial agreement to publication would be sought. With a significant number of others, I was copied into this minute. **[WITN4505048]**. I responded on 18 January, noting that in the draft advice to Ministers, the word 'theoretical' had been omitted implying a greater degree of risk than SEAC's previous statements and suggesting alternative wording that might be considered **[DHSC0004464_104]**. [See also the public summary of SEAC's 11 January meeting **[DHSC0004464_077].**

3.31. On 26 January 1999, Dr Wight sought input from Dr McGovern and me on the blood and blood products section of the review of action taken to prevent the theoretical risk of person–to–person transmissions of vCJD, which her Division (PH1) were putting together for Ministers **[MHRA0035165_026].** I replied providing a draft on 5 February 1999 with my suggested text on the precautions taken and conclusions **[DHSC0041226_128]**. The material part read as follows:

- *"Potential donors with risk factors for iatrogenic and classic CJD are excluded from giving blood. Various exclusions have been introduced over the past 10 years (e.g. people who received human growth hormone (1989); people with a family history of CJD (1996); people who have had cornea transplants (1997); people who had brain surgery or an operation for a tumour or cyst on the spine before August 1992 (April 1998).*
- *The National Blood Authority were instructed to lecuodeplete the blood supply in July 1998 following advice from SEAC. Leucodepletion - the removal of white cells from blood and blood components - should reduce the risk of nvCJD infection through blood transfusion. All platelets and around 10% of red cells are now leucodepleted. Universal leucodepletion of blood for transfusion will be in place by October, 1999;*
- *Following advice from the Committee on Safety of Medicines in February 1998 (confirmed in May 1998), the Bio-Products*

Laboratory began importing plasma for the manufacture of plasma-derived blood products, e.g. Factor 8 and 9, albumin, immunoglobulin. This should eliminate any risk there may have been from infectivity in these products. All mainstream blood products from the Bio-Products Laboratory (BPL) are now manufactured using non-UK plasma. Hyperimmune products (including Anti-D) will follow in April 1999. A commercially produced Anti-D product, using non-UK plasma has been available in the UK for some time but in short supply. The Committee on Safety of Medicine has recently (February 1999) licenced a second Anti-D product manufactured outside the UK, which should improve the supply.

...

Conclusions

...

Risk reduction measures have been taken against the theoretical possibility that nvCJD could be transmitted by blood transfusion or blood products. Action to remove white cells (leucodepletion) from blood for transfusion will be fully implemented by October 1999. Blood products - including anti-D - from non UK plasma will be in place by April/May 1.999. A procedure was established in 1997 via the CJD Surveillance Unit in Edinburgh to notify the National Blood Authority of any CJD patient who had been a blood donor so that if possible their blood can be removed from the blood supply chain."

3.32. On 1 February 1999, I was the HSD1 representative at a meeting to discuss the implications of the case of a vCJD patient who had died at the end of 1998, having undergone a liver transplant in 1993 **[WITN4505049].** Contact with BSE was thought to be the most likely route of infection. Blood/blood products were not thought to be the most likely route of infection but the implications in this regard– as discussed at the meeting– were summarised at paragraphs 14-16

and 26-27 of the meeting minute. See further my email of 2 February 1999. **[WITN4505050]**

3.33. On 8 February 1999, Mr Austin circulated his draft submission to Ministers on the arrangements for publishing the Det Norske Veritas report **[DHSC0004790_069;DHSC0004790_070;DHSC0004790_071;DHSC0004790_072;BART0002084_002;DHSC0004790_065; DHSC0004790_066]** and I was copied into this draft. There is what may have been a very late draft of the final submission (dated 15 February 1999) to the Secretary of State. Dr McGovern and my colleague Gwen Skinner were the HSD1 recipients. **[DHNI0000042_002] [WITN4505051]**. The submission notes that the authors of the DNV report concluded that:

> *"blood from people with nvCJD may contain infectivity that could be transmitted through blood transfusion. However…this has not been proved conclusively. The aim of the report was not to ascertain whether or not nvCJD infectivity could be transmitted through human blood or blood products but rather to assess which components of human blood and blood products are risk factors to human health by analysing the processes involved in blood transfusion and the production and use of blood products assuming the infectivity was present."*

3.34. DNV had identified two patients groups that had a significantly greater risk than others – patients receiving treatments using intravenous immunoglobulin and those receiving blood clotting agents for the treatment of Haemophilia A. They identified two measures that would be likely to have a significant impact on reduction of risk:

(i) Leucodepletion

(ii) The elimination of UK sourced plasma products.

The submission informed the Secretary of State that "*after consideration of the report, SEAC concluded that it saw no reason to change its earlier advice recommending the leucodepletion of blood*". There was also an updating Q&A provided to the Secretary of State by Mr Austin on 18 February 1999

[DHSC0004464_025], [WITN4505052] [WITN4505053] and, on the same date, the public summary of the SEAC meeting of 11 January **[DHSC0041226_100].**

3.35. On 17 March 1999, Gwen Skinner provided the CMO's Office with a simple account of actions taken so far and implications in relation to the vCJD risks for blood / blood products, which was sent on behalf of Dr McGovern. **[WITN4505054].**

3.36. On 12 April 1999, Dr McGovern minuted Dr Metters on the next meeting of the US FDA which was due to take place on 2 / 3 June, giving early warning of the 'almost certain' advice on deferrals of certain donors with a history of UK travel or residence, and raising the issue of whether DH should be prepared to release the work done by its Economics And Operational Research Division or send someone to present the work, if approached **[DHSC0004790_031].** Dr Metters replied on 10 May 1999 **[WITN4505055].** Dr Metters considered it preferable for the EOR work to be put in the public domain in a way that would allow that Division to present their model to the FDA meeting.

3.37. On 19 May 1999, Dr McGovern put a submission to Baroness Hayman (through Dr Adam (Acting Director of HSD)) providing the Minister with a requested update on anti-D immunoglobulin. His concluding summary was as follows:

> *"BPL is on target to supply the NHS with non UK derived anti-D from 24 May. The indication 'antenatal prophylaxis' will be reinstated on the licence at the same time. There will be sufficient anti-D to allow for increased demand due to extending its use to routine antenatal prophylaxis. There is general professional consensus in favour of routine antenatal prophylaxis with anti-D and grade A evidence to support it. Endorsement of the RCOG guideline by NICE will be sought"* **[WITN4505056].**

3.38. On 2 June 1999, Dr McGovern provided a further briefing note to Dr Metters on the FDA's meeting now due to take place on 3- 4 June **[WITN4505057]** with copies going to Ministers' private offices. At the December meeting, the FDA

had voted 6-3 in favour of introducing restrictions. It was predicted that the FDA would now vote with a larger majority in favour of donor deferral. There was the potential for media interest. Dr McGovern noted the potential for some knock on effects on the UK blood product programme due to the risk of reduction in US plasma supply (from which UK blood products were now being made) however US stocks at that stage were currently very good. Dr McGovern provided suggested lines to take.

3.39. I did not usually attend meetings of the MSBT though a member of my team provided the Secretariat function. The Committee met on 3 June 1999 **[WITN4505058].** The meeting considered, amongst other issues: an update on leucodepletion (all blood collected after 31 October would be leucodepleted but there would be some non-leucodepleted blood with a remaining shelf life); BPL's progress in issuing non-UK plasma derived anti-D (which had started on 24 May and was now secure); and the position on obtaining legal advice in relation to potential donors who had received vCJD implicated blood. As to the latter point, the minutes recorded that:

> *"Dr Metters advised that the Department had taken the view informed by best ethical advice that there was no duty to inform individuals that they had received vCJD implicated blood products because there was as yet no screening test, nor any treatment for vCJD. Informing such people would raise issues such as the worried well, life insurance and mortgage applications. The position would change with scientific knowledge about transmission through blood/blood products, the development of a screening/diagnostic test and an effective treatment for vCJD. Meanwhile the possible harm outweighed the common law responsibility to inform those who had received implicated blood or blood products. Dr Robinson said that the NBA would need a specific direction from the Department on managing this situation. It was agreed that the Department would seek legal advice on this and give a clear direction to the NBA."*

3.40. On 11 June 1999, Dr Metters wrote to Professor Will at the National CJD Surveillance Unit, with his comments on the draft information sheet on blood

and CJD being supplied to the relatives of individuals interviewed in the course of the study he was undertaking **[DHSC0032411_146].** Dr Metters gave the Department's view that for cases of vCJD there was justification for public health protection to pass on their details to the blood service, though this would not apply in the case of controls.

3.41. In late June 1999, final contributions were being sought on DH's Health Circular 1999/999 on Variant Creutzfeldt-Jakob Disease (vCJD): Minimising the Risk of Transmission **[WITN4505059],** and the circular was published on 1 July **[WITN4505060]**

3.42. On 20 July 1999, I put a submission to Baroness Hayman on the Review of UK Blood Products Manufacturing **[WITN4505061].** As the introduction to the submission set up, we had been working since the autumn of 1998 with the Scottish Executive Health Department and Treasury officials on a review of blood products manufacturing. vCJD and its impact was relevant background to, but not the principal focus of, this submission, and I have addressed it under section 4 of this statement. Relevant to vCJD, however, I would note that:

- the review had been requested by the then Chief Secretary to the Treasury (Alistair Darling) in February 1998, upon giving Treasury approval to the use of non-UK plasma for the manufacture of blood products.
- the increased costs of importing plasma because of the theoretical risk of vCJD was identified as one of the factors affecting the performance of BPL and PFC with – in the case of BPL – an increase in costs of its main raw material of around 40%.

3.43. On 3 August 1999, Dr McGovern provided a further briefing note to Dr Metters and Lord Hunt on the US and Canadian decisions on deferring previous UK residents from donating blood **[WITN4505062].** Lord Hunt had recently succeeded Baroness Hayman as Parliamentary Under Secretary of State for Health in the House of Lords. He noted that on 17 June, the US FDA Blood Safety Committee had advised all blood authorities that US donors who lived in

the UK for six months (cumulative) or more between 1980 and 1992 should not give blood, and that Canada had followed suit. Dr McGovern set out the issue in the following terms,

> *"The US/Canadian decision may be seen as questioning the safety of the entire UK blood supply, and raises the prospect of exploring 'international blood markets" to secure a supply from countries free of BSE/vCJD. The issue of a formal search for an alternative source of blood was raised by the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT) at their last meeting 3 June. Members recommended that Ministers be approached for a view. This note outlines the issues and seeks your advice."*

3.44. Dr McGovern then addressed the safety of UK blood and the current UK need for blood. He then addressed the (very considerable) problems that would be encountered in seeking to secure a safe and reliable source of labile blood from outside the UK. Under his concluding, 'Action' section, Dr McGovern noted,

> *"While it is very unlikely that the provision of an alternative blood supply for the UK would be feasible in the short or medium term, Ministers' advice is requested on whether we should formally explore the position. Do Ministers wish us, nevertheless, to explore whether there are any other alternative supplies so that, if challenged, we can confirm that every avenue has been explored?"*

3.45. There then followed some minutes and meetings on this issue, which for the most part were at a more senior level than my own, but about which I was likely kept broadly informed at the time.

3.46. On 10 August 1999, Dr Metters sent a minute to the Private Secretary for Lord Hunt, copied only to the Secretary of State's Private Secretary **[WITN4505063].** Dr Metters pointed to the importance of recognising the balance of risks and argued that if Ministers were minded to refer the safety of blood back for discussion by Advisory Committees, it would first be wise to establish whether or not alternative supplies of blood could be identified.

3.47. On 11 August 1999, the Secretary of State Mr Dobson met Lord Hunt to discuss Dr Metters' minute of 10 August **[WITN4505064].** The short note of that meeting records:

> *"SofS and Lord Hunt discussed Dr Metters' minute dated 10th August. They agreed that we should:*
>
> *i) Report our actions to date to SEAC, (i.e. on sourcing and leucodepletion);*
>
> *ii) Ask SEAC and MSBT to confirm their advice in the light of these actions and the American/Canadian deferral;*
>
> *iii) in the light of SEAC's and NISBT's response, consider whether or not alternative supplies of safe blood could be found.*
>
> *SofS also said he would like to talk to the CMO about this on his return to the UK the following week"*

3.48. On 12 August 1999, Dr Metters minuted Dr McGovern stating:

> *"You will have seen Mark Ferrero's note of 11 August. I have failed in my attempt to persuade Ministers that we should make some greater attempt to find if there are alternative sources of blood before referring the issue back to SEAC and MSBT. However, I think I have persuaded them that both these committees need to be consulted.*
>
> *I have certainly persuaded Mark that if SEAC are to receive a paper it must deal not only with the question of safety of supply but also the demand for blood from surgeons, anaesthetists, physicians and so on. We cannot run the risk that SEAC will come up with an answer which disregards the patient's needs for blood transfusion to save life or preserve health. I think that point at least is established.*
>
> *Clearly it would be sensible for SEAC's discussion on blood to co-opt one or two experts who can talk about the reasons why it is essential that the blood supply is maintained."* **[DHSC0032411_117]**

3.49. On 17 August 1999 Dr McGovern also provided a line to take and Q&A briefing on the subject **[WITN4505065].**

3.50. On 18 August 1999, Dr McGovern provided a briefing note for the CMO for a meeting on the subject with the Secretary of State scheduled for 20 August **[DHSC0032422_115]**. In the discussion between the Secretary of State and CMO, the Secretary of State decided to put the position to SEAC and the Committee for Safety of Medicines for further advice, (see the later submission of 18 October 1999, addressed at paragraph 3.61, below.)

3.51. On 10 September 1999, Dr McGovern sent Mr Austin papers, ahead of SEAC's further consideration of the issue **[WITN4505066].** The matter was later addressed in the paper SEAC 58/5 **[WITN4505067]** with the updating reports on the measures already taken **[WITN4505068]**

3.52. I attended the SEAC meeting on 20 September 1999, solely for the item on blood **[WITN4505069].** The minutes record that, "The Committee welcomed the progress that had been made towards the implementation of the policy on leucodepletion and noted the comments from Dr Morgan that clinicians were increasingly considering how they could reduce the use of donated blood without prejudicing patient health. The Committee concluded that it had nothing to add to its earlier advice with regard to blood destined for transfusion."

3.53. Following the SEAC meeting, on 21 September 1999, Alan Harvey of PH1 suggested to me that a short submission was now necessary 'simply to inform Ministers the Committee are content that no further steps are necessary to safeguard UK blood supplies' **[DHSC0041226_062].** The following day, I provided Mr Harvey with draft advice on blood for SEAC to give to Ministers, which was in the following terms **[DHSC0041226_075]**:

> *"We reviewed the public health action currently being taken to reduce the theoretical risk of transmitting vCJD through blood and blood products in the light of:*

- the recent decision by the US and Canada to defer blood and plasma donors who have spent six months cumulatively or more in the UK between 1980 and 1996;

- recent published research.

We were pleased to note that, as a result of advice from this Committee and the Committee on Safety of Medicines, all licensed blood products are now manufactured using non-UK plasma, and all blood collected in the UK will be leucodepleted from 1 November 1999.

Having considered the available evidence, the Committee concluded that no further steps were necessary to safeguard UK blood supplies."

3.54. Mr Harvey advised that this could be addressed either as part of the SEAC meeting summary (short of specific advice to Ministers) or as advice to Ministers which would give it a higher profile and would require a response from Ministers **[WITN4505070].**

3.55. A meeting was arranged for 6 October 1999, to discuss vCJD: blood donors and duty of care. This was with senior members of the NBA, their solicitors, Dr Hewitt of the National Blood Service, Dr McGovern and me – I arranged for Mr Dunleavy of the DH Solicitor's Division also to attend **[WITN4505071].** The issue was what to say to, and how to approach, those who may come forward to give blood if they themselves had received transfused blood from a donor who subsequently developed vCJD. The NBA had received legal advice to the effect that it was appropriate to tell the potential donor of the situation and arrange for the provision of counselling and treatment. At this stage, the advice from the Department was that set out in circular PL(CO)(98)(1) (dated 6 February 1998, from Dr Winyard [**BART0002418**]), to the effect that there was no need to inform patients who had received vCJD implicated blood components on the basis that:

"i. it is thought unlikely that nvCJD will be transmitted in this way;

ii. there is no diagnostic test for nvCJD;

iii. even if a test was available, there is no preventative treatment that could be offered'

3.56. In noting these issues to Mr Dunleavy, I commented:

"These three statements still hold true. However, they do not necessarily override the specific legal concerns raised by [the NBA's solicitor] in connection with the NBA. It may also be becoming harder, given an increasing emphasis on patients' rights and a distrust of paternalism to justify the stance that information should be withheld from patients on the grounds that it might cause unjustified worry." **[WITN4505071]**

3.57. Ahead of the meeting, Mr Dunleavy set out his views in a minute to me dated 5 October 1999 **[DHSC0041362_009]**. He was extremely doubtful that there could be a lawful across the board decision not to notify affected patients, although the circumstances of particular individuals might excuse their being told. He thought the need to tell affected persons was stronger still in the case of potential donors.

3.58. The meeting took place on 6 October 1999, and following it I emailed senior colleagues to advise them of the main conclusions that "(i) the NBA should immediately set up a system to exclude individuals from giving blood who have been identified by the NBA/CJDSU study as having received blood from people who subsequently developed vCJD and (ii) that, if those people present as blood donors, the NBA has a duty to tell them why it is not possible to accept their donation." **[WITN4505072]** I provided an early draft letter to the NBA but noted that some of the issues raised had implications beyond blood.

3.59. There were further exchanges concerning the implementation of this and whether to await advice from Treasury Counsel [see for example: **DHSC0041362_008;DHSC0032422_105;DHSC0004087_030;DHSC0041362**

_004;DHSC0041362_005; DHSC0041362_010; WITN4505073 and WITN4505074].

3.60. On 15 October 1999, the CSM confirmed to Dr McGovern that, "The Committee [had] reviewed its decision of May 1998 in respect of the change of source of blood products away from UK plasma, and have advised that no farther regulatory action is required." **[WITN4505075]**

3.61. On 18 October 1999, Dr McGovern put the submission to the CMO and Lord Hunt regarding SEAC's advice on the Blood Supply which also covered advice given by the Committee from the Safety of Medicines. **[DHSC0006248_004].** His submission noted as follows:

> *"**Advice***
> *Secretary of State discussed the issue with CMO and decided to put the position to SEAC and CSM for further advice, SEAC noted that, as a result of its advice and that of the Committee on Safety of Medicines. "licensed blood products are now manufactured using non-UK plasma, and all blood collected in the UK will be leucodepleted from 1 November 1999". In addition the draft public summary which the Committee intends to publish 21 October concludes "that no further steps are necessary to safeguard UK blood supplies". On 14 October CSM also "reviewed its decision of May 1998 in respect of the change of source of blood products away from UK plasma and have advised that no further regulatory action is required"*
>
> ***Action***
> *Ministers are asked to note this advice. Officials will report this back to MSBT."*

3.62. On 20 October 1999, I received confirmation from NBS of the blood donor exclusion criteria for CJD **[WITN4505076]**. Further discussion followed about

the need to ensure consistency between exclusion criteria for blood and tissue donation.

3.63. At its meeting on 28 October 1999, the MSBT discussed the outsourcing of labile blood components (i.e. whether labile blood products could be sourced from outside the UK; progress on leucodepletion; the production of blood products from non-UK plasma; the position for potential blood donors who had received vCJD implicated blood; the safety of Fresh frozen plasma **[NHBT0004333]**.

3.64. On 18 November 1999, Dr Wight (the Senior Health Officer in Public Health Branch 6 (new and emerging infections)), circulated a pre-publication version of an article by Paul Brown on the risk of transmission of CJD through blood and blood products, which she had been sent by Professor Will of the CJDSU. **[WITN4505077]**. Professor Will had noted that the findings were reassuring, although the final sentence of the article indicated that further information was required from similar experience in vCJD.

3.65. On 8 November 1999, Dr McGovern was one of a number of senior officials copied into a submission from the CMO to Secretary of State addressing the expenditure incurred to date and the best estimate of the worst case potential cost to the NHS of policies under consideration on measures aimed at minimising the risk of person to person transmission of CJD, including vCJD **[WITN4505078]**. The action already taken in relation to blood and blood products was £88 million pa (£63m for leucodepletion and £25m for sourcing blood products from non-UK plasma).

3.66. On 29 December 1999, Dr McGovern circulated for internal comment a further draft of the letter to the NBA to give the requested Department advice concerning the proposed deferral of potential donors who have been shown to have received blood from people subsequently shown to have developed variant CJD **[WITN4505079]**.

vCJD developments in 2000

3.67. Following input from others in the Department (see for example Dr Troop's minute of 4 January 2000) **[DHSC0041226_058]**, Dr McGovern's final letter to the NBA was sent on 12 January 2000 **[WITN4505080].** The thrust of Dr McGovern's letter was that:

(1) The legal advice was that the database flagging process was not a breach of the old or new Data Protection Acts. Further, there was 'probably no requirement' under either Act to inform people who have received implicated blood components that they were being or had been flagged to avoid their blood getting into national supplies.

(2) However, in the spirit of openness and 'contracts' with donors, the blood services would need to consider telling, or offering to tell, the donor why their blood could not be accepted. As there was still little scientific knowledge to inform the discussion with the donor, the appropriate Health Department should be contacted in the first instance and every such incident discussed and managed on a case by case basis.

(3) The NBA had agreed to develop a protocol for dealing with these cases in discussion with the Department of Health and the proposed 'Expert Group on the Management of CJD Incidents'.

(4) The 'Expert Group on the Management of CJD Incidents' was to provide a mechanism for the development of a consistent approach to the handling of situations where patients may have been exposed to the potential risk of secondary vCJD infection. It was to include consideration of cases where patients were operated on using instruments found to have been used on patients who subsequently developed vCJD, as well as patients who have received implicated blood or blood products. The Group was due to have its first meeting on 25 January, under the Chairmanship of Professor Jeffries.

(5) The decision to flag such potential donors was purely precautionary, not based on any new scientific information, and had been taken in the face of profound uncertainty. The most recent scientific opinion was that while blood may contain low levels of the infectious agent of CJD, blood components had never been identified as a cause of CJD in humans. The information on vCJD was however in evolution and as there was still no test for the agent, the implications of a positive test would in any event be difficult to ascertain, as there were no known treatments for the disease. In addition, it was not known whether the agent can be transmitted by blood and cause disease in recipients. In light of those factors, the Department's policy remained that people who may have been exposed to the vCJD agent through blood or blood products should not be informed as set out in Executive Letter PL(CO) (98) 1. However, that policy was to be kept under review in the light of developing science and counsel's opinion was to be sought.

3.68. On 7 February 2000, Dr McGovern alerted colleagues to the fact that the EC were considering deferral of UK donors and those who had lived in the UK during the time of BSE **[DHSC0006455_089].** The next day, Dr McGovern provided a submission to Lord Hunt on this development **[DHSC0006455_085].**

3.69. Also on 7 February 2000, Dr Wight minuted Dr Adam, Dr Troop and Dr McGovern (amongst others) to raise the complications that had arisen over ethical approval for Professor Will's lookback study **[DHSC0046909_037].** The local ethics committee felt unable to continue to endorse the study in light of the advice that had been given to the NBA. However, the study was of significant importance. I was copied into this minute, but resolution of the issue was taken forward by Dr Wight.

3.70. On 14 February 2000, Dr Wight provided an urgent submission to the Secretary of State (by now Mr Milburn) concerning the development that "*...researchers at the UK's Institute of Animal Health have taken pooled heart blood from mice with experimental BSE disease, separated out the plasma, and inoculated this*

into the brains of a further 48 mice. We have just learned … that four of these mice went on to develop the disease". SEAC were to meet the next day and Ministerial agreement to consult with SEAC and seek their urgent advice was sought **[WITN4505081].**

3.71. On 28 April 2000, Alan Harvey provided a submission to Yvette Cooper (the Parliamentary Under Secretary of State for Public Health) advising of the first findings from samples of human tonsil / appendix tissue. None of the first 3,000 samples had shown 'positive', though these were early results **[WITN4505082]**.

3.72. In May 2000, I contributed a suggested answer to a PQ from Lord Lucas where he raised the findings of the paper by Paul Brown, in which it was suggested that leucodepletion did not reduce infectivity **[WITN4505083]**.

The suggested reply was:

> "*Leucodepletion was introduced on the advice of the Spongiform Encephalopathy Advisory Committee (SEAC) as a precautionary measure against the theoretical risk of transmitting variant CJD through blood transfusion, A detailed risk assessment of variant CJD infectivity in blood commissioned by the Department of Health from Det Norske Veritas (February 1999) concluded that "leucodepletion appears to have significant benefit in reducing the risk of variant CJD infection through blood transfusion". This assessment was considered and accepted by SEAC.*
>
> *We are continually reviewing the available evidence on the effectiveness of leucodepletion but, to date, there has been no new evidence to justify a change of policy. The article by Paul Brown describes experimental studies with scrapie and sporadic CJD and concludes, on the basis of preliminary data, that the negligible plasma infectivity detected in experiments in mice is not significantly reduced by leucodepletion. It does not consider variant CJD, except to say that the risks of blood borne transmission are unknown, or provide*

conclusive evidence on the effectiveness of leucodepletion in reducing the risk of variant CJD"

The background note explained:

"In raising his question, Lord Lucas is probably concerned that:

- *one of our precautionary measures against the theoretical transmission of vCJD through blood transfusion is ineffective;*
- *the NHS is having to bear the cost of leucodepletion (around £60m a year) for no good reason.*

However, the article he quotes (which deals with classic, not variant, CJD) does not demonstrate this, and the weight of expert opinion is still in favour of leucodepletion as a sensible precautionary measure. We are, however, keeping the situation under continual review in the light of new scientific evidence.

We have provided a rather lengthy reply to this question in order to give a full explanation of the position."

3.73. On 12 May 2000, Dr Wight minuted Dr Troop the DCMO on the issue of those who had received blood from donors who developed vCJD [**DHSC0046949_103**]. The NBA had been advised by the CJD Surveillance Unit (CJDSU) that 13 people had received blood from donors who went on to develop vCJD, of whom 3 were of the age to potentially be blood donors. Dr Wight noted the position that the NBA view was that the blood from these three people should not be accepted in the event of them coming forward as donors and that they would be duty-bound to inform the donor why their blood was not acceptable. However, Dr Wight noted that while MSBT had discussed how this situation might be managed, it had not specifically considered whether the risk justified excluding these donors, and a scientific evaluation of the TSE risk did not appear to have been undertaken at any stage. The issue had been discussed by Dr Jeffries' group on 10 May. The CJDSU considered that the decision to exclude these people from donating blood was illogical in terms of

the risk they presented compared with the general population. Dr Jeffries' group had recommended that a meeting be convened involving the NBA, MSBT and TSE experts, to address whether recipients of blood from people who later develop vCJD should be excluded from giving blood, on the basis of risk; and if so, how and at what stage should they be informed, and what they should be told about the level of risk. Dr Wight suggested that Dr Troop might wish to chair a special ad hoc multi-disciplinary meeting. Dr Troop agreed to do so, noting that the course was sensible given that the issue had been dragging on **[WITN4505084].**

3.74. Ahead of the meeting, there was an exchange of minutes between Dr Wight and Chris Warncke of the Solicitor's Division, into which Dr McGovern and I, among others, were copied **[DHSC0046909_032 and WITN4505085]**.

3.75. The meeting was held on 16 June 2000 chaired by Dr Troop with 14 members in attendance, together with 6 officials of whom I was one **[NHBT0009063_002]**. There is a full minute of the ethical issues / considerations discussed under agenda item 5 and the discussion under agenda item 6. The group agreed that the method that was most suitable for addressing the problem was for there to be a system whereby donors could decide whether or not they wished to be informed of the circumstances in the event that their blood had to be excluded. The conclusion was that:

"- *The NBA should draft a protocol for identifying recipients of blood from vCJD donors if they come forward as donors, and making information available for those who want it.*

- *the NBA would put the draft to the group for comment and a further meeting of the group be arranged if necessary.*

The ten recipients who were not eligible to present as blood donors had not been traced and it was felt that they did not need to be informed. However, although they were not eligible to present as blood donors there was a potential for them to be organ donors. This remained an important issue, which needed to be thought through.

3.76. In early September 2000, we had to address the development that BSE had been shown to be transmissible by blood transfusion in sheep, a finding that was due to be published in a paper by Professor Chris Bostock in the Lancet. On 7 September, I circulated a first draft statement in case the story leaked ahead of its publication in the Lancet **[WITN4505086]**. There was a meeting to discuss this the following day summarised in an email by Alan Harvey, with agreement that there was a little more time before publication and a submission for Ministers would be prepared the next week **[WITN4505087]**. I provided an amended media line in case the story did break **[DHSC0041227_040][DHSC0041227_018][DHSC0041227_019]**.

3.77. The following week, on 13 September 2000, Jill Taylor of my team provided the submission to Lord Hunt on the research finding **[WITN4505088]**. On the safety of UK blood, the submission noted that:

> *"There is no evidence that CJD or vCJD have ever been transmitted through blood or blood products in the UK. All blood products supplied to the NHS are now made from non-UK plasma, imported from countries where there is no evidence of vCJD, In addition all blood for transfusion is now being leucodepleted (removal of the white blood cells}, These measures were put in place to reduce the theoretical risk of transmitting vCJD. The national haemovigilance system (SHOT - Serious Hazards of Transfusion) indicates that blood safety in the UK is excellent and is amongst the best in the world"*

3.78. A line to take was provided in paragraphs 13 – 15 of the submission (a Q&A brief was also provided) and Ministers were invited to agree the line to take. Media queries were going to be handled by Professor Bostock himself, Professor Peter Smith (Chair of SEAC) and Dr Wallington of the NBA.

3.79. There were further exchanges on 14 September 2000, ahead of the article's publication the following day **[WITN4505089; WITN4505090; WITN4505091; DHSC0042291_095]**

3.80 On 15 September 2000, Dr McGovern minuted Keith Jones, Chief Executive of the MCA (Medicines Control Agency), to apologise for the fact that we had failed to inform and involve MCA on the development, and we were to create a standard circulation list for all further CJD briefings to avoid a recurrence **[WITN4505092].** A handwritten note by someone at MCA, which I would not have seen at the time says:

> *"Unfortunately the briefing to Ministers which was not copied to MCA contained a misleading statement about licenced blood products which will need to be corrected – see submission. Especially disappointing in view of KHJ's [Keith Jones] chairmanship of Scientific Committee in Brussels which has been asked to evaluate this evidence and produce a scientific opinion suitable for adoption by the Commission."*

The documents I have been shown do not indicate which statement MCA felt was misleading, so I am unable to offer comment on this.

3.81. On 19 September 2000, I emailed Dr McGovern, Dr Adam, Dr Troop and the Private Secretaries to Lord Hunt and the CMO to raise a press release issued that day by the pharmaceutical company, Octapharma **[WITN4505093]**. The concerns were that their press release had highlighted that FFP was still made from UK plasma, it referred to concern regarding the transmission of vCJD from blood and promoted their own product as "made from nvCJD-free plasma". As I said in the email, we saw this as "*…totally irresponsible and unjustified action on the part of Octapharma*". Central to this was that in the absence of a test of vCJD, no responsible body could advertise its products as containing "nvCJD-free plasma". I provided lines to take in response. In response, on 26 September, Lord Hunt's office asked what action could be taken against Octapharma requesting advice by 2 October **[DHSC0004224_085]** and I raised this for legal advice. **[DHSC0017160]**

3.82. SEAC met on 29 September 2000 **[DHSC0032270_003]**. The BSE blood transfusion case in sheep to a single animal was discussed within agenda item 4. I attended the meeting for that item only. I made four contributions:

(1) Professor Smith made the observation that, "To some extent, this result has been anticipated by the control measures that SEAC recommended previously in respect to human blood" and asked if there was anything I wanted to say at that stage. I replied: "At the moment all red cells and other blood components are leucodepleted. The only issue we are still looking at is in relation to plasma. The majority is imported from the US, but there are circumstances where UK plasma is used as fresh-frozen plasma which has been highlighted in the media this week. The reason why we use this is because it has not so far been possible to find another source, or a substitute product that is suitable. However we are currently working with the National Blood Authority on a risk assessment to clarify some of these issues and hope to have some feedback by the end of the year." And I confirmed to Professor Smith that the FFP was not pooled but from a single donor.

(2) Later in the discussion Professor Smith asked me if the national blood service had considered the option adopted in the US, Canada and Australia i.e. of not using UK – resident donors (by implication importing all labile blood needs). I replied, *"We have certainly looked at the possibility of simply importing all our blood from elsewhere. We use something like 2.5 million units of red blood each year and there is no way we could get that quantity of blood from anywhere. We also need to be confident that we can supply a safe supply in terms of viral contamination*".

(3) I noted that DH was trying to encourage more autologous blood transfusions for reasons other than CJD (the minutes erroneously read 'autonomous').

(4) I summarised the position on those who had received vCJD-implicated blood – see the exchange starting at **[DHSC0032270_003].** Within this exchange I was asked what would happen to the blood service if a blanket ban was made on blood recipients giving blood, and I replied that:

> *"It has been estimated that this would lead to a l0% drop in blood stocks, which has always been considered to be risky. It would deplete the blood supply too much to be considered. However, this is something*

that has been introduced in France, and I think this is something that we do need to keep considering as a possible way forward". When asked what would prompt the Department to take this step, I commented, "*I think that would be something that we would be looking to the blood advisory committee to give a view on. I think at the moment it is thought that such action would have such an effect on the blood supply in the UK that it would put lives at risk for that reason, and the balance is currently in favour of not doing it. Presumably if we received further information that suggested that there was more than a theoretical risk of transmission through this route then that might be prudent to do that".*

3.83. On 2 October 2000, Alan Harvey provided a submission to the Parliamentary Under Secretary of State for Health, Gisela Stuart, updating the Minister on the position on BSE and vCJD in France **[DHSC0042291_072]**. Dr McGovern and I were copy recipients for our Division HSD2. Mr Harvey noted that:

"Up to now, the French have not placed a ban on blood donations from those who have visited the UK. This decision has apparently been based on a risk assessment revealing that such action would be disproportionate, given that a far greater threat is posed from the historic consumption of imported beef or beef products. But in the light of the recent published paper from the Institute of Animal Health (Bostock et al) showing that infectivity can be passed on through blood, the French Blood. Transfusion Service are shortly to review the position. SEAC on 29.9.00 looked at this issue and concluded that no additional steps were necessary to protect the safety of UK blood over and above the precautionary steps that have already been taken."

3.84. On 3 October 2000, Mr Harvey reported to the Secretary of State on SEAC's meeting of 29 September, including that on the transmission of BSE by blood transfusion in sheep, the Committee agreed that no additional measures were necessary to protect the blood supply beyond those precautionary measures already taken. [**DHSC0040997_033**].

3.85. On 4 October 2000, I provided a joint HSD/MCA submission in response to Lord Hunt's request for advice on what action might be taken in regard to Octapharma **[WITN4505094, DHSC0046909_025]**. The recommendation was that MCA should follow their standard procedures for potentially misleading advertising. Lord Hunt's office communicated in response that the Minister did wish for action to be taken, by following the standard MCA procedure for potentially misleading advertising **[DHSC0006244_018]**. The submission also informed Lord Hunt that,

> *"We are currently working with NBA on a risk assessment of FFP for consideration by MSBT, probably in January. This includes a comprehensive option appraisal of all future possibilities for FFP provision, including the importation of plasma and the use of commercially produced products such as Octoplas."*

3.86. On 9 October, Lord Hunt's office responded to the submission with confirmation that Lord Hunt was

> *"…content to proceed with action against Octapharma as set out in the submission (ie for the MCA to follow their standard procedures)."* **[DHSC0042291_067].**

3.87. On 16 October 2000, Mr Harvey put a submission to Dr Troop and Mr Milburn on handling SEAC's Press Conference following their meeting of 29 September. Dr McGovern and I were among the HSD2 copy-recipients. **[WITN4505095]**. The submission within the updated press release from SEAC on BSE transmission in sheep by blood transfusion included that,

> *"… Members were asked to consider whether, in the light of this finding, further measures to protect human or animal health were needed.*
>
> *On the question of the safety of human blood and blood products, the Committee concluded that the measures the Committee had previously advised should be taken on a precautionary basis had to a considerable extent anticipated such a finding and the previous recommendation with respect to leucodepletion remained appropriate. The Committee*

recommended no additional control measures at this time, but noted that it would be important to ascertain the extent to which leucodepletion reduced or eliminated infectivity in the blood of sheep experimentally infected with BSE."

3.88. I contributed to a Q&A briefing for a SEAC press conference held on 19 October 2000 [**WITN4505096**].

3.89. I have addressed the Department's consideration of financial assistance to those infected with HCV through infected blood / blood products in section 2 of this statement, above, and do not repeat the details here. I should note, however, that the decision to provide financial assistance to those who contracted vCJD was raised in support of the HCV case, following the publication of the BSE Inquiry report and the Government's acceptance of the case for financial support for vCJD.

3.90. I put a submission to Lord Hunt on 6 November 2000, following a request for a meeting with the Haemophilia Society on recombinant treatment. vCJD was of course a significant part of the background to this but I have addressed this under the Recombinant Clotting Factors section of my statement at 4.35, below.

3.91. On 10 November 2000, there was the first meeting of the CJD Incidents Panel, chaired by Professor Michael Banner [**WITN4505097**]. The PH6 (communicable disease) branch had led on this and the panel was set up to support the NHS in the increasing number of incidents involving potential transmission between patients through clinical interventions. It was set up as a subgroup of SEAC/ACDP (Advisory Committee on Dangerous Pathogens), to which it reported. I attended most, if not all, of the Panel's meetings.

3.92. On 14 November 2000, I raised with Dr McGovern an article in the Evening Standard which was mainly concerned with FFP but wrongly claimed the Deputy CMO had issued a statement that anyone who had received a blood transfusion would in future be barred from giving blood. [**DHSC0041167_203,**

WITN4505098]. Dr Troop subsequently sent a rebuttal to the newspaper which was also used to form lines to take for future briefing **[WITN4505099]**.

3.93. On 15 November 2000, I was copied into a submission from the MCA (Dr Nicholson) to Dr Jones and Lord Hunt on extending the restriction on the use of UK-plasma to other countries affected by one or more cases of vCJD **[WITN4505100]**. I was one of the officials involved in a telephone conference (DH and MCA) the same day **[WITN4505101]**. The CMO later commented on the options set out in this submission that only patient/public safety, not 'sensitivities' should guide our actions **[WITN4505102]**. Lord Hunt asked for further information on the supply issues, number of products in question and the scale of the withdrawal **[WITN4505103]**.

3.94. On the same day, 15 November 2000, I attended a meeting with colleagues from the Economics and Operational Research Division and members of the National Blood Service, to consider approaches to a further risk assessment of the vCJD risks for FFP which had been recommended by the MBST **[NHBT0041597]**. Separately, I was advised that a further 5 recipients who had received blood from one of the vCJD cases who was a blood donor had been identified. Of these, 3 were transfused between 1997 and 1998, and were young enough to be potential blood donors. There were now 20 patients (previous total 15) who had received blood from donors who have gone on to develop vCJD, of whom 7 (previous total 4) were flagged as potential blood donors. **[WITN4505104]**.

3.95. Also on 15 November 2000, Alan Harvey forwarded me a copy of an email from the British Embassy in Bonn. This informed us that two German newspapers had reported that the blood donation working group at the Robert Koch Institute had decided that anyone who had spent more than 6 months in total in the UK between 1980 and 1996 should be excluded from donating blood in Germany until further notice. **[DHSC0041227_011]**

3.96. On 20 November 2000, [**WITN4505105**] Dr McGovern and I were amongst those copied into an email note to Lord Hunt's private office concerning products of concern derived from French sourced albumin as an active ingredient, one of which was a Factor IX product. It was noted that the product concerned (Betafact) was not thought to have been used in hospitals in England; that if it was used, it was expected that sales would have been low, and there was no record of it having been dispensed in the community. Alternative products available were Replenine from BPL, Mononine from Centeo and Alphanine from Grifols, as well as recombinant Factor IX. At this stage, I believe that this issue was being handled by my colleagues in the Medicines, Pharmaceutical and Industry (MPI) Division and we were being copied in for information.

3.97. On 21 November 2000, I provided a briefing for Prime Minister's Questions concerning the Guardian article that had been published that day stating that the NHS was considering banning blood transfusion recipients from giving blood because of vCJD risks [**WITN4505106**]. This drew on previously agreed lines in this area and also included that:

> *"One possible action to minimise the theoretical risk from variant CJD would be to exclude people who have had a blood transfusion from giving blood. However, we need to look carefully at what impact this would have on reducing the theoretical risk from variant CJD against the real risk of significantly reducing the amount of blood available to the NHS for life-saving operations. The National Blood Service are therefore undertaking a survey of donors to assess this."*

3.98. I also provided information to Emily Hands from the Communications Directorate in relation to queries from the Guardian about the 1997 recall of some Factor VIII batches [**DHSC0042291_032 and WITN4505107**].

3.99. On 23 November 2000, Dr Troop the DCMO minuted me to convey her anxiety on vCJD and Blood issues, stating:

> *"I feel anxious about this issue for two reasons:~*

i. the Fresh Frozen Plasma - which Andre is now addressing;
ii. people who have received blood from people who have had vCJD and are not told. We are looking to tell people who are found to have been operated on with the same instruments as people who subsequently are found to have vCJD, so we are out of step.
iii. the outcome of the meeting we had some months ago to discuss telling such people when they arrived to give blood - I have received no feedback has action taken place?
2. We need to be very clear what we are doing on all three fronts".
[DHSC0004344_013]

3.100. There was a further meeting to discuss options for Fresh Frozen Plasma on 27 November which both Dr McGovern and I attended, together with Peter Bennett from EOR and members of the NBS **[SCGV0000210_006].** Four options were agreed for presentation to MSBT at their meeting on 22 January, and an action plan agreed of necessary steps ahead of that meeting. I also ensured that colleagues in Scotland, Wales and Northern Ireland were briefed on the action we were taking. **[WITN4505108]**

3.101. On 29 November, I emailed Dr McGovern as my branch head to follow up on Dr Troop's concerns on progress on vCJD and Blood Issues (the email makes it clear that Dr McGovern had either already emailed me on the topic or spoken to me, since my email started, *"I'm sure you're right. There is no doubt some back covering going on here")*. **[WITN4505109].** I explained to him the indication I had received that the National Blood Service had not yet progressed the "revamping" of their consent forms. I had undertaken to write to them to set out precisely what we wanted the NBA to do and that it would be helpful if they were well advanced with this or, even better, had the work done in time to report to the January meeting of the MSBT. I went on to say,

"Of course if there is a decision to exclude all transfusion recipients from giving blood, this would simplify the process – or at least alter it, and the leaflet for donors would have to be drafted differently. If we were able to go to MSBT in January for a decision on exclusion of transfusion recipients

(see my earlier email) there may be no point pushing NBA to produce a leaflet before then."

I noted that there was a degree of frustration that the CJD Incidents Panel had focussed on surgical instruments rather than blood issues and I was awaiting a response from Peter Jones in the PH Division on the question of the panel discussing the issue of whether/how to inform recipients of blood from vCJD donors

3.102. On 5 December 2000, André Hare from the EOR Division circulated a document canvassing experts' views on the potential vCJD infectivity of Fresh Frozen Plasma as part of the actions ahead of the MSBT meeting **[WITN4505110].**

3.103. On 6 December 2000, Dr Troop minuted the Secretary of State's Office concerning the Chief Secretary to the Treasury's response on the funding of measures to reduce vCJD transmission risks; this was in relation to the significant costs involved in reducing transmission rates through surgical instruments. **[WITN4505111, WITN4505112].**

3.104. On 8 December 2000, Dr McGovern emailed Dr Troop (copied to Lord Hunt's private secretary among others) to give an early warning of the possible withdrawal of blood products and albumin following the discovery that a patient recently found to have vCJD, donated blood that was used in making these products **[WITN4505113]**. The affected products were batches of Factor VIII, Factor IX, intravenous Immunoglobulin and Albumin. They had already passed their expiry date but there was concern about products that had been exported, and concern regarding possible onward use as an excipient in products for human use, where those products might still be in date. Dr McGovern noted the difficulty of whether to inform recipients (contrasted with the position with recipients who were operated on with instruments). The vCJD Incidents Panel were due to discuss this but not until their February 2001 meeting. On the same day, Dr Lee of the MCA alerted Ministers to the issue **[MHRA0020987]**. In response, Lord Hunt asked Dr McGovern whether the advice of the Incidents

Panel could be obtained more quickly, and how long it would take to put together consistent lines on informing people – see his private secretary's email of 12 December 2000 **[DHSC0046909_007]**. Gisela Stuart had also asked for further information on the issue as she was due to attend the European Health Council in Brussels **[WITN4505114]**. Dr Kavanagh of the MCA provided Ms Stuart with an update / further information on 13 December **[MHRA0020987]**.

3.105. Lord Hunt met Dr Troop on 14 December 2000, to discuss plasma-derived products from other countries with vCJD. I was copied into the note of actions arising from the meeting **[MHRA0021043]**.

3.106. On 15 December 2000, I put a submission to Lord Hunt to update him on the action taken since the MCA's submission of 13 December on the potentially vCJD implicated blood products and following his request to Dr McGovern **[WITN4505115]**. On the action being taken, I explained as follows:

"BPL are writing today to the major distributors of BPL products and, on Monday, to hospital chief executives and clinicians to inform them of the incident and listing the batches of implicated product supplied. They have written similarly to their overseas customers. This is not a recall, however, as the products are all past their expiry date and should, in any case, have been caught by the recovery and replacement exercise in 1998 (following the ban on the use of UK plasma) NBA have set up a special customer service line to deal with enquiries from hospitals and clinicians."

3.107. On the issue of informing patients, I set out that:

"In 1998, after two recalls of blood products containing plasma from vCJD donors, the Department issued advice to NHS Trusts addressing the issue of whether patients who had received these products should be told. This advice, which still stands, was that these patients should not be told because:

- *the risk that vCJD might be transmitted in this way is low;*
- *there is no diagnostic test for vCJD*

• even if a test was available, there is no treatment.

The guidance goes on to state that: "In deciding whether or not to inform a particular patient, the benefit/harm balance for their individual situation must be carefully considered. In communicating with patients who have received implicated products, it is therefore individual clinicians to decide whether to follow this general ethical advice,"

This advice is now out of step with the view that has been taken on incidents involving vCJD-implicated surgical instruments. These patients will be given the opportunity to decide where or not they wish to be told. We had planned to refer this to the next scheduled meeting of the vCJD Incidents Panel on 22 February, but are now working on arranging a special meeting of the Panel in mid January."

3.108. On the same day, I put a second submission to Lord Hunt on the National Audit Office's Report into the National Blood Service [**DHSC0032174_055**]. The report was favourable, recognising that the Service had made good progress towards providing an effective national service at the same time as coping with the emergence of variant CJD. It found that:

- effective measures were in place to ensure that blood was safe for transfusion;
- the Service had taken action to ensure a sufficient supply of blood for the NHS;
- hospitals were broadly satisfied with the responsiveness of the Service;
- the Service had cut its costs by some 5.44% between 1995/96 & 1998/99.

Areas identified for improvement were:

- the experience of giving blood. One key issue was the need to reduce waiting times;
- efficiency and accountability, e.g. by benchmarking and developing better performance indicators;
- responsiveness of complaints from hospitals, involving more hospitals in clinical audits and disseminating research findings more widely.

3.109. The same day, Jill Taylor from my team also put a submission to Lord Hunt, concerning his forthcoming meeting with the Manor House Group [**WITN4505116**]. vCJD featured in that briefing in regards to the reasoning for payments being made to vCJD victims, in comparison to those infected with HCV, and in the context of recombinant products.

3.110. There was a further submission to Lord Hunt from the MCA (Dr Lee) on 19 December 2000, advising the Minister that the Irish Health Minister would be making a statement on the oral polio vaccine that had been produced using albumin from the implicated plasma [**WITN4505117**] see the statement issued at [**DHSC0004735_138**]. Lord Hunt asked for further information on 20 December **[DHSC0004735_135].** Alan Harvey (PH6) minuted his branch Head Dr O'Mahoney on 21 December, to record the apparent impasse on the timing of the next Incidents Panel meeting [**DHSC0046909_097**]. I was also copied into a letter from Dr Troop to Dr Mortimer of the PHLS in which she outlined the work being done around minimising vCJD from blood transfusions [**WITN4505118**].

vCJD developments in 2001

3.111. On 2 January 2001, Dr O'Mahoney minuted Dr Troop on the timing of the CJD Incidents Panel's consideration of the blood / blood products advice **[DHSC0046909_095]**, Dr O'Mahoney requested agreement to a timetable that would permit the Panel to provide the advice at their meeting scheduled for 22-23 February 2001, rather than mid-January.

3.112. On 9 January 2001, I alerted colleagues in the Finance directorate to the consideration being given to excluding blood transfusion recipients from being blood donors, and the potential for this to impact on the cost of blood to the NHS **[WITN4505119]**. The Economics and Operation Research Division's full report was unlikely to be available for the MSBT meeting on 22 January but I updated Dr Troop that EOR should be able to report on their work in progress

or provide a summary of their provisional results. I had passed on to Mr Hare in EOR the first results of the NBS survey, which suggested that 7.7% of donors were able to say that they had had a transfusion or a major operation likely to have required a transfusion, since 1980, rising to 11.4% if operations before 1980 were included, and to 14.5% if including those who were not sure. I added:

> *"We would need to look very carefully at the impact on the blood supply of any exclusion of transfusion recipients but, on the face of it, excluding 7.7% of donors a vCJD risk reduction measure seems feasible if you accept that continuing to take blood from the "not sure" means that some transfusion recipients will continue to be used."* **[WITN4505119]**

3.113. On 7 January 2001, Mrs Izzard of the Medicines Pharmacy and Industry Division, Pharmaceutical Pricing Regulation Scheme Branch minuted me with details obtained from Schering, the company which held the marketing authorisations for Pulmocis and Vasculocis, the products that had been made using French plasma **[WITN4505120].** Schering were raising doubts about the risk benefit of switching from French to US plasma.

3.114. I circulated a draft paper on the Fresh Frozen Plasma risk assessment ahead of the MSBT meeting and received comments on this, see e.g. **[DHSC0041167_020, NHBT0041578_001]**. The finalised Secretariat paper on this topic was MSBT 22/2 **[WITN4505121; DHSC0038725_096; NHBT0001985]**. The paper summarised the conclusions of two papers and provided some analysis:

- An analysis by DH EOR of the potential risk of vCJD transmission via FFP and how that risk might be reduced by sourcing the product from the US (paper 1);
- An analysis by NBS of measures available to reduce the risk of viral transmission via FFP using UK sourced plasma and the options available if a decision was taken to switch to US plasma (paper 2);

3.115. The paper concluded by posing a series of questions for MSBT:

(i) On the basis of the risk assessment in Paper 1, were there sufficient grounds for ceasing to use UK FFP?

(ii) If a switch away from UK FFP was recommended, and an alternative source was available from the US what requirements would MSBT wish to see in place to minimise viral risk and vCJD risk (assuming a low undetected level of vCJD in the US?)

(iii) If insufficient supplies of US-sourced FFP were available to meet NHS demand should US sourced FFP be phased in (e.g. provided in the first instance to neonates and children born after 1996)?

(iv) If continued use of UK-sourced FFP was recommended, should NBS introduce Methylene Blue treatment of FFP?

(v) What action should be taken to reduce inappropriate use of FFP?

3.116. On 15 January 2001, Alan Harvey alerted me to concerns which Professor Will of the CJDSU had raised arising from the fact that the batch numbers of the potentially implicated bloods from the vCJD donor had been provided in the BPL information release. **[DHSC0004735_132]**. Professor Will had raised that some hospitals / clinicians might therefore 'go it alone' and advise patients before any advice had been disseminated from the Incidents Panel. He had also had two reports from clinicians who were already aware of patients in this category who were showing neurological impairment. In neither case did the CJDSU suspect vCJD, but it was of concern to Professor Will that the clinicians were already drawing a potential link. Professor Will was also being asked whether he wished to receive lists of patients who received the blood for the purposes of future reference / look back.

3.117. On 18 January 2001, Alan Harvey alerted Professor Banner to the fact that on 16 January, the UKHCDO had circulated a fax to members of their advisory committee. The fax had sought comments on a handling strategy for bringing to the attention of Centre Directors and patients the fact that certain products, used on patients before 1998, contained plasma from a donor who went on to develop vCJD. **[DHSC0006287_100] [DHSC0006287_101]**. Under the proposed approach by the UKHCDO, patients were to be invited to return to

Centre Directors a reply sheet indicating whether they would wish to know if they/their child had received one of the potentially contaminated batches. Mr Harvey provided the fact sheet prepared by my team and made the point that the Panel may be able to draw some useful lessons from the responses which arise from the UKHCDO initiative. Karin Pappenheim, Chief Executive of the Haemophilia Society also faxed me the letter she had sent to Society members **[WITN4505112]** including the Society's view that patients should be informed about any issues relating to their treatment, and should receive individual advice, and if need be, counselling.

3.118. On 19 January 2001, I put a submission to Lord Hunt on the campaign for universal provision of recombinant clotting factors. vCJD was part of the background to this issue but I have addressed it more fully in the recombinants section of this statement at paragraph 4.46, below.

3.119. The MSBT met on 22 January 2001, Chaired by Dr Troop and Dr McGovern **[DHSC0014973_005]**. While other members of my team usually provided the secretariat function and attendance, I was present in that role for this meeting. The minutes record the discussion of the risks of FFP and the members' agreement that:

"(i) there were sufficient grounds on a precautionary basis to look at the feasibility of a switch to US plasma;

(ii) if there was to be a switch to US sourced FFP:

(a) Members had a clear preference for using single unit voluntary donated, MB treated plasma, If supplies were limited, this should be used for neonates and children;

(b) Members would need to have confidence in the processes for viral inactivation;

(c) Members would not favour using pooled solvent detergent treated FFP unless a 2nd viral inactivation step could be incorporated to deal with non lipid viruses;

(iii) there was a need for a wider scoping exercise addressing safety, supply (need for sustained alternative provision) and logistics;

(iv) the issue should be brought back to MSBT for a special meeting in April

Action
- Secretariat to provide NBS with written instructions to investigate feasibility of ensuring sustained supplies of US plasma.
- Secretariat to take up issue of cryoprecipitate with MCA"

3.120. The exclusion of transfusion recipients from giving blood was also discussed. The minutes record the committee's agreement, that the issue should be brought back for further consideration at the April meeting and that it should have EOR's risk assessment and an NBS implementation plan; and that the committee would also need to address the impact of the measure on reducing risk from recycling of viruses.

3.121. On 24 January 2001, I contacted John Stephenson of the Research and Development Directorate's Policy Research Programme Branch to seek his assistance and guidance on a request from the Irish Government for a sample of the original BPL albumin which they wished to use for testing with suitable animal models. [**DHSC0004735_116**]. I understood that BPL only had very small quantities available.

3.122. Professor Banner had concerns about the secretariat support for his panel, and about the lack of consultation around the wording of DH's announcement on decontamination of surgical instruments [**WITN4505123**]. My team in HSD2 were copied into exchanges on this but were not centrally involved.

3.123. There were media reports on 29 January 2001, to the effect that the Government had taken the decision to tell the 22 people who had received transfused blood from donors who had gone on to develop vCJD that they may have been infected. We provided briefing for Prime Minister's Questions, in case the issue was raised [**DHSC0046949_009**]. Additional briefing followed to cover a further article in the Times the next day [**DHSC0046909_085]** and from

a Private Notice Question from Nick Harvey MP [**DHSC0046909_087**]. There was a good deal of media enquiry at this stage with requests for information made to my team and colleagues in PH 6 [**DHSC0004735_106; WITN4505124; DHSC0004735_099; DHSC0004735_102**] as well as requests from Ministers for lines to take and for prioritisation of further action (see e.g. the message to me from Lord Hunt's Private office, [**DHSC0004735_107**].

3.124. I was involved at this stage (i.e. January – February 2001) in submissions to Ministers concerning recombinant clotting factors but I add the detail of this in the next section of this statement.

3.125. On 1 February 2001, Dr Hill (Chairman of the UKHCDO) faxed Dr McGovern on the notification of blood donors who had developed vCJD, noting:

"You are aware of the approach adopted by the UKHCDO in notifying the haemophilia patients I have been trying to think of the other issues we need to address and need consideration:-

1. Development of a different approach to informing the public.

2. Safety nets to be in place prior to such announcements to reduce the concerns of those who may be affected by this.

3. Having identified individuals who have received implicated products, do they need to be considered as "more risky" than the general public in terms of public health risk? Obviously with haemophilia patients do we need to take any precautions with those receiving dental treatment or having operations, unless such procedures are already defined as high risk procedures (e.g. neurosurgery and tonsillectomy)?

4. Do we adopt a similar approach to recipients of batches of albumin and Intravenous immunoglobulins that have been implicated to avoid the criticism of being paternalistic and withholding information?

I think it is important that we have advice on these issues so that they can be addressed uniformly throughout the Health Service." **[WITN4505125]**

Unfortunately, searches have not found a response to Dr Hill.

3.126. On 2 February 2001 Mrs Izzard in the MPI Division put a submission to Mr McKeon (in the same Division) and Lord Hunt **[DHSC0041427_066]** regarding the issue of plasma products from other countries with vCJD (which had been raised in Mr McKeon's minute of 20 November 2000 (see paragraph 3.96 above). I emailed Andy McKeon later that afternoon expressing concern that action was not proposed in relation to the Factor IX product (Betafact/Novofact) sooner than March **[DHSC0041427_063].** I cautioned about the context of the Haemophilia Society's media campaign and the dangers of being seen to have delayed implementing the recommendations of the Committee on Safety of Medicines in this regard.

3.127. On the same day, 2 February 2001, I alerted Lord Hunt's office to the BBC's Watchdog Health check programme on vCJD and blood products. I noted that the BBC interest was being fuelled by the Haemophilia Society as part of their campaign for recombinant products **[DHSC0032156_068].**

3.128. On 6 February 2001, Dr Adam minuted having appeared on the Watchdog programme the previous night **[DHSC0020839_043]**. She noted:

"There were two allegations which I ignored, but are potentially problematic:

** that the NBS letter from December continued to take the line that it is no benefit to patients to be told that they may have been exposed to risk (please could I see a copy);*

** that we have "gagged" hospitals over the last few days. I think that we need to get the interim guidance out asap. Assuming that the CJD Incidents Panel takes the line that each person who may have been exposed to risk should be able to decide whether they wish to know or*

not, we need to get NHS Trusts gearing themselves up to be able to offer this choice.

On the basis of my crash course last night, I am not sure how we propose to do this. Where there are defined patient groups (people with haemophilia or Ig deficiency), if we only write to those who have been exposed to one of the products, won't they work out that others, haven't yet been informed and draw their own conclusions? And what about the albumin recipients [who] must come from a much wider group?

I am sure that these are the questions which are preoccupying the Panel! However, I think we much provide urgent follow up to the NBS letter, and set out clearly for the NHS how we expect them to handle this. And presumably we need to take the patient groups with us, as well as the clinicians (I am not sure how representative the RFH consultant is, but she was very critical of our inaction)."

3.129. I replied to Dr Adam the next day, 7 February 2001 **[DHSC0004735_137]**. I explained the background and Lord Hunt's original wish that the CJD Incident Panel should meet urgently in January to review the earlier guidance (which was recognised to be out of step with the 'patient choice' approach being adopted on surgical instruments) but that this had not proved possible. Instead, guidance on blood / blood products was being integrated into the framework for managing vCJD incidents being developed by the Panel. The media attention had meant that it was no longer practicable to await further guidance from the Incident Panel and interim guidance was necessary which we aimed to get out within a week.

3.130. The interim guidance that was prepared (but not at this stage issued) was in the form of a draft letter from Dr Troop **[WITN4505126]**.

3.131. On 9 February 2001, the CMO (Sir Liam Donaldson) was contacted by the Isle of Man Blood Transfusion Service **[DHSC0038590_076]**. Dr Wardle of that service, raised the earlier DH advice that there was no need to inform patients

who had received blood components or products, collected from donors who subsequently developed vCJD. He contrasted that with the approach being taken to informing haemophiliacs who had received Factor VIII from the same batch of plasma, and with advice that Dr Wardle had received from the Medical Protection Society on the duty to inform patients of situations which may have caused them harm. Dr Wardle sought a written statement, giving a risk assessment and guidance on disclosure, from the UK Department of Health, upon which the Isle of Man DHSS could base its own response to the situation.

3.132. On 13 February 2001, Mr McKeon provided a further submission to Lord Hunt on plasma products from other countries with vCJD **[DHNI0000043_016]**. On the Factor IX product Betafact/Novofact, the position was that it had only been used at St Thomas' Hospital, about a year previously and was not currently used by them nor was it in use in other UK Centres. It was noted that the Haemophilia Society may be concerned that Ministers have not implemented the CSM's advice and suspended or revoked the licence even though the product was not used in Britain. Mr McKeon's overall advice was for the CSM to be asked to give further advice on full knowledge of the supply position once CPMP's position was known (the supply position was difficult because another product, Pulmocis (a diagnostic agent in lung perfusion impacting) was widely used and there was no readily available alternative). Mr McKeon noted the option, on Betafact/Novofact, of specifically requesting that the manufacturers do not export any product to the UK until the issues were resolved, although there was unlikely to be any requests for it in any event. Dr Troop responded to this on 23 February 2001 **[WITN4505127]**.

3.133. On 13 February 2001, I was one of the recipients of a memorandum from Tom Kelly providing text for a response to the Public Accounts Committee on three areas, one of which was their concern about non-disclosure of information around vCJD **[DHSC0032174_005]**. This gave the chronology following the notification to BPL on 12 December 2000, noting that this matter had been in the public domain and had not been raised by the Committee.

3.134. The CJD Incident Panel met on 22 – 23 February 2001 **[WITN4505128]**– see in particular paragraphs 69 – 75 of the minutes. The upshot of their consideration of the December 2000 case was that:

"The Panel recognised the importance of providing advice on this matter in a timely manner. It was agreed that a subgroup of relevant experts on the Panel would meet as soon as possible to further discuss this Incident and report back to Mr Lister and the NBA with their advice. The Deputy Chief Medical Officer and the DH were free to provide advice in the meantime without the Panel's comment, but this would not receive the support of the Panel." (§74)

3.135. Professor Banner wrote to Dr Troop following the meeting **[DHSC0006287_098]**. While thanking Dr Troop for sharing the draft interim guidance, Prof Banner stated,

"Members expressed grave reservations over several aspects of your letter as drafted and suggest that you may wish to delay sending the letter until the Panel has had time to develop advice. The Panel considered that it would be unhelpful if messages coming from the Deputy Chief Medical Officer were to be inconsistent with advice from the CJD Incidents Panel. Therefore, the Panel has asked the Secretariat to organise a meeting of a small subgroup of the Panel to provide you with the Panel's advice in as timely a manner as possible, given the resources available to the Panel. The Secretariat is trying to organise a meeting of the subgroup within the next 2 weeks and will keep you informed of progress. I hope this is compatible with your need for urgent action in this instance."

See also my email to Nick Raisen in Pat Troop's office of the same date **[DHSC0020839_037]**

3.136. SEAC held its 65th Meeting on 28 February 2001. I attended for the item on the safety of human blood regarding Fresh Frozen Plasma and minimising vCJD risk (within part 5 of the agenda and minutes, and papers SEAC 65/9 and 65/10)

[WITN4505129] [WITN4505130] [WITN4505131], see in particular paras 5.15 to 5.27 of the minutes. I updated Andre Hare of EOR4 on SEAC's views on the risk assessment of FFP following the meeting **[DHSC0038725_021].**

3.137. On 28 February 2001, Mr Harvey sought advice from the solicitor's division on whether the names of all the current cases of vCJD could be notified to all the regional blood transfusion services **[DHSC0014516].** Howard Robert of Sol C4 provided the advice in response, on 5 March 2001 **[DHSC0004122_048]**. He advised that particular disclosures might - depending on the facts - be defended but a general policy of disclosure without consent would present unacceptable legal risks.

3.138. On 2 March 2001, Lord Hunt's Private Office communicated the Minister's decision on plasma products from other countries with vCJD, to the effect that he was content that the CSM should reconsider all of the evidence in March **[DHSC0032156_054]**.

3.139. On 6 March 2001, I alerted Ministers and our Communications Division to the impending announcement of the Irish Government to ban those who had spent more than 5 years in the UK between 1980 and 1996 from being blood donors as a precautionary measure against vCJD **[WITN4505132]**.

3.140. On 14 March 2001, I provided the lines to take following queries raised by the Guardian about the consideration being given to preventing those who had received blood transfusions from themselves giving blood ***[DHSC0004735_064]***.

3.141. I attended the CJD Incidents Panel subgroup which met on 26 March 2001 **[WITN4505133] [DHSC0020723_087]**. The Panel was presented with a paper which summarised the position to date **[WITN4505134]**.

3.142. The note sets out the full terms of the Panel's advice but in essence, they considered that: (i) any risk of transmission was very low and did not justify

restriction on these individuals donating blood, tissues, organs or requiring special precautions if undergoing surgery; (ii) the names of those who might have received the implicated products should be placed on a database to allow follow up to inform future risk assessment; (iii) those affected had a right to choose whether to know or not. The Panel was still in the process of developing guidelines on the best mechanisms for achieving these objectives and would provide further advice as the guidelines progressed; (iv) some clinicians caring for haemophilia patients had already informed patients without necessarily providing them with the opportunity not to know. This action was not in keeping with the spirit of Panel advice. However, the Panel recognised that this group of patients is exceptional, in their prior experience of exposure to other diseases through their treatment and that such patients were more likely to receive careful counselling from their clinicians than could be expected generally. Nonetheless, the Panel recommended that the UKHCDO and individual clinicians take note of the Panel's advice in dealing with any future incidents that may be reported.

3.143. On 29 March 2001, Dr Hudson of the Medicines Control Agency provided a submission to Dr Jones and Lord Hunt summarising the advice given by the CSM at the meeting of 22 March on plasma products from other countries with vCJD. **[DHNI0000043_010]**. As regards the Factor IX product Betafact/Novofact, the recommendation was for Ministers to instruct MCA to seek the companies' agreement voluntarily to remove it from the UK market, failing which it should be referred to the CPMP.

3.144. On 3 April 2001, I put a submission to Lord Hunt seeking the Minister's decision on whether to seek to appeal the decision of the High Court in the Hepatitis C Litigation (A & Others v National Blood Authority and another) **[WITN4505135]**. The liability implications regarding any patients infected with vCJD, if it could be shown that the illness was transmitted via blood or blood products, was one of a significant number of factors to which I referred in this submission.

3.145. On 12 April 2001, I was copied in to a minute from Michael Adam (Sol C5) to Dr Hudson of the MCA, concerning a letter from a member of the public who had asked, in terms, whether they had received pooled plasma that contained a donation from a donor who went on to be diagnosed with vCJD. **[DHSC0020811_295]**.

3.146. The risk assessment in relation to Fresh Frozen Plasma was further considered at the MSBT meeting on 19 April 2001 **[WITN4505136]**. The conclusion was that members of the committee agreed that:

> *"(i) there were sufficient grounds on a precautionary basis to look at the feasibility of a switch to US plasma;*
>
> *(ii) if there was to be a switch to US sourced FFP:*
>
> *(a) Members had a clear preference for using single unit voluntary donated, MB treated plasma. If supplies were limited, this should be used for neonates and children;*
>
> *(b) Members would need to have confidence in the processes for viral inactivation;*
>
> *(c) Members would not favour using pooled solvent detergent treated FFP unless a 2nd viral inactivation step could be incorporated to deal with non lipid viruses;*
>
> *(iii) there was a need for a wider scoping exercise addressing safety, supply (need for sustained alternative provision) and logistics;*
>
> *(iv) the issue should be brought back to MSBT for a special meeting in April."*

3.147. On 30 April 2001, Dr McGovern minuted the CMO on the ongoing work to follow up the 'Better Blood Transfusion' initiative **[WITN4505137]**. He noted that all the work on risk assessment relating to the unknown contribution of blood transfusion to the transmission of vCJD has emphasised that the better use of blood and avoiding its use are important risk reduction measures. See also in this regard my submission of 1 May 2001 **[WITN4505138]**.

3.148. Work was ongoing on Dr Troop's amended letter, giving interim guidance which went through a number of drafts, see e.g. the May 2001 draft at **[WITN4505139]**, my email to John Farrell of MPI of 18 May **[WITN4505140]** and Dr Robinson's input of the same date **[NHBT0001122_001].**

3.149. On 7 May 2001, I was one of several officials asked to contribute to the response to the EU Health Working Group's draft Council conclusions on the epidemiological situation of vCJD and the need for a proactive strategy on TSEs and other zoonoses **[WITN4505141].** See further Mr Harvey's briefing of 31 May 2001, which addressed Fresh Frozen Plasma at §8*ff* of the background note **[WITN4505142]**.

3.150. On 22 May 2001, Dr McGovern provided Dr Troop with a briefing for her meeting the following day, with Martin Gorham and Dr Robinson of the NBA to discuss the implications of vCJD for the NBA **[DHSC0042292_092].**

3.151. On 25 May 2001, Karin Pappenheim of the Haemophilia Society wrote to Dr Edwards, referring to the recent identification of a plasma donor with vCJD and asking to be kept in touch with the work of the CJD Incidents Panel. She added:

> *"We have been in discussion with Charles Lister, your colleague at the dept, on ways of improving the response in future should further vCJD donors be identified."* **[DHSC0038590_120]**

3.152. The CJD Incidents Panel met again on 4 June 2001 **[DHSC0004189_021]**. Following this meeting, a sub-group was established (under Professor Dame Lesley Southgate) to consider blood-related aspects of the draft framework document. This would give advice to healthcare professionals on the actions to take when a patient who has undergone a medical intervention is subsequently diagnosed as a CJD case.

3.153. On 8 June 2001, Mr Harvey minuted Dr Troop on the meeting scheduled for 12 June 2001 with the Chairs of SEAC, the ACDP/SEAC joint working group, and of the CJD Incidents Panel **[WITN4505143]**. The background was Professor

Banner's earlier unhappiness about his panel not being consulted and tensions concerning the division of responsibilities between the committees.

3.154. The MSBT met again on 11 June 2001 [**NHBT0002411_003**]. I was not in attendance. Fresh Frozen Plasma was discussed at agenda item 3; exclusion of transfusion recipients was discussed at item 5 of the agenda; the CJD Incidents Panel draft framework document was addressed at item 6 of the agenda.

3.155. In early July 2001, there was publicity surrounding the prospects for a diagnostic test for vCJD. Dr Robinson of the NBA was to give an interview contribution. I alerted the Chief Medical Officer's office to the interview and the likely issues [**WITN4505144**]. I also emailed the DH Communications Division on 4 July noting that:

> *"I've decided not to copy round the NBA brief, prepared by their press office, because it was frankly poor and over defensive. However, I've talked through the key messages with Angela Robinson who is pretty clear about what needs to be said - being open about the unknowns on vCJD & blood; the need to validate any screening test; the importance of contingency planning (e.g. around the potential impact of a screening test on the blood supply and the provision of information to donors) and the need to reduce blood usage and promote autologous blood/synthetic alternatives."* [**WITN4505144**]

3.156. On 18 July 2001, in the context of preparing a briefing to Yvette Cooper on a possible compensation scheme for haemophiliacs with HCV, I sought information for comparison purposes, of the proposed payments to those who had been infected with vCJD [**WITN4505145**].

3.157. On 23 July 2001, I noted that the increasing cost of US plasma (now necessary for BPL's production as a precaution against vCJD) remained a significant budgetary pressure for the 2001/2002 year but that costs for importation of

fresh frozen plasma would not be needed until the middle of 2002/03 **[DHSC0006253_018]**.

3.158. On 24 July 2001, Dr Philippa Edwards suggested that it may be appropriate to remove the risk assessment for plasma derivatives in the CJD Incident Panel framework document (and to defer discussion with patient groups) until more work had been done on the risk assessment **[DHSC0006287_062]**.

3.159. The sub-group to consider the management of incidents involving Blood and Blood Products chaired by Professor Southgate met on 2 August 2001 **[DHSC0033680] [DHSC0020723_066]**. The group endorsed the Panel's suggestion that an expert group be convened to draft a risk assessment for plasma derivatives. The actions arising were summarised as:

- The risk assessment for blood components and plasma derivatives should be developed further.
- Until this risk assessment was available, the Panel would need to make pragmatic decisions regarding the current incidents awaiting advice, adopting a precautionary approach.
- The draft framework document should be amended to include areas where the Panel was particularly concerned, highlighting that some of the concerns were due to the lack of relevant data
- The secretariat would arrange a further meeting (a subgroup of the current attendees) to further discuss the management of incidents involving blood and blood products, paying particular attention to contacting/ identifying recipients.

3.160. On 3 August 2001, we were informed of a further, strongly suspected, case of vCJD in a person who had a history of blood donation within the last 5 years **[NHBT0046501_003]**. I gave advice on the immediate handling, the same day **[DHSC0004344_061]**.

3.161. On 6 August 2001, Alan Harvey put a submission to Dr Troop on the CJD Incidents Panel's consideration of blood and plasma derivatives

[**WITN4505146**]. Mr Harvey's minute explained both the position reached on risk assessment of blood components/plasma derivatives and the recent suspected vCJD case:

"A precautionary line on blood

6 The Panel have been deciding in which category to place those who have received contaminated blood components/plasma derivatives, As you know, they took into account a 1998 DNV risk assessment analysis, together with some further explanations from Pip Edwards, Based on this, they recently concluded that the blood recipients of blood components and certain plasma derivatives should fall into the highest risk group and therefore "contacted", But, as you will recall from our meeting last week, all this has yet to happen. This is because Pip believes the Panel may have misunderstood some of the RA assumptions In coming to their conclusions on plasma derivatives, some errors in her own explanatory text, and new data which have led experts in the field to question some of the assumptions. We agreed last week that as a matter of urgency, the risk assessment findings need to be reworked and an expert group convened. This will nonetheless take a couple of months. Pip's view is that the findings are likely to show a reduced category of risk for recipients of plasma derivatives but no change in the category of risk for recipients of blood components.

7 In the meantime, Professor Banner is insisting that a precautionary approach should apply. He, with support from others on the Panel, argues that those who have received the contaminated blood components/plasma derivatives hitherto should be treated as high risk and contacted forthwith, notwithstanding the uncertainty. He doesn't want to wait for the reworking of the RA to establish a more informed position on the plasma derivatives.

Possible MCA product recall

8 Following an incident, contaminated blood components - with a very short shelf life - In practice would not be able to be recalled. But plasma derivatives are medicinal products and subject to special 24 hour emergency procedures under the Medicines Act As you know, there has already been one incident involving plasma derivative product recall. You will be aware that this gave rise to inconsistent lines being taken by clinicians with regard to informing patients. The Panel is concerned to ensure we do things better next time

9 You need to be aware that a possible further potential Incident Is, right now, under active Investigation. There is some confusion about the spelling of the surname of a donor who then went on to develop vCJD, which is still being sorted out (it may be that no donation ever took place). Should it be confirmed as an incident, once again the MCA may need to invoke their procedures to recall unused products."

3.162. Mr Harvey set out two options on the proposed way ahead. The first would involve: (i) setting up a mechanism for counselling, (ii) seeking PHLS assistance, (iii) being ready to provide copies of the Panel's draft decision-making framework to clinicians directly involved in individual cases, and (iv) arranging to meet representatives of the Primary Immunodeficiency Association and the Haemophilia Society, followed by letters being issued from Professor Banner triggering the contacting of all implicated individuals. The second option was to hold off on (iv) and press the case for waiting for the reworked risk assessment to be done. It was noted that Prof Banner had been 'unmoved' by arguments on the merits of awaiting the further risk assessment and Mr Harvey sought Dr Troop's agreement to the first option.

3.163. In the event, checks revealed that the new vCJD victim had not in fact been a blood donor (see Patricia Hewitt's email of 5 September 2001) [**DHSC0004434_115**].

3.164. On 21 August 2001, Mr Harvey provided a submission to Dr Troop and Lord Hunt on the CJD Incidents Panel's proposed public consultation on its framework documents [**WITN4505147**]. The latest draft of the framework document was annex A to that submission. Stephen Waring (PS/SofS) provided Mr Harvey with the views of the Secretary of State on this submission, on 29 August 2001 [**DHSC0006340_021**].

3.165. On 22 August 2001, Peter Garwood from the National Blood Service provided me with a note on the availability/cost of US plasma for FFP [**NHBT0061053**]. I would have requested this to inform my bid for the spending review. Peter followed this up with a further email on 23 September 2001 [**WITN4505148**].

3.166. On 24 August 2001, I put a submission to the Secretary of State with proposals to secure supplies of US plasma for fractionated blood products as a result of severe market pressures [**DHSC0008129**]. This ultimately led to the decision to acquire the US company; Life Resources Incorporated (Project Red).

3.167. On 31 August 2001, I raised concerns about a proposed amendment to the EU Blood Directive which was aimed at ensuring that any products imported from outside the EU came only from non-remunerated donors [**DHSC0038658_069**]. While the UK supported the principle of voluntary blood donation, the practical implication of a ban on the importation of products from remunerated donors would be to prevent the import of US plasma. UK production (and by extension the treatment of UK patients) now largely depended upon this, given the precautions taken against vCJD. I then put a submission to Mr Hutton, the Minister of State, seeking his agreement to a draft briefing for Catherine Styler (the Labour Link MEP) to seek to ensure effective opposition to this proposed amendment [**DHSC0004284_018**]. Mr Hutton agreed the briefing and it was sent by Jonathan Orr (International Business and Communications Unit Manager) [**DHSC0038658_033, DHSC0038658_046**]. See also Jonathan's email to me of 5 September 2001 [**DHSC0038658_039**].

3.168. On 7 September 2001, Mr Harvey provided the Secretary of State with responses to the queries he had raised on the CJD Incidents Panel's proposed public consultation **[WITN4505149]** and the Secretary of State responded through his Private Secretary on 13 September 2001 **[WITN4505150]**. Lord Hunt then raised further queries (17 September) to which Mr Harvey replied on 21 September 2001 **[WITN4505151]**. I remained one of many officials copied into these exchanges.

3.169. On 20 September 2001, I emailed Dr Troop with a draft submission to Ministers on the CJD Incident Panel's interim advice on the management of blood / blood products incidents (covering minute **[DHSC0038590_079]**, draft submission **[DHSC0038590_080]**). I was anxious to get a quick response from Ministers ahead of a meeting we had arranged between Michael Banner and Don Jefferies, UKHDO, the Haemophilia Society and the Primary Immune Deficiency Association to explain the reasons for the advice and to discuss handling. Unfortunately, DHSC have been unable to find the final submission and, if sent, a response from Lord Hunt.

3.170. On 26 September 2001, I alerted Dr Troop (ahead of a meeting with the NBA) to the NBA's proposal to switch to US-sourced Fresh Frozen Plasma for neonates, children and selected adult patients **[DHSC0042292_054]**.

3.171. On 27 September 2001, I chaired a meeting to discuss the Management of Incidents involving CJD and Blood Donations, which was the meeting planned to permit the CJD Incidents Panel (Professor Banner and Professor Jeffries with Dr Edwards as Secretariat), to explain and update on their proposed approach to (amongst others) the Haemophilia Society, the UKHCDO and the Primary Immunodeficiency Association **[WITN4505152; DHSC0006287_002]**.

3.172. On 30 September 2001, the compensation scheme for vCJD victims was announced **[WITN4505153]**.

3.173. On 5 October 2001, Alan Harvey provided a submission to the CMO on CJD expert support, for clinicians providing information and advice to patients who have been put at possible risk of CJD from medical interventions [**DHSC0006304_002**]. The proposal was for such support to be made available enlisting the support of the London Prion Unit, the National CJD Surveillance Unit, and the PHLS. This had been discussed at the meeting of 27 September with the patient groups.

3.174. The CJD Incidents Panel consultation document was launched at a press conference on 10 October 2001, and the Panel met again on 18 October 2001, although I was unable to attend this particular meeting [**WITN4505154**]. Amongst other areas discussed, the Panel decided against the suggestion that letters to potentially affected patients should not be issued until after the revised blood risk assessment had been completed.

3.175. The MSBT met again on 22 October 2001 [**WITN4505155**] with vCJD issues featuring extensively (see the matters discussed at Items 3; 5; 6; 7; 8; and 11).

3.176. On 26 October 2001, I was involved in representations concerning the draft Blood Directive for which proposed compromise wording was to be discussed by the Committee of Permanent Representatives, [**DHSC0041366_073 and DHSC0041366_064**]. The issue was again ensuring that the wording of the Directive on unpaid blood donations did not cause harmful disruption to the supply of plasma products to UK patients, given that UK production was now dependent upon the import of US plasma as a vCJD precaution. We had pursued a primary position that a requirement on non-paid blood donations fell outside the Commission's area of competence (Cabinet Office Legal Advisers eventually disagreed with this position), failing which it was important that the compromise wording would permit the continued use of imported US plasma. I put a submission to Hazel Blears on the same day, 26 October **[WITN4505156].** Political agreement was reached on 15 November around a text that did not prevent the UK importing US plasma from paid for donations.

3.177. The Department hosted the Better Blood Transfusion Conference on 29 October 2001, and Jill Taylor provided a briefing to Mr Hutton who was to give the closing speech **[WITN4505157].** The background briefing noted that better blood transfusion is an essential underlying part of the vCJD risk reduction strategy which up to now includes making all therapeutic blood products from imported plasma (from the USA) and leucodepletion (removal of the white cells) of the blood supply.

3.178. On 30 October 2001, the CMO sent a response to Dr Wardle's letter, see paragraph 3.131 above **[DHSC0032258_050]**. Although Dr Robinson had sent an earlier response on behalf of the NBA, there was a significant delay in providing this reply. The records suggest that the letter had unfortunately been with me and my team for a significant period before I had sought input from Dr Edwards, and the CMO's Private Office understandably criticised the length of time we had taken to produce a draft response **[DHSC0006838_067, DHSC0006838_068, WITN4505158]**

3.179. On 7 November 2001, I received a further paper from the NBS (Peter Garwood) on their proposals for US plasma derived FFP for neonates, children, and selected adult patients **[WITN4505159].**

3.180. On 15 November 2001, I was one of those copied into a submission from Peter Jones to Dr Troop on the handling of diagnostic tests for CJD/vCJD **[DHSC0004102_027]**.

3.181. On 20 November 2001, I provided briefing for the CMO, following an article in the Sunday Mirror, '21 ex-patients have CJD blood but don't know' **[WITN4505160]**. I included these lines to take:

> ***"How many haemophiliacs have received implicated clotting factors?***

We do not have this information. All haemophilia patients who received these products have been identified by their local Haemophilia Centres but we have not asked to see this information centrally.

Some haemophiliacs who received vCJD implicated products are being denied surgery/dentistry. What advice are you giving to clinicians?

We are looking to the CJD Incidents Panel to provide advice on these issues. The Panel is currently undertaking a consultation exercise on a proposed framework which sets out the basis for the advice that will be given in cases such as this. Furthermore, in order to assist the Panel with its work, the Department of Health has commissioned an update of the assessment of the risks associated with treatment with products derived from blood donations from individuals who later develop variant CJD, In the meantime, the Panel is providing advice on a precautionary basis and we would urge any clinician or dentist who Is uncertain about the action they should be taking to contact the Panel for advice.

Briefing was also provided for Hazel Blears for an adjournment debate on the same day **[WITN4505161]**.

3.182. There was also publicity at this time alleging a crisis in blood supply based on fears that donors would stop donating blood if they were to be told if they had CJD/vCJD. There was not in fact a crisis of blood supply at this time and the story appeared to be based on a misunderstanding of the scenario planning undertaken by the NBA should a screening test become available. See in this regard, the press articles of 25 November 2001 at **[WITN4505162]**, my email to Mr Hutton's Private office of 26 November 2001 **[DHSC0004735_045]** and the briefing for Prime Minister's Questions, 27 November 2001 **[WITN4505163]**.

3.183. On 3 December 2001, there was the first meeting of the CMO's National Blood Transfusion Committee Chaired by Prof Gordon-Smith **[WITN4505164]**. I was one of two attendees for the Department. The move towards the use of US

source FFP for young children was discussed as was the CJD Incidents Panel's Consultation Document.

vCJD developments in 2002

3.184. On 4 January 2002, Professor Will of the CJDSU updated me that of the recipients of potentially contaminated vCJD labile blood components, 9 had died and 13 were alive, with no indication from death certification that any of the deaths were related to vCJD **[WITN4505165]**.

3.185. On 29 January 2002, I sent a briefing to Prime Minister's Questions to cover publicity indicating that the 22 recipients of transfused blood from donors who went on to develop vCJD were to be informed that they may have been infected **[DHSC0032156_034]**. The briefing noted that:

> *"Government policy has been that people potentially exposed to vCJD via blood should not be informed as there is currently no diagnostic test available for vCJD and no treatment for the disease. This has shifted towards giving people the right to choose whether to be told. The Panel are going a stage further by recommending that some people – including the 10 surviving transfusion recipients - should be told regardless of their wishes as they may represent a public health risk to others (e.g. if they give blood).*
>
> *A decision on whether to accept the Panel's recommendations will be taken in the light of the responses to consultation which are still being assessed.*" **[WITN4505166]**
>
> There was an additional briefing which followed on 30 January 2002 **[DHSC0046909_085]**.

3.186. There was a further meeting of the MSBT on 30 January 2002 **[WITN4505167]** with the matters discussed at Items 4 – 7 and 10 being directly relevant to vCJD. This included, at item 4, a presentation by DNV on their risk assessment. DNV's conclusions, according to the minutes **[DHSC0037567]** were:

- It was not possible to make a reliable assessment of the risk from any vCJD infectivity that may be present in the blood of a person incubating the disease.

- There was no evidence to confirm that the blood of a person with CJD or vCJD was infective.

- Evidence from animal models suggested that the blood from an animal infected with a TSE may be infective, albeit at a low level.

- If there was infectivity present in blood at the level suggested by animal models, then the infectivity present in a full unit of red cells, platelets or plasma from an infected donation may be sufficient to cause infection. It noted that this conclusion seemed to be valid across a wide range of assumptions.

- The infectivity levels in certain plasma derivatives if made from a pool containing infected donations may also be able to cause infection. It was noted that this conclusion was highly uncertain and varied significantly with the assumptions made.

3.187. In discussion, members of the Committee, including members of the Incident Panel, expressed disappointment that some of the data used in DNV's paper on Serious Hazards of Transfusion was out of date. There was some discussion about other risk assessments that had been undertaken and the work of the CJD Surveillance Unit which was looking at infectivity in a wide range of tissues including bone marrow. In addition, the DH Economic and Research Division (EOR - Andre Hare and Peter Bennet) were carrying out modelling to predict what proportion of observed cases of vCJD could be through blood consistent with DNV's suggested level of infectivity.

3.188. Ahead of the DNV report going to the Committee on Safety of Medicines and to SEAC in April, a small expert group was established to look at the assumptions in the DNV report and to make comparisons with other risk

assessments and the CJDSU was asked to forward any material that might be helpful. Professor Ironside of the CJDSU was also asked to provide MSBT with data on whether infectivity required one critical dose level or whether it could be cumulative.

3.189. On 1 February 2002, I emailed Dr Troop noting that the publicity around the 22 patients had generated a small number of calls from people asking if they were amongst the recipients. I sought guidance on handling such calls in particular how to handle a caller who turns out to be one of the (at that stage) ten surviving recipients **[DHSC0037567]**.

3.190. On 18 February 2002, I alerted colleagues in PH6 and more broadly in the Department to the fact that the NBS had notified me of a probable new case of a blood donor who had developed vCJD **[DHSC0032156_033]** There were seven donations (mostly issued as red cells but one of red cells and FFP). Because the switch had been made to using US plasma, blood products were not an issue. The Incidents Panel were shortly to be informed (it became incident PI 105). I updated Dr Troop on 28 February 2002 **[DHSC0032156_028].** There were exchanges on how to respond to these cases given that the arrangements were not yet in place to ensure that clinicians had the appropriate access to information and support for their patients, see for example **[DHSC0038507_060] [DHSC0038652_166]**.

3.191. On 1 March 2002, Olivier Evans (a civil servant in my team on the European fast-stream) provided a submission to Yvette Cooper seeking her approval for a briefing pack for UK MEPs on the text of the Blood Directive which by this stage had been reached at Common Position and ratified by Jurist-Linguists **[WITN4505168]**. The text that had been adopted in Common Position would allow the UK to continue to import plasma from the USA as a vCJD risk reduction measure until a screening test was developed, however it was noted that any changes to the agreed text could potentially reduce the safety protection currently in place to address the theoretical risk of vCJD through blood products. See also the updating submission from Emma O'Sullivan of 25

March 2002 **[WITN4505169]** and the UK Permanent Representation to the EU to me of 24 May 2002 **[DHSC0046086_067]** and 6 June 2002 **[DHSC0046086_065]**.

3.192. On 8 March 2002, I was copied into the email from Dr Edwards (on behalf of Professor Banner) to Dr Ludlum, commenting on Dr Ludlum's draft communication to Scottish patients affected by potential exposure from donors who had gone on to develop vCJD **[DHNI0000049_019].**

3.193. The Second Meeting of the CMO's National Blood Transfusion Committee took place on 11 March 2002, although I was not able to attend the meeting **[WITN4505170]**, FFP and engagement with the work of the CJD Incidents Panel were both addressed.

3.194. The CJD Incidents Panel met again on 17 April, including an open meeting in the afternoon **[DHSC0020839_075] [WITN4505171]**. In the morning meeting, on blood, the updated position on the further risk assessment by Det Norske Veritas was noted. Dr Troop had written in reply to the Panel's concern about adequate support systems needing to be in place before individuals were informed, and it was noted that the Department was actively considering how this could be provided as well as looking at the scope for hospitals to trace products. The NBS wanted clarification on what action it should take given the earlier DH advice not to inform recipients and the Panel's advice that some of the patients would fall into the 'contactable' group. There was further reference to the need for adequate long term support for all patients as well as training and support for the clinicians involved. Professor Gordon Smith of the CMO's National Blood Transfusion Committee was to be approached for advice and the Incidents Panel strengthened by someone with expertise in the consequences of providing worrying information.

3.195. On 22 May 2002, Dr Edwards consulted me and others on a draft reply to Karin Pappenheim of the Haemophilia Society who was seeking an update on the

blood risk assessment being conducted by DNV [**WITN4505172 and DHSC0038590_011**].

3.196. On 28 May 2002, I was copied into Dr Edwards' update to Professor Banner on incident PI 105 [**DHSC0006838_004].**

3.197. On 14 June 2002, Olivier Evans provided a further submission to Yvette Cooper on the Blood Directive [**WITN4505172A**]. By this stage, it was not considered that the proposed amendments would jeopardise the UK's ongoing ability to use imported US plasma as a vCJD risk reduction measure (see the comments on the proposed amendment 20).

3.198. On 17 June 2002, I emailed Dr Vicki King regarding our decision not to take part in a visit to Octapharma's plant in Vienna (NBS members were attending). I saw no need for DH attendance given that NBS were attending and I set out a summary of the position on their product Octaplas [**DHSC0004575_078**].

3.199. MSBT met on 25 June 2002, and I attended this meeting as one of seven DH observers. The draft minutes are at [**WITN4505172B**]. DNV's risk assessment of vCJD infectivity in blood was discussed at agenda item 5; vCJD transmission through blood components (reconciling modelled risks) was discussed at item 6 on the agenda; the option of excluding transfusion recipients from being blood donors was discussed at item 7and the Blood Directive was addressed at item 9. DHSC searches have been unable to locate the final minutes of this meeting.

3.200. Against the background of PQs that had been tabled by Baroness Masham [**WITN4505173**], on 8 July 2002, I asked Charles Dobson and Peter Burgin of the MPI Division whether NICE would be likely to look at recommendations to the NHS on whether to use NBS UK sourced FFP or Octoplas **[DHSC0020875_079].**

3.201. I attended the NBA accountability review meeting on 10 July 2002, which was chaired by Professor Linsey Davies [**WITN4505174**]. NBA's vCJD risk reduction measures were addressed under the heading "Health Improvement/Outcomes".

3.202. On 18 July 2002, I put a submission to Mary O'Mahony and Dr Troop on FFP [**DHSC0020875_053**]. I set out the issue and recommendation as follows:

"Issue

1. We have some potential handling difficulties around our policy on FFP brought into focus by the introduction this month by NBS of methylene blue treatment of FFP for neonates and children born after 1 January 1996. As the rationale for choosing this date relates to vCJD, this raises a number of questions which are difficult to answer in the absence of a decision to import US FFP for this age group

2. This position is exacerbated by:

• recent PQs and correspondence questioning our continued use of non-virally inactivated UK sourced plasma;

• the same challenge from Octapharma who produce a commercially available solvent detergent treated, pooled FFP made from US plasma but at a significantly higher cost than NBS FFP. As well as lobbying MPs and clinicians, Octapharma are mounting legal challenges, arguing that (a) the pricing policy on NBS FFP is anti-competitive (ongoing for the past four years and currently with the European Commission) and (b) that NHS purchasing policy for FFP breaks European procurement rules (a new challenge on which SOL are obtaining Counsel's advice).

Recommendation

3. To invite Ministers to agree that NBS should begin the process immediately of importing US FFP for neonates and children born after 1 January 1996 (the lead in time is 6-9 months). This is on the grounds that:

• we would be hard placed to defend a decision not to adopt this precautionary measure for this particularly vulnerable group given the outcome of the risk assessment, the cost/benefits analysis and the feasibility study. Therefore, if we are going to have to do it at some point, it may be wise to reduce the risk of future criticism by going ahead now.
• the introduction of MB treatment for this age group does not make sense without the decision to import from the US.

These two points are developed further below. I am also arguing that we can be confident of finding the funding for the relatively low cost of this initiative - £700K in 2003/04 - from whatever is made available for blood in the SR, even if there is nothing specifically earmarked for FFP. Lack of identified funding for this initiative should not, I feel, be a reason at this stage for delaying a decision any further."

3.203. In conclusion, I asked if Mary O'Mahony and Dr Troop were content for us to go to Ministers straight away recommending that NBS are instructed immediately to begin the process of importing US FFP for neonates and children born after 1 January 1996.

3.204. I was then able to put a submission to Hazel Blears and Dr Troop on this issue, see my submission of 25 July 2002 **[WITN4505175]**. I sought the Minister's decision as to whether she was content for officials to instruct NBS to start the process of importing US FPP for neonates and children born after 1 January 1996, and for a press statement to be issued.

3.205. I was copied into a minute of 1 August 2002 from the Solicitor's Division on initial advice that had been obtained from Counsel on Octapharma's complaint **[DHSC0044209_080]**. On the same day I updated Dr King on the position of other European countries, the US and Canada in terms of their use of untreated FFP [**DHSC0004575_027; DHSC0004575_028**].

3.206. On 6 August 2002, Ms Blears' Private Secretary responded to my submission on FFP noting that:

> *"The Minister has now seen your submission on FFP. She is generally content for you to go ahead with securing this from the US and for using it in children born after 1 Jan 1996. She has however raised a couple of queries, and is I think wary of press releasing this decision at this stage.*
>
> *Her questions are a) what is the status of the recent research? b) is FFP from unpaid donors? and c) would a press release highlight the position of other groups? It would be helpful to address these concerns in due course."* **[DHSC0017728]**

3.207. On 8 August 2002, Dr King provided a response to Ms Blears in a brief further submission **[WITN4505176]**. The Minister had some further questions (they are evident from the handwritten annotations on the submission) and these were addressed in an email from Dr King to the Minister's Private Secretary on 13 August 2002 **[WITN4505177]**.

3.208. Ms Blears then made the public announcement on FFP on 15 August 2002 **[WITN4505178]**. This stated that NBS would be importing FFP from the United States for new born babies and children born after 1 January 1996 as an added precaution against the theoretical risk of vCJD transmission. The FFP would be in single units rather than pooled and would be sourced from unpaid donors. There would be further treatment to reduce the risk of transmission of viruses by Methylene Blue viral inactivation.

3.209. On 30 August 2002, there was notification of a further probable case of a blood donor who had gone on to develop vCJD **[WITN4505179]**.

3.210. On 6 September 2002, Dr Edwards emailed Dr Troop to provide an update to assist in the response to the complaint from Haemophilia Directors that they

had had to wait too long for advice from the CJD Incidents Panel on the risks of transmission of vCJD through plasma derivatives **[DHSC0038507_037]**.

3.211. On 9 September 2002, I provided the Secretary of State with a draft response to a constituent of Liam Fox MP concerning viral infection from FFP. This was another response which had regrettably been long overdue, for which I undertook to write to apologise [**DHSC0006564_147**]. Hazel Blears provided the Ministerial letter of response on 8 October 2002 [**WITN4505180**].

3.212. SEAC's meeting on 11 September 2002, discussed the release to the CJD Incidents Panel of the detailed confidential minutes of SEAC's recent discussion of the blood risk assessment [**DHSC0037352**]. I was copied into a summary of the meeting's main outcomes from the DH point of view.

3.213. On 18 September 2002, I was also copied into a submission from Dr Amal Rushdy to Dr Troop on revision to the name and terms of reference of the MSBT, and setting up a subgroup of the committee as a means of obtaining advice in relation to cells, tissues and organs as an interim arrangement [**WITN4505181**]. Part of the recommendation on membership was to strengthen the committee by adding expertise in Transmissible Spongiform Encephalopathies, and cross-representation from other relevant committees such as SEAC and the vCJD Incidents Panel. Previously, such expertise has been invited externally.

3.214. On 30 September 2002, Professor Gordon-Smith chaired the third meeting of the CMO's National Blood Transfusion Committee; I was one of the attendees [**DHSC0038552_082**]. Recommendations on the type of FFP were discussed extensively. We have only been able to locate the draft minutes. The Chairman,

> *"….agreed to draft specific recommendations on behalf of the NBTC to present to the MSBT at its meeting on 22nd October 2002.*
>
> *These recommendations will take into account the safety of FFP in relation to risks such as transfusion-transmitted infection including viral*

infection and vCJD, and non-infectious risks such as TRALI. The recommendations will include the following:-

- *the ideal product is single unit viral-inactivated plasma sourced from male, untransfused donors from the United States (but this is not available)*
- *the second best product is pooled solvent-detergent treated sourced from the United States*
- *in the event that there are insufficient supplies of these products, UK sourced viral-inactivated plasma from male, untransfused donors would be next best, and could be used for patients over the age of 60 years"*

I reported on this discussion to Dr King the same day, **[DHSC0038552_099; DHSC0038552_101]** noting that some aspects of these recommendations would go against the views of the MSBT.

3.215. On 3 October 2002, I was copied into a submission from Dr Stephenson of the Research and Development Division to Dr Troop on research funding in relation to screening blood donations for vCJD **[DHSC0032156_014]**. Dr Stephenson was in favour of MSBT establishing a working group to advise NBS on designing the protocols and facilities necessary to assess tests to screen blood donations and blood products for CJD. See in this regard, the meeting held later on 19 November 2002 **[WITN4505182]**.

3.216. The MSBT met again on 22 October 2002, chaired on this occasion by Dr King as Dr Troop was unwell; I was one of seven DH observers **[NHBT0034821]**. vCJD transmission through blood components was raised under matters arising at 3.4 in the minutes; FFP was addressed under agenda item 4 with members of the CMO's Blood Transfusion Committee attending for that discussion; the implications of vCJD for blood safety and supply was addressed under agenda item 5; and screening blood donations for vCJD under item 6.

3.217. On 1 November 2002, Dr Edwards and I were copied into a Scottish Health and Community Care Ministerial submission, in which Sandra Falconer advised Scottish Ministers that the Scottish Haemophilia Directors had decided to write to haemophilia patients asking them whether they wished to know if they were exposed to a batch of Factor VIII or Factor IX clotting agent derived from a patient who subsequently developed vCJD **[DHSC0004735_026].**

3.218. On 27 November 2002, in terms of addressing necessary budget cuts, I identified that the budget for further expansion of the use of US-imported FFP was a potential area for a cut **[DHSC0006156_030]**. This was the only cut to the blood budget that I was able to propose for the reasons set out in my email. I cannot, at this distance in time, offer any more detailed explanation, except to note this bid was already scaled back from an original bid of £65m; £82m and £84m **[WITN4505183]** and that I was confident we would be able to meet the Ministerial commitment announced in August 2002. Also this was clearly in the context of defending our other bids which we felt had higher priority, including funding for recombinant clotting factors. In the end, £8.5m was retained for FFP in year three (2004/05) **[WITN4505184]**.

3.219. On 4 December 2002, I provided briefing for Ms Blears ahead of a meeting the following day with the Chair and Chief Executive of the NBA **[WITN4505185]**. Preparations for the vCJD screening test were one of the issues the NBA wished to raise and my briefing covered this, relying on information I had received from Dr Stephenson **[WITN4505185]**. (I note in passing that this briefing covered the letter from Martin Gorham to which I have referred at paragraph 1.16, above).

3.220. On 10 December 2002, I alerted Dr Troop to the concern that the MDA were considering withdrawing the Methylene Blue product used by NBS to virally inactivate FFP for neonates and young children. The concerns centred on the risks involved in the use of Methylene Blue **[WITN4505186]**. Notwithstanding this, my understanding is that Methylene Blue continued to be used beyond the point where I left the blood team in May 2003.

vCJD developments in 2003

3.221. In early January 2003, I was advised of a threatened claim for psychological trauma by a haemophiliac in relation to being told that he had received Factor VIII from plasma donated by an individual who had subsequently gone on to develop vCJD. In an email of 6 January 2003 to Sally Chapman at the NHS Litigation Authority, I noted that:

> *"One factor that may influence any case is that a number of haemophiliacs were given a choice about whether they were given this information - the majority received a letter describing the incident and were given the option of knowing whether they were one of the recipients. Most decided they wanted to be told. In other cases, however, clinicians decided to tell people without offering this choice.*
>
> *For the future you need to be aware that, if Ministers accept the recommendations of the CJD Incidents Panel, more patients will be told that they may have been exposed to increased risk from vCJD. The Panel has recommended (in a consultation document issued in October 2001) that some categories of patients potentially exposed to vCJD through surgical instruments or blood should be informed of this exposure and be told that, as a precautionary measure, they cannot donate blood, organs and tissue and that special arrangements (eg single use instruments) may be needed if they require surgery."* **[WITN4505187]**

3.222. Ms Blears wrote to the General Manager of Octapharma on 21 Jan 2003 **[WITN4505188]**, the letter included clarification about FFP use in the UK, and the use of Methylene Blue treated FFP.

3.223. On 28 January 2003, I provided a further briefing to Ms Blears, because the NBA Chief Executive Martin Gorham had not been able to make the meeting held on 5 December 2002 **[WITN4505189]**.

3.224. On 29 January 2003, we received notification of a probable new case of a blood donor who had gone on to develop vCJD **[WITN4505190]**. This notification (unlike the more recent ones) involved plasma forwarded for fractionation **[WITN4505191]**. I informed BPL that the DH view was that '*... nothing should go public until the CJD Incidents Panel has given its advice, we have agreed what advice to give to patients and we have key groups such as the Haemophilia Soc, the UKHCDO and the PIA signed up to a communications strategy.'* **[WITN4505192]**.

3.225. On 4 February 2003, Rowena Jecock put a submission to the CMO (via his PS Dr Dickson) on whether he wished the CJD Incidents Panel to provide advice to the blood services on the actions to take in cases where a vCJD patient is discovered to have been a recipient, rather than a donor, of blood **[WITN4505193]**. The CJD Incidents Panel met again two days later on 6 February **[WITN4505194]**. Amongst other matters, it was noted that on the risk assessment for blood and plasma derivatives, Professor Southgate's sub-group would be meeting on 10 April 2003 to translate the existing risk assessments, and the uncertainty over which approach is best, into the Panel framework for advice. On the framework document, the Chairman was due to meet the CMO on 14 February 2003. It was noted that the Panel felt handicapped in its work whilst agreement of the document remained pending.

3.226. On 12 February 2003, I was copied into a submission from Mary Holt to the CMO, following up on the CMO's suggestion of a conference / seminar on the ethical and social issues surrounding a diagnostic test for CJD, should such a test become available **[WITN4505195]**.

3.227. The MSBT's vCJD subgroup met for the first time on 17 February 2003 and I attended as part of the Secretariat team **[WITN4505196, WITN4505197].** We had held a meeting with Professor Jeffries to discuss the group ahead of its first meeting **[WITN4505198]**.

3.228. I was copied into emails from Dr Edwards on behalf of the CJD Incidents Panel on 11 and 12 March 2003, regarding the final version of the DNV risk assessment. This was to be considered at the meeting of the sub-group that would be held on 10 April [**WITN4505199, WITN4505200**].

3.229. On 26 March 2003, Martin Gorham wrote to the CMO to express concern about the delay in the provision of definitive advice to the UK Blood Service regarding notification to individuals who have been transfused with blood from donors who have subsequently developed vCJD [**WITN4505201**]. It was noted that the cases had been reported to the Incidents Panel but confirmed advice from the panel was still awaited, one of the outstanding issues being adequate support mechanisms for individuals once notified. We have been unable to trace a response to this letter.

3.230. The CMO's National Blood Transfusion Committee met on 1 April 2003; it was unfortunate that in my absence for which apologies had been sent, no DH member had attended, a matter which was drawn to my attention by the Committee's Secretary [**WITN4505202**]. There was further discussion on the recommendations on the types of FFP and the paper that had been prepared for the MSBT meeting on 22 October 2002. The Committee (excluding NBS members) agreed that its original recommendation on the type of FFP stood. The Chairman indicated that he would make minor changes to the paper prepared for the MSBT and submit it to the CMO with the Committee's Annual Report. It was said that it was clear that users of FFP want clear, unambiguous guidelines on the preparation to be used in different circumstances.

3.231. The MSBT vCJD sub-group met for a second time on 8 April 2003 [**WITN4505203, WITN4505204 and WITN4505205**]. Professor Jeffries chaired the meeting and again attended as part of the Secretariat. I sent an informal read-out to Dr King of the main points of interest for our team [**WITN4505206**]. This noted that the main outcome was that the group considered that they now had enough information on which to base a recommendation to MSBT on the necessary framework for protocols and facilities necessary to assess tests. The

CJD Incidents Panel Ad hoc group on the use of the 2003 DNV blood risk assessment met on 10 April 2003 [**WITN4505207, WITN4505208**]. Professor Jeffries also chaired this meeting and I was one of two DH attendees. The purpose of the meeting as minuted at item 4 was:

"4. … to decide on two issues:

• which method was most appropriate to use for estimating infectivity in blood and blood products

• at what level of risk it would be appropriate to take precautions.

5. The meeting was also asked to consider the proposals in the CJD framework document and suggest if the proposals could be improved.

6. The CJD Incidents Panel would consider the recommendations from this meeting at its next meeting in June. The proposals would then be agreed with the UK Chief Medical Officers before implementation."

On the best method to estimate infectivity in blood, the protein content approach was rejected. The committee consensus was that the other two methods adopted could be equally defended on scientific grounds. The group agreed to use 1% as the threshold figure. Panel members were given time to forward suggestions for improvements to: the mechanisms for acquiring the information required to carry out the assessment required in the Panel's Framework document; the mechanism for identifying patients potentially at risk in the framework document; the mechanism of informing contactable patients; the mechanism for informing the wider group of an incident and giving patients the option to find out about potential exposure; and the mechanism of ensuring precautions are taken to protect public health.

3.232. The MSBT vCJD Subgroup held its third meeting on 16 May 2003, which I again attended in the Secretariat capacity [**WITN4505209**] and [**WITN4505210**].

3.233. In preparation for leaving the team, I provided some informal handover notes for my successor Richard Gutowski. This included notes on the MSBT, CMO's

National Blood Transfusion Committee, the CJD Incidents Panel, the EU Blood Directive, the position on FFP and Recombinant Clotting Factors (see the next section of this statement) [**WITN4505211**].

SECTION 4: RECOMBINANT CLOTTING FACTORS

4.1. I am asked what decisions and actions I took in relation to recombinant Factor VIII and in particular:

(d) The dealings I had with the UKHCDO in this regard.

(e) The dealings I had with blood products licencing authorities in this regard.

(f) The dealings I had with the Chief Medical Officer in this regard.

RECOMBINANT CLOTTING FACTORS: OVERVIEW OF KEY ISSUES

4.2. My involvement with issues concerning recombinant factor products was in my role as Grade 7, and later G6, Head of Blood Policy between October 1998 and May 2003. Securing funding to provide recombinant clotting factors for all haemophilia patients was one of the achievements in this role of which I was most proud.

4.3. In broad outline, on taking up this post, DH's position was that:

- On what were described as humanitarian (rather than effectiveness grounds), the Secretary of State had agreed in February 1998 to the central funding for 1998/1999 of recombinant Factor VIII for new patients and those under 16. This decision recognised that these patients were less likely to have been exposed to infectious agents than older haemophiliacs and would consequently benefit most from recombinant products;
- For patients outside these groups, recombinant Factor VIII could be prescribed if assessed to be the best treatment by their clinicians; it was a matter for the local Health Authorities to assess whether they were prepared to fund such treatment on the basis of cost effectiveness.

4.4. When I joined the blood team, the Haemophilia Society were pressing the case for the NHS in England to fund recombinant clotting factors for all haemophilia patients. By the end of 2000, Scotland, Wales and Northern Ireland announced that all haemophilia patients there would be placed on recombinants. Later on, the Newcastle Haemophilia Centre made the same decision.

4.5. I understood and was personally supportive of the case made by the Haemophilia Society. However, we first needed to address a number of issues:

- *Understanding the volume of product required by patients*. Dr Hill of UKHCDO and Karin Pappenheim of the Haemophilia Society were very helpful in this regard
- *The supply situation*. Our research suggested that there was insufficient product on the market to meet the needs of the NHS immediately. Any introduction of recombinants would therefore have to be phased. This was also complicated by the fact only 3rd generation recombinants, still in development, would be entirely free from human albumin and thus guaranteed to eliminate risks from blood born viruses and the unknown risk from vCJD (2nd generation recombinants were 'albumin light'). We also knew that third generation products were likely to be very expensive.
- *How this would be funded* given that money had been fully allocated in the current spending review period.

4.6. In January 2001, Ministers accepted my recommendation for a phased introduction of recombinant clotting factors for adult haemophilia patients in England over 4-5 years starting in 2002-03. However, I pointed out that this would require some re-prioritisation of funding for 2002/03 and said that a detailed, fully-costed, implementation plan would be needed before final decisions were taken.

4.7. By March 2001, I had established that funding to start the roll out of recombinants in 2002-03 was not available either from health authority allocations or from within the Department. Our only option was therefore to put a bid into the next spending review round (SR 2002) which I did in July 2001.

This was for a three year roll out starting in 2003-04. We were then locked into the SR 2002 process and unable to make an announcement about the availability of funding for recombinants until decisions were made. This finally happened in February 2003.

4.8. This delay was frustrating but it enabled me to lay the ground for the roll out, working with the NHS Purchasing and Supplies Agency (PASA), the Haemophilia Society and the UKHCDO for example. With a three year roll out, with most of the funding made available in year 3, there would be difficult decisions to make on how this would happen in practice, including agreeing a priority order for who would receive the new treatments. I was also open about the fact that we did not know whether the funding allocated would be sufficient, to place all patients on recombinant products by 2005/06 given rising usage and uncertainties around the pricing of third generation products. Any additional funding required from 2006/07 to complete the transition would need to be considered in the context of the next spending review.

4.9. I wanted all decisions taken on how the recombinant money was spent to be made in an open and collaborative way. I therefore established the Recombinant Clotting Factors Working Group, with representatives from the Haemophilia Society, UKHCDO, the RCN Haemophilia Nurses Association, NHS commissioners and PASA to oversee and make decisions on the process. The first meeting was held on 19 March 2003 and was ongoing when I left the blood team in May 2003.

CHRONOLOGY

4.10. Once I was in post, a chronological account of the main aspects of my involvement, based on the records made available to me for the purposes of this statement, is as follows:

Recombinants developments in 1998

4.11. I was copied into a circular dated 12 October 1998 from Dr Christopher Ludlam, Chairman UKHCDO to the other members of its Executive Committee

[**DHSC0006917_050**]. Against a background of anxiety about some purchasers not continuing to fund recombinant Factor VIII (particularly for those under 16) and the prospect of further price increases, Dr Ludlam was seeking views as to which patients currently on recombinant Factor VIII should revert to plasma derived concentrate if the need arose. He attached an earlier letter (of 25 September 2008) which he had written to Dr Winyard, Director Health Services, NHS Executive in this regard [**BART0000986_003**].

4.12. On 3 November 1998, I put a submission up to Baroness Hayman, the Parliamentary Under-Secretary for Health in the Lords on NHS Blood Prices for 1998 – 1999 **[[WITN4505212]**. The purpose of the submission was to alert the Minister to the potential impact on the following year's blood prices of the combined effect of leucodepletion, imported plasma, NAT testing and measures to increase blood donations, and how this would be handled in the announcement of Health Authority allocations to be made the following week. I noted that, from April 1999, the Department would be moving to a system of national prices based on a standard blood commissioning agreement for the main blood components. Although recombinant products were not the focus of this submission, I noted that this increase in blood prices would be coming into effect on top of the cost of the provision of recombinant Factor VIII for new patients and children under 16 which Health Authorities were due to take on from 1999 (they had initially been centrally funded for 1998/1999).

4.13. I note from the UKHCDO meeting minutes of 13 November 1998 [**HCDO0000468**] that I am recorded as having had a discussion with Dr Ludlam in which I indicated my understanding that for those who had started on recombinant treatment as under-16s, funding should continue for that treatment after they had turned 16.

4.14. On 30 November 1998, Dr Mike McGovern put a submission to Baroness Hayman on Haemophilia B, Factor IX supplies and Recombinant Factor IX. The submission was copied to the offices of the Secretary of State (Frank Dobson) and Minister of State for Public Health (Tessa Jowell), as well as Senior Officials

and others directly involved, myself included **[WITN4505213]**. The advice section of Dr McGovern's submission stated as follows:

> *"We recommend that recombinant Factor IX be used for new patients with Haemophilia B and those under 16 years of age as is the case for haemophilia A following Secretary of State's decision earlier this year. As treatment with recombinant Factor VIII was centrally funded for 1998/99 this should also apply to recombinant factor IX. However, given the much smaller sums involved (between *5k and 12.5k on average per Health Authority for the rest of the year) and the fact that no central provision has been made for recombinant factor IX the financial effects would be more easily and more appropriately managed if Health Authorities were asked to meet the costs from their existing allocations. For 1999/2000 Health Authorities have been asked to fund recombinant Factor VIII for new patients and those under 16 from their central allocations and this should apply to recombinant factor IX also."*

Dr McGovern suggested that the Department should communicate in these terms with the Health Service, Haemophilia Society and the UKHCDO and also publicise it in the CMO's proposed letter to clinicians about treatment with UK and non-UK derived blood products. Baroness Hayman's Private Office conveyed the Minister's agreement to this course on 7 December 2008 **[WITN4505214]**.

4.15. On 23 December 1998, Dr McGovern wrote in reply to Dr Ludlam on both Factor VIII and Factor IX ('*Issues raised in your recent letters to Frank Dobson and Graham Winyard*') **[WITN4505215]**. On recombinant IX, he reported that Ministers had agreed that recombinant factor IX should be provided on the same basis as recombinant factor VIII, once it had received marketing authorisation. On continuation of treatment, Dr McGovern noted that the central funding was for 1998/9 only but that DH would expect those started on recombinant Factor VIII as a result of the policy statement to continue to receive it as clinically appropriate. Dr McGovern further addressed the position of management of patients on recombinant Factor VIII who develop antibodies;

management of brothers one falling within and one falling outside the policy; and recombinant Factor VIII treatment for those within the new policy guidance but who were already on recombinant treatment **[WITN4505215]**.

Recombinants developments in 1999

4.16. On 4 January 1999, Dr McGovern provided a background note for Baroness Hayman about the management of people with haemophilia A, treatment with recombinant Factor VIII and HCV, following correspondence from Barbara Roache MP **[DHSC0041158_182]**. The note explained the then current policy on the funding of recombinant Factor VIII treatment and the justification for it. It explained that the funding of recombinant Factor VIII treatment for new patients and those under 16 had been on humanitarian rather than effectiveness grounds. Addressing the argument that recombinant Factor VIII should be made available for all those with haemophilia A, Dr McGovern stated,

> *"There are three issues -clinical effectiveness, availability and cost. Clinical effectiveness: quite simply, no study to date has demonstrated that recombinant factor VIII is good value and this is the Department's current position. This is likely to change when/if prices fall. Availability: the product is made by Baxter laboratories and demand currently outstrips supply. There is not enough of the currently licensed recombinant factor VIII to support treatment of those under 16 and new patients. Other second and third generation products are under development and it is likely that the companies are depending on unsatisfied demand for the Baxter product to drive sales of these ever newer and more expensive products. Cost: the likely extra cost of providing recombinant factor VIII to all people in England with haemophilia A would be in the order of £50 million pa, bringing the average total cost of treatment alone for these 2,000 patients to £77-80 million pa."* (Original emphasis).

On local negotiation on treatment, Dr McGovern set out that:

> *"Barbara Roache's constituent's son's age is 22 and he is hepatitis C positive. From the framing of the letter it would appear to me that the*

family have already discussed the issue with the treating clinician. The words used 'cost effectiveness' quite clearly indicate that they have been advised that recombinant factor VIII in this case is not an option on the basis of clinical benefit. Clearly the mother thinks differently. However just because the Secretary of State or the Department do not support a policy that recombinant factor VIII be provided for all patients does not mean that clinicians cannot prescribe it or Health authorities should not pay for it. As indicated already many health Authorities do just this. This was the basis for the advice to the family to discuss the situation with the local haemophilia director again. However the main issue remains that the evidence that recombinant factor VIII is more effective than plasma derived has not been forthcoming. Those providing care have to do so in the context of local need. Affordability unfortunately is part of this consideration especially in areas of high cost treatments. This is the [kind] of area which NICE will address when this is set up later this year."

4.17. On 4 January 1999, Dr McGovern minuted Dr Sheila Adam regarding the planned Health Services Circular on Recombinant Factor IX with a draft of the circular [**WITN4505216**]. On 22 January 1999, Health Services Circular HSC 1999/006 on Recombinant Factor IX was then issued to the Chief Executives of all Health Authorities and NHS Trusts in England [**DHSC0004591_076**]. The summary explained that,

"Recombinant factor IX will be licensed in January 1999. This will allow its prescription for children under the age of sixteen and for new patients, in line with policy for recombinant factor VIII set out in HSC 1998/033. The move to using recombinant factor IX in these patients will result in small in-year cost pressures for Health Authorities and NHS Trusts. From April 1999 the cost of recombinant factor IX should be met from general allocations."

The circular required Health Authorities and NHS Trusts with Haemophilia Centres to ensure that "policy on providing recombinant Factor IX, when it becomes available later this year, is the same as for recombinant Factor XIII.

4.18. Various minutes and emails in January 1999 addressed an issue I had raised concerning the potential need for a call on additional money for recombinant Factor VIII treatment because the central funding costs for 1998/1999 would exceed the £2.6 million originally forecast. The HA claims totalled £7.5 million. **[WITN4505217]; [WITN4505218]; [WITN4505219]; [WITN4505220]; [DHSC0006917_049; WITN4505221]**.

4.19. On 12 February 1999, Dr McGovern supported by me and Julia Gale were the Health Service Directorate attendees at a meeting to review UK Blood Products manufacture. The meeting was chaired by David Hewlett **[WITN4505222]**. These meetings were part of the review of UK blood product manufacture that had been requested of DH by the Chief Secretary to the Treasury (Alistair Darling) in February 1998, when Treasury approval was given to the use of non-UK plasma for the manufacture of blood products. By this stage of the review, reports had been received from both BPL and the PFC, Scotland. Amongst other areas for further work, it was agreed that more work was needed to consider the case for BPL and PFC moving into production of recombinant products.

4.20. A further meeting of this group was held on 7 April 1999 **[WITN4505223]**, this time chaired by Dr McGovern. Recombinant products were discussed (see the minutes at section 3.6). Whereas the Scottish Office had told SNBTS that PFC should not produce recombinant products, BPL were looking into the production of recombinant Factor IX and monoclonal Anti-D. It was agreed that a consistent policy was needed between the Scottish Office and the NHS Executive on this issue.

4.21. I worked closely with Dr Julia Watson, a DH Economist to develop detailed proposals, and also with DH lawyers, Treasury and Scottish Office officials among others.

4.22. The culmination of these discussions was a submission from me to Baroness Hayman dated 20 July 1999 [**SCGV0000061_035**]. While the submission came from me, it went through a number of draft iterations with input from a number of colleagues including those senior to me. The issue and summary recommendation at the top of the submission was as follows,

> "*Issue*
>
> *1. As you will recall, we have been working since last Autumn with Scottish Executive Health Department (SEHD) and Treasury officials on a review of blood products manufacturing in the UK, the aim of which is to ensure value for money in the use of UK fractionation capacity and a reasonable return on public investment. This has involved us in considering options for the future of the two NHS-owned plasma fractionators - the Bio Products Laboratory (BPL) and the Edinburgh-based Protein Fractionation Centre (PFC).*
>
> *2. Before we proceed any further, we would welcome your views on our emerging conclusions and your guidance on which options you would like us to explore in greater depth. The central question is whether we should explore options that would involve significant private sector investment in BPL.*
>
> *3. This submission has been agreed with Scottish Executive and Treasury officials. Scottish Executive officials are submitting a parallel submission to Susan Deacon MSP.*
>
> *Recommendation*
>
> *4. We recommend that you agree to consider options that require private sector investment in BPL and that external consultants be contracted to carry out market analysis and develop the options further."*

4.23. While the focus of this submission was on future options for blood manufacturing in the UK, paragraph 14 of my submission referred to recombinant products in the analysis of the "main factors affecting the performance of BPL and PFC" which were:

> *"• the increased costs of importing plasma because of the theoretical risk of nvCJD - BPL and PFC have now stopped processing plasma from UK blood donations. In the case of BPL, this has raised its main raw material costs by around 40%. If and when it becomes possible to test blood donors for nvCJD, use of UK plasma will resume, although this may not be for some years yet;*
>
> *• improvements in technology (recombinant blood products) and reductions in the demand for plasma products (albumin) by the NHS and the introduction of competition have left the UK overall with considerable excess fractionation capacity:*
>
> *BPL's fractionation capacity is around 800 tonnes per annum (although it has the potential to expand to 1000 tonnes) but its throughput this year will be only around 440 tonnes (300 for the NHS, 140 for export);*
>
> *PFC's fractionation capacity is around 100 tonnes per annum, with some built-in scope for increasing production by introduction of extra shifts. Most of this capacity is currently used in supplying the NHS. This is expected to rise to 150 tonnes per annum in 1999 to accommodate a commercial contract to fractionate Taiwanese product for Taiwan;*
>
> *Looking at the UK as a whole, out of a total fractionation capacity of 900-950 tonnes per annum, only around 400 tonnes is now required to meet the UK NHS demand for BPL's and PFC's products. By 2001/02 this could drop to a maximum of only 300 tonnes per annum (200 tonnes for the NHS in England and Wales; 100 tonnes for the NHS in Scotland*

and Northern Ireland), due to a combination of three factors: the reduction in NHS demand for albumin, the increasing availability of recombinant alternatives to plasma-derived Factor VIII and Factor IX (which neither BPL nor PFC produce), and forecast improvements in yields

- *the very high fixed costs associated with plasma fractionation technology which means that only large-scale production is commercially viable (in BPL's case, around 40% of their costs are fixed for reasonable changes in throughput). Consequently there has been significant consolidation in the plasma fractionation industry worldwide, and some of BPL's competitor companies are now operating plants with capacities of up to 2,000 tonnes per annum. BPL estimates that the optimal throughput for its plant is now around 1,000 tonnes of plasma per annum, more than twice the current level."*

4.24. The conclusion section of my submission stated as follows:

"It seems clear that retaining the status quo for BPL is not an option on its own. Even if it were to remain part of the NHS, BPL would have to increase its reliance on exports considerably in order to survive and probably extend its range of products. There would also need to be a firm commitment from the Department on capital investment and continuing subsidies. The Trading Fund option is attractive in that it would give BPL more flexibility in retaining surpluses and raising capital, but is only a viable proposition if it is trading healthily, which may not be the case for some years. In any case, the industry is changing so fast that a further review would probably be required in 2-3 years time if BPL remains in NHS ownership.

We do not have the necessary expertise within the Department to assess the options available to us for private sector investment in BPL. We would therefore welcome your views on whether you are content for us to employ external consultants on a confidential basis to assess

these options. If so, a detailed specification for this work could be drawn up and agreed with you, with a view to commissioning a report by the Autumn. Depending on the consultants employed and the time needed to complete this work, this could cost in the region of £40-50,000. We plan to find this money from the NBA's existing 1999/2000 cash limits as an efficiency saving.

If you are content, we would also explore further the scope for extending BPL's freedom of operation whilst remaining NHS owned (eg through a trading fund), and for supplying the UK NHS from PFC, so that we can present you with a full range of costed options later in the year."

4.25. In September 1999, Lord Hunt (who succeeded Baroness Hayman as Health Minister in the Lords in late July 1999) indicated a preference for PFI solutions to BPL's under capacity problems and ruled out outright privatisation. Lord Hunt asked for a further paper to put to the Secretary of State on this issue (see the reference in the later briefing for the NBA Accountability Review, 3 November 1999, [**DHSC0032284_049**]).

Recombinants developments in 2000

4.26. On 7 January 2000, I provided a submission to Lord Hunt. The submission was in relation to seeking approval for BPL to enter into a contract with the Canadian company Haemacure to manufacture a plasma-based product, Fibrin Sealant **[DHSC0006411_122] [DHSC0006411_123]**. The submission mentioned that a note on the wider issue of UK blood product manufacturing was in preparation for the Minister. In addressing the background to BPL's situation and its need to be involved in the export market (Annex A to the submission), I noted that the UK market for plasma products,

> *" ...has changed substantially with the introduction of recombinant (ie synthetic) clotting factors and a reduction in albumin usage. The UK demands for products likely to be placed on BPL are too low to sustain the Elstree factory. At present, BPL exports product which is surplus to NHS requirements but, in order to break even, BPL's exports would need to exceed 50% of total output. Downsizing would be very uneconomic. The aim of the current review is therefore to find ways - probably involving public private partnerships – to address this under capacity problem."*

4.27. On 13 January 2000, there was a DH – UKHCDO meeting attended by Dr Hill and Dr Dolan from the UKHCDO and Dr McGovern supported by myself, Gwen Skinner and Ann Willins for DH **[WITN4505224]**. A wide range of issues was discussed. Under the heading, "Changes in product availability", the informal note of the meeting recorded that:

> *"Product developments were a problem in that the suppliers rapidly stopped supply of the earlier product, substituting the new, with increases in cost. England has second highest price for recombinant F8, Germany being highest. Some regions are providing RF8 beyond those groups which the Govt specified. Prices varied from place to place in UK. Second generation products will come on stream from August (Bayer). May be 7p or 8p rise plus VAT. 45p plus VAT at moment (big customers), 50p plus (small).*

It was agreed there should be discussion with NHS supplies, which wd be able to take better overall control. (Check whether Howard Stokoe is still there.) UKHCDO wd ask, at their Exec mtg, whether this shd be on a regional or national basis. In effect, for prices, it wd be national anyway. (At present, Trusts purchase individually. Costs go up in year and budgets get restricted until a convincing argument for an increase is made.) Need to secure a spectrum of products, and iron out financial problems."

4.28. On 21 February 2000, I provided Lord Hunt with a draft note to send to Mr Milburn the Secretary of State on taking forward the review of UK Blood Products manufacturing **[WITN4505225]; [WITN4505226] [WITN4505227**;]. On the same day I put a submission to the Secretary of State who had raised a query about an earlier submission on laying a contingent liabilities minute before Parliament in relation to BPL. Mr Milburn had asked why BPL was not simply closed down given that it was operating under capacity and needed central subsidy. I noted that,

"In fact we are the midst of reviewing the future of BPL for that very reason. The review was requested by the Chief Secretary and is being carried out jointly with HM Treasury and the Scottish Executive. The review has considered a number of options, which we have discussed with Lord Hunt, including selling off the factory to the private sector. Our recommendation, however, is to look in detail at options for establishing BPL as a public/private partnership, and Lord Hunt will shortly be putting recommendations to you for taking this work forward. BPL currently supplies 60% of the blood products used by the NHS in England & Wales (some of which are in short supply on the international market) so simply closing down the factory is not an option."

4.29. I attended a meeting of the National Blood Authority on 29 February 2000. Under the monthly report from BPL, it was noted by BPL that the uptake of recombinant Factor VIII had been lower than expected in England

[**WITN4505228**]. At this meeting I also reported on the review of BPL and that we were awaiting the agreement of the Secretary of State to proceed.

4.30. On 27 March 2000, my colleague Gwen Skinner put a submission to Lord Hunt on Haemophilia and HCV Infection – Treatment / Care. **[WITN4505229]** The purpose of the submission was to follow up on Lord Hunt's direction for the Department to look to do more for people with haemophilia infected with HCV, focussing on counselling provision. The submission raised as one of a number of possibilities the option of providing all people with haemophilia with recombinant products (see paragraph 12 of the submission, and Annex C at paragraph 12 *ff*). In the consideration at Annex C, it was noted that policy in Scotland and Wales was to provide Recombinant Factor VIII and IX for all people with haemophilia whereas in England Ministers had required Health Authorities to provide recombinant Factor VIII and later Factor IX for new patients on those under 16. The possible option was described as, *"to request that all HAs in England fund recombinant Factor 8 and 9 for all people with haemophilia. This will have no direct relevance to those who already infected with hepatitis C, but it is likely to please the haemophilia community as a whole*". The cost was estimated at £40 million per annum in additional cost of the products, plus the effect of BPL losing its home market for coagulation factors. The 'elephant traps' identified was there may not be sufficient quantities available and not all haemophiliacs may want recombinant products.

4.31. On 28 March 2000, I provided Lord Hunt's Private office with a draft speech and briefing in advance of a PQ on blood products from Lord Morris, in relation to which Lord Morris had subsequently been offered a 'dinner hour debate' on 30 March 2000 [**WITN4505230**]. Recombinant treatment was one of the issues raised by Lord Morris in the debate itself [**WITN4505230**].

4.32. On 13 April 2000, Lord Hunt minuted the Secretary of State on the review of UK Blood Products Manufacturing [**DHSC0041330_023**]. This was a revised version of the note I had sent on 21 February 2000. Lord Hunt was in favour of including some form of public/private partnership arrangement and commission

external experts to develop options; he was against outright privatisation. Since it does not directly relate to recombinant products, I will not address the further detail on the review of blood products manufacturing save to note that:

(1) Mr Milburn agreed to the commissioning of an external review (see my submission to Lord Hunt of 9 and 12 May 2000) **[WITN4505231]**; **[DHSC0004291_060]; [DHSC0041246_115]; [WITN4505232]**;

(2) The NBA led the review, overseen by a Steering Group chaired by the Chief Executive of NBA. The Steering Group appointed PA Consulting Group to carry out the review;

(3) The option appraisal was completed by PA Consulting Group in February 2001. It recommended that "a Whole Organisation Joint Venture is the most attractive option available for BPL." This conclusion was endorsed by the Department's Private Finance Branch;

(4) Further options were put in a submission to Yvette Cooper on 20 December 2001 **[WITN4505233]; [WITN4505234]; [WITN4505235]; [WITN4505236]; [WITN4505237]; [WITN4505238]; [WITN4505239]; [WITN4505240]; [WITN4505241]**.

(5) However, the priority became securing the supply of non-UK plasma against the background of the World shortage. The route of securing that supply was the purchase of Life Resources. That process and turbulent movements in the commercial blood products market meant that the assumptions underpinning the PA consulting review recommendation became out of date. They were revisited after I had left post.

4.33. Returning to the chronology on recombinants, on 19 June 2000, Ms Skinner provided Lord Hunt with a briefing note ahead of a meeting with the UKHCDO leaders which the Department had initiated to build up the relationship and discuss ideas for strengthening haemophilia services **[DHSC0004033_002]**. The extension of recombinant Factor VIII treatment was one of the issues raised for discussion. On this topic, Ms Skinner's briefing suggested,

> *"Could Dr Hill/Dr Hay give us some more information about this? We understand that Wyeth are expanding their production of RF8 and in theory this will make enough available for all. RF 8 has not been in*

plentiful supply, there has not been enough for haemophiliacs in all age groups. Dr Hill may recommend an extension of provision, as a means of building the confidence of all haemophiliacs, especially those who have hepatitis C.

(Though this sounds attractive, there would be consequences for BPL who work with human plasma only. Additionally, recombinant Factor 2 [sic] is twice the cost of the plasma derived product, which would take the annual cost for a person with moderate/severe haemophilia from £20k to £40k. You might want to say that you will consider a referral to NICE, and ask Dr Hill when the increased supplies are likely to be available.)"

4.34. On 22 September 2000, Karin Pappenheim, Chief Executive of the Haemophilia Society wrote to Lord Hunt, urging that the risk of transmissions of parvovirus B19 lent more weight to the argument that recombinant factors should be made available for all haemophiliacs whatever their age and viral status and wherever they live in the UK [**HSOC0000367**]. She sought a meeting with Lord Hunt.

4.35. On 6 November 2000, I provided a submission to Lord Hunt in relation to this request. I noted that the letter had unfortunately been held up in the correspondence section [**DHSC0004000_029**]. There was, at the same time, interest in the issue from The Guardian and an Adjournment Debate in the Commons tabled by Robert Syms MP, which – at that stage – it was envisaged John Hutton was to cover. The recommendation in my submission was as follows:

"We suggest a joint meeting with the Haemophilia Society and the UKHCDO to discuss these issues. The UKHCDO, who you met earlier this year, share the Society's objectives on recombinant products and it would make sense to bring them into the discussion.

One way forward might be to refer this issue to NICE but we would need to consider whether this would be appropriate. In many ways, a decision

for the NHS in England to follow the rest of the UK in providing recombinant products for all haemophiliacs would be a safety issue rather than one based on clinical and cost effectiveness which is not really in NICE's remit.

For now, we recommend that a meeting is arranged as soon as possible. Mr Hutton can then respond to Robert Syms on Thursday by saying that representations have been received from the Haemophilia Society making the case for universal provision of recombinant, and that Ministers are meeting them and the UKHCDO soon to discuss this."

4.36. In the submission I also noted, as regards rough costs, that the additional cost to the NHS would be £12-20 million for Factor VIII and a further £10 million for Factor IX, though this might be reduced by central purchasing. The products were subject to VAT and a judicial review had established the products were correctly subjected to VAT. I made the point that it was clear (because of the financial restraints under which we were operating) that the cost would not be affordable during the financial year 2001/2002.

4.37. Lord Hunt's meeting with the Haemophilia Society and the UKHCDO took place on 24 January 2001.

4.38. On 9 November 2000, I provided a revised speech for the adjournment debate raised by Robert Syms MP **[DHSC0006258_033]**. It was John Denham, rather than John Hutton, who in the event responded to the debate for the Government.

4.39. Opening the debate, Mr Syms stated **[WITN4505242]**,

"*The current situation is pretty inequitable, particularly across different postcodes. Recombinant factor 8 is being provided to all haemophiliacs in Scotland and Wales, regardless of age and viral status, but in England it is restricted to children under 16 and a few people whose health authority has a policy of prescribing it. The Government took an*

important step in 1998 in making recombinant factor 8 available to all children; they now need to extend that to adults, as in Ireland and other European countries."

He later added,

"In a recent issue of The Lancet, more research evidence regarding the theoretical risk of transmission of variant CJD through blood was discussed. In the same week, representatives of the Haemophilia Society attended a special expert seminar held by EMEA--the European agency for the evaluation of medicinal products--on viral safety of plasma products with regard to non-enveloped viruses, particularly parvovirus B19 and hepatitis A. Taken together, the evidence from The Lancet report and from the EMEA seminar provide further justification for the Government's decision two years ago to ensure that all previously untreated under-16s with haemophilia should be treated with recombinant, as opposed to plasma-derived, products.

Although I am aware that there is, as yet, no evidence that either classical or variant CJD have ever been transmitted to people with haemophilia through blood products, new research shows that we cannot be certain that no risk of infection is associated with those products. Constituents of mine and others have told me that, although they were reassured in the past, their community has been badly affected, first, by HIV and, secondly, by hepatitis. They believe that if CJD rears its head, the haemophilia community is likely to be the first to feel the consequences. The significance of the findings, with the possible implication that blood donated by symptom-free vCJD-infected human beings might be infectious, is such that researchers chose to publish that finding immediately, without waiting for the completion of the study.

Considerable anxiety is generated in the community by fear of blood-borne viruses and diseases that might escape modern inactivation

processes used in the manufacture of plasma products. The Haemophilia Society believes that it is most important that the Government take an early decision to ensure that recombinant blood products are given to everybody with haemophilia in England--not only to under-16s, but to adults as well."

4.40. Mr Denham in reply stated [**WITN4505243**],

"…As the hon. Gentleman said, over the past 10 years, new recombinant, or synthetic, clotting factors have been developed. The Haemophilia Society and others have petitioned us to make recombinant factor 8 and factor 9 the treatment of choice for people with haemophilia, largely on the ground that recombinant products are regarded as free from the risk of transmission of as yet unknown viruses and the theoretical risk of variant CJD.

Our position continues to be that the clinical case for recommending the use of recombinant clotting factors has not yet been made. Plasma-derived clotting factors have had an excellent safety record since the introduction of viral inactivation in the mid-1980s and there is no evidence that the recombinant product is more effective as a treatment.

None the less, two years ago the Government responded to the fears expressed by people with haemophilia--particularly families with haemophiliac children--about the theoretical risk of variant CJD. We required NHS trusts to provide recombinant factor 8 for all new haemophilia patients and children under 16 from April 1998, and factor 9 from April 1999, as soon as it became available. The policy was worked out with the Haemophilia Society and the UK haemophilia centre doctors' organisation, and I hoped that it eased the anxieties of many parents about their children's future well-being.

Clinicians are, of course, free to prescribe recombinant products for all their patients if they choose, although I acknowledge that many health authorities have decided not to fund the treatment, on the basis of the

clinical evidence of safety and effectiveness relative to cost. Even so, it is estimated that more than 50 percent of the clotting factors prescribed in the NHS in England are currently recombinant.

I also acknowledge that in Wales and Northern Ireland all haemophilia patients are offered recombinant products. The same will be true in Scotland by the end of March next year. I understand that the decision that led to that situation came from individual health boards, and was not made at national level.

In recognising that individual health authorities have taken different decisions, it is important to note the lack of evidence that there is anything to choose between recombinant and plasma-derived products in terms of safety and effectiveness. Of course, I understand why many people with haemophilia, because of their past experience of infection from blood products, are genuinely concerned about potential future risks from those products.

In September, we received fresh representations from the Haemophilia Society putting the case for universal provision of recombinant clotting factors in England. I can inform the hon. Gentleman that my noble Friend Lord Hunt will shortly be meeting the society and other members of the Haemophilia Alliance to discuss the issue.

***Mr. Syms:** I thank the Minister for giving way. One or two people have moved from England to Wales because they believe that they will get the product prescribed in Wales. The society told me that it knows of at least two such cases. It is important to get matters right, and I am glad that the meeting has been arranged.*

***Mr. Denham:** My noble Friend leads on these matters and I await the outcome of those discussions. We have responded to the Haemophilia Society by recognising that we should hear it put its case."*

4.41. As part of the ongoing BPL review which was now being considered by a Steering Group of which I was a member, I prepared a paper dated November 2000 entitled, "Future Supply of Plasma Derived Products to the NHS" **[WITN4505244]**. The focus of my paper was on how BPL could secure a supply of sufficient, competitively priced product in the event of a global shortage, because this security of supply issue would be a key criterion in judging the acceptability of future options for BPL. Part of the background to this was the assessment by BPL that sales of plasma-derived Factor VIII and Factor IX would decline to very low levels in the UK due to the increasing use of recombinant products. On that basis, it was thought that only more rarely used clotting factors like Factor VII and Factor XI would be at risk of future supply problems in terms of BPL's output.

4.42. As set out in addressing vCJD at paragraph 3.104*ff, above*, in December 2000 the issue arose of patients who had received blood products from a donor who gave plasma in 1996 who had since been diagnosed with vCJD. The MCA had put a submission to Ministers on this on 13 December 2000. In my follow up submission to Lord Hunt on 15 December 2000 **[WITN4505245]** I noted that BPL's letter to distributors, hospitals and clinicians about the case was likely to attract media attention and that it would be seized on to bolster the campaign for universal provision of recombinant clotting factors. At paragraph 7, I set out the then extant guidance that:

- patients who had received blood products containing plasma from vCJD donors should not be told because the risk that vCJD might be transmitted was low, there was no diagnostic test for vCJD, and even if a test was available, there was no treatment.
- But that it was for individual clinicians to decide whether to follow this general ethical advice based on the individual patient.

I then noted that,

> *"This advice is now out of step with the view that has been taken on incidents involving vCJD-implicated surgical instruments, where patients will be given the opportunity to decide where or not they wish to be told. We had planned to refer this to the next scheduled meeting*

of the vCJD Incidents Panel on 22 February, but are now working on arranging a special meeting of the Panel in mid January."

4.43. On the same day, 15 December 2000, Jill Taylor from my team provided Lord Hunt with a briefing note ahead of his meeting with the Manor House Group on 18 December [**WITN4505246**]. Provision of Recombinant Factor VIII was one of the issues on which a background note was supplied.

Recombinants developments in 2001

4.44. On 4 January 2001, I emailed Nick Raisen (Private Secretary to Dr Pat Troop, DCMO) [**WITN4505247**]. The email was a write-up of a briefing I had given orally to Dr Troop on recombinant products. My note included the following:

"Synthetic clotting factors offer no therapeutic benefit over plasma-derived products. The issue is one of safety. Plasma derived clotting factors have had an excellent safety record since the introduction of viral inactivation in the mid 1980s, and we have taken steps to minimise the risk from vCJD. However, the Haemophilia Society and UKHCDO argue that, as long as we continue to use the plasma-derived product, haemophilia patients are at risk from new or undetected viruses and still, potentially, vCJD - and there are products available now that could eliminate that risk. Scotland, Wales and Northern Ireland have all moved towards universal provision of synthetic clotting factors (Scotland aims to complete the process by April 2001) which puts us under additional pressure to do likewise.

A shift towards provision of synthetic clotting for all haemophilia patients in England would have to be phased in over a period of perhaps 2-3 years. There is still insufficient product on the market to supply the whole of the needs of the NHS immediately. There would also be substantial cost implications for the NHS which we are currently calculating (I should have figures by the middle of next week showing numbers of haemophilia patients in England currently receiving

synthetic and plasma derived products). We would want to involve PASA in negotiating central contracts to get best value for money. I will be putting this information in a submission to Lord Hunt, hopefully by 12 January.

This is not an issue that has ever been put to an Advisory Committee. The only group that could perhaps look at it is NICE and they have declined to do so on the grounds that it's primarily a safety issue and therefore outside their remit. In Scotland they have devolved decision making on funding for synthetic clotting factors to Health Boards and decisions on phasing in were given to a Recombinant Factor 8 Consortium Group made up of Health Board representatives and others. Wales and Northern Ireland have similarly devolved decision making on this issue."

4.45. On 15 January 2001, Dr Hill of the UKHCDO emailed me with a summary of product usage for haemophilia A and B patients showing the numbers and products used [**WITN4505248**]. I would have wanted this information to improve the cost assessments for moving all patients to recombinant products. Dr Hill made that point that:

"Given the current situation where Bayer are unable to supply existing orders for the paediatric centres, the adults could only be switched over a prolonged phased programme provided the supplies can increase product and supply the UK with these quantities. If we could establish the principle to change, it would be a major step forward. It will obviously be important to look at how we place contracts to bring the cost down as much as possible."

4.46. On 19 January 2001, I put a submission to Lord Hunt on the campaign for universal provision of recombinants [**WITN4505249**]. While the immediate impetus was the meeting with the UKHCDO and Haemophilia Society on 24 January, this was a wider submission which set out the current position, the arguments in support, the supply issue, costs implications, the impact on BPL

and a proposed way forward. The recommendation in my submission was as follows:

> *"We recommend that Ministers agree to a phased introduction of recombinant clotting factors for adult haemophilia patients in England over 4-5 years starting in 2002-03. However, this would require some re-prioritisation of funding for 2002/03, and would pre-empt decisions on priorities for the rest of the phasing period. A detailed, fully-costed, implementation plan would be needed before final decisions are taken."*

4.47. The conclusion of the submission asked Lord Hunt if he was content to agree to a phased introduction of recombinant clotting facts for adult haemophilia patients in England over 4-5 years and for officials to develop a fully-costed implementation plan in consultation with the Haemophilia Alliance, Regional Specialised Commissioning Groups, PASA and others. While I was the author, a major recommendation of this kind in a Ministerial submission would have needed to be cleared with Finance and also agreed with my more senior colleagues, such as Dr McGovern and Dr Troop.

4.48. In the email to Lord Hunt's Private Secretary covering this submission, I pointed out that a phased introduction starting in 2002/2003 did not have any provision in Health Authority allocations or central budgets. As a result, implementing the policy would require some re-prioritisation of funding for 2002-2003 as well as the ongoing costs commitment. As such, I noted that it was a decision that required the explicit clearance of the Secretary of State, Mr Milburn. **[WITN4505251]**

4.49. On 22 January 2001, Lord Hunt's Private Secretary confirmed that Lord Hunt agreed my proposed course of action and she had forwarded the submission to Mr Milburn's Private Office for his agreement as a matter of urgency [pg. 186]; **[WITN4505250]**.

4.50. Following Lord Hunt's meeting with the Haemophilia Society and UKHCDO on 24 January 2001 there was increased media pressure on the recombinants

issue, which overlapped with news coverage in relation to the plasma donor who had developed vCJD. On 26 January 2001, I provided Nadine Smith in the Communications Division with information on recombinants relevant to the BBC Watchdog programme **[DHSC0004735_113]** and again on 30 January 2001 in relation to 'treatment strikes' by haemophiliacs, following a query from the Guardian **[DHSC0004735_102]**.

4.51. On 31 January 2001, I provided the draft of a note for Lord Hunt to send to Mr Milburn on recombinants. On 2 February 2001, Lord Hunt's Private Office sent the finalised note from the Minister to Mr Milburn, following the draft I had prepared **[DHSC0042461_189]**. The note started by explaining that:

> *"1. Last week I met representatives from the Haemophilia Society and the Haemophilia Doctors Organisation to discuss their campaign for all haemophilia patients to be given synthetic clotting factors. I also sent you a submission from officials on this issue, dated 19 January.*
>
> *2. Since the meeting, the Haemophilia Society has mounted a very high profile media campaign, linking their demand for synthetic blood products to concerns about vCJD transmission. I am therefore convinced that we need to agree a Government response to the campaign very soon, and would welcome the opportunity to talk this through with you."*

4.52. Having set out the factual background, the note from Lord Hunt continued,

> *"4. Despite the extremely high cost of providing haemophilia patients with treatments free from the risk of blood borne infection, I believe it would be almost impossible to defend a refusal to move in this direction;*
>
> - *although synthetic clotting factors are no more efficacious than the plasma –derived equivalents, they are undoubtedly safer in that they are free from risk of blood borne infections;*
> - *because they need massive amounts of clotting agent, haemophiliacs are particularly vulnerable to blood borne infections. It would therefore*

be naïve to claim that the events of the early 80s could not repeat themselves, either with vCJD or with an as yet unidentified virus;

- *there has been a trend in NHS treatment of moving towards synthetic alternatives to human or animal derived products, when these become available, on grounds of safety. For example we no longer use human growth hormone or animal derived insulin;*
- *Wales and Northern Ireland already provide synthetic products for all their haemophilia patients. Scotland will have done so by 31 March 2001. The Republic of Ireland moved exclusively to synthetics over 3 years ago.*

5. Officials have proposed a five-year phasing-in period, starting 2002-03, and I support this. The speed of this would depend on the ability of manufacturers to supply, and an implementation plan would need to be drawn up in discussion with them (through PASA) and in consultation with haemophilia organisations. One option would be follow the approach taken in Scotland and phase-in by age bands. Assuming sufficient availability of product, approximate costings for this would be:

Year	***Age Band***	***In Year Cost***	***Cumulative Cost***
2002-03	*20-29 year olds*	*£10.0m*	
2003-04	*30-39*	*£12.2m*	*£22.2m*
2004-05	*40-49*	*£9.5m*	*£31.7m*
2005-06	*50-59*	*£6.5m*	*£38.2m*
2006-07	*60+*	*£9.0m*	*£47.2m*

The aim would be to reduce these costs through central contracting as Scotland have done. But if manufacturers can supply product quicker than anticipated, there will be pressure on us to accelerate this timetable."

4.53. On 5 February 2001, Mr Milburn's Private Secretary responded to Lord Hunt [**WITN4505252**], explaining (by reference to the submission of 19 January) that:

"SofS saw the submission of 19 January on recombinant clotting factors over the weekend, He thinks there are three key issues:

(i) would we be buying a completely human-free product (see paras 10 11 it is not completely clear what we are proposing using)? If not, are we in danger of finding ourselves with the Haemophilia Society and others raising at some point in the near future the risks from 1st generation recombinants compared with 2nd generation?

(ii) *SofS does not think we can agree the switch until the future of BPL is sorted, otherwise do we enter into an open-ended commitment?*

(iii) *has anyone identified where the funding for this would come from?*

I would be grateful for further advice from Charles Lister on these points asap, Emma/Sue [Private Secretaries to Lord Hunt] would Lord Hunt be happy to wait until we have the further advice before speaking to SofS about this issue? Once we have the advice, he might want to talk it through with SofS?"

4.54. On 9 February 2001, I emailed Mr Milburn's Private Secretary with responses to the issues the Secretary of State had raised and apologised both for the delay and the length of the reply I was providing **[WITN4505253]**. I had sought input from finance colleagues in the Department. I indicated that:

- A commitment to fund recombinant would lead to pressure to complete phasing in a lot sooner than in 5 years.
- Following campaigning from Haemophilia North, Newcastle Haemophilia Centre has decided to phase in recombinant products for all their patients.
- As to whether there was any human-sources element in the products and the risk of creating pressure to move from 1st generation to 2nd generation recombinants, I explained that 1st generation recombinant used human albumin; the 2nd generation product new to the market was 'albumin light'; and the 3rd generation scheduled for 2003 was to be entirely synthetic. The 2nd generation product was not more expensive than the 1st, but the

3rd was expected to carry a price premium. The manufacturer – Baxter – suggested they could meet the demand by the end of 2003/2004. I suggested that we could no longer rely on a phased implementation ending as late as 2006/7.

- On the read-across to the wider options for BPL, I suggested that it was inevitable that BPL would lose NHS sales and the phasing-in would allow for proceeding in a managed way. BPL's problems were acute, with or without an NHS market for plasma-derived clotting factors, and I indicated that we considered there was nothing to be gained by holding up the decision on recombinants until the future of BPL was settled. I noted that the outcome of the BPL review would be sent to Ministers later that month. We did not assess that the recombinant decision would put off potential investment partners in BPL.
- As to the source of the funding, I noted that there were no cost commitments before 2002/3 but it would be a new cost commitment for 2002/3 not taken into account in the last spending review. It could only be afforded by pre-empting growth in HA general allocations or by replacing or deferring some existing central spending priority within the indicative plans for years 2 and 3 of the SR period. Finding savings from the wider Health Services Division allocation would be difficult as the majority was allocated to implementing the NHS Plan priorities and the recombinant costs would bite into that significantly.

4.55. On 14 February 2001, I forwarded to Dr McGovern and others a copy of a paper by PA consultancy addressing the impact on BPL of a decision to switch to recombinant clotting factors for all haemophilia patients in the UK **[WITN4505254; WITN4505255]**. The report's conclusion was that there would be an impact on BPL's profitability, such that the switch to recombinants would have a double impact on the public purse. However, the impact on finding a potential partner for BPL was less clear to anticipate; the move to recombinants would likely be factored in as an existing market trend. The strategic reasons for investing in BPL would probably not be altered but the price a partner would pay could be reduced.

4.56. On 16 February 2001, I alerted the relevant Health Ministers' private offices to renewed media interest in cases of haemophiliacs refusing treatment with plasma-derived clotting factors providing lines to take [**DHSC0034513**]. Part of the lines to take was that Ministers were actively considering the case for providing recombinants to adult patients and there was currently a worldwide shortage of supply. I noted that Lord Morris had tabled a PQ asking when Ministers were going to reach a decision.

4.57. On 20 February 2001, I was one of several officials copied into an email from Mr Milburn's Private Secretary summarising the discussion on recombinant products between the Secretary of State and Lord Hunt that morning [**DHSC0042291_003**]. He noted that,

> *"SofS expressed concern that a move to 2nd generation clotting factors might simply move the argument on to 3rd generation factors. SofS asked for the answers to three questions before taking a decision on this issue:*
>
> *(i) an assessment of who the next group would be lobbying us on this type of issue, eg people undergoing eye surgery demanding single use instruments;*
>
> (ii) *an assessment of where the funding would come from to pay for this. We cannot assume we have the £45 million or so needed;*
>
> (iii) *if the other Nations have agreed the switch to 2nd generation, can we get in to some kind of joint negotiation with them to push the supplying company to bring the price down?*
>
> *You kindly agreed to commission this."*

4.58. Lord Hunt's Private Secretary added her own additional notes from the Ministerial discussion [**DHSC0042291_003**]:

> *"Lord Hunt said that the Haemophilia Society's campaign asking for recombinant factor VIII to be available to all haemophiliacs in England was ongoing and at the moment we are facing particular pressures because:*

- of the recent batches of blood products which were made from a donation from someone who later developed vCJD and the possible risk this poses;

- Scotland has made the decision to phase in the use of synthetic clotting factors;

-Newcastle HA has decided to make synthetic clotting factors available to haemophiliacs in their locality.

SoS commented that because the 1st and 2nd generation products still used some human albumin we could not guarantee that they were risk-free. He speculated about whether it might be better to wait until the entirely synthetic 3rd generation product was available in 2003. PS(L) explained that Scotland are phasing in the 1st and 2nd generation products, but he accepted that if England were to do the same we would gradually come under pressure to introduce the more expensive 3rd generation product

PS(L) also said that he thought the Haemophilia Society would not accept a decision to wait until the 3rd generation product is available and they would continue their campaign. On the issue of funding, PS(L) said Finance colleagues have suggested that funding to phase in 1st and 2nd generation products would need to come out of current resources and would have to be phased in gradually from 2002/03 SoS did ask for a further note on the 3 points listed in your email. Can I just elaborate on these a little to take account of further comments Lord Hunt made after the meeting:

(i) an assessment of who the next group would be lobbying us on this type of issue, e.g. people undergoing eye surgery demanding single use instruments; (i.ee. if our current position is that there is only theoretical risk from these products but we decide to make available alternative treatments anyway what other demands would we face for other treatments/products?)

(ii) an assessment of where the funding would come from to pay for this. We cannot assume we have the £45 million or so needed; (PS(L) suggested revisiting the estimate of costs - Charles I think you said that if we negotiated the same deal as Scotland it would only cost us £35m? Can you provide a further breakdown or other options for funding.)

(iii) if the other Nations have agreed the switch to 2nd generation, can we get in to some kind of joint negotiation with them to push the supplying company to bring the price down?

PS(L) has asked if this new submission could be sent up before the end of the week because he would like to try and resolve the issue with SoS within the next couple of weeks. Can I ask that you send me a draft by 5.00pm on Thursday and then if Lord Hunt is content we will try to get it to SoS for his weekend box."

4.59. After again consulting with colleagues, on 22 February 2001 I provided the requested further submission to both Mr Milburn and Lord Hunt [**WITN4505256**]. The key points I made in response to the Secretary of State's further queries were that:

- There was no obvious group that might lobby next on this kind of issue;
- There would be savings through central contracting, but these would not be great;
- The only way that costs could be managed was by a fairly lengthy phasing strategy (which was forced on the department in any event). The only source of the funding was by pre-empting growth in HA general allocations or by replacing of deferring some existing central spending priority in years 2 and 3 of the current Spending Review period.

4.60. I then set out a summary of the current position and discussion of the three options that appeared to arise from the earlier Ministerial discussion, namely: (i) do nothing; (ii) phased introduction of recombinants; or (iii) wait for the purely

synthetic (i.e. 3rd generation) recombinant product. My conclusion was as follows:

> *"On the basis of the above arguments, we recommend that the most defensible position for Ministers to adopt is to:*
>
> *(i) agree to a **lengthy phased introduction of recombinant clotting factors starting in 2002-03**, thus ensuring consistency of approach throughout the NHS and eliminating accusations of post code prescribing;*
>
> *(ii) make clear that this is **conditional on the introduction of England-wide or, if possible, UK-wide contracting** to keep additional costs to a minimum;*
>
> *(iii) **instruct HAs to fund the additional costs from reprioritisation of general allocations** but on the understanding that long-term phasing will spread these costs over a number of years."* (Original emphasis).

4.61. After I had already sent this submission, colleagues in the FPA (part of the Department's Financial and Performance Directorate) provided feedback on the financial approach I had suggested [**WITN4505257**]. An amended submission with a revised conclusion was put up to Ministers [**WITN4505258**].

> *"On the basis of the above arguments, we recommend that the most defensible position for Ministers to adopt is to:*
>
> • *agree to a lengthy **phased introduction of recombinant clotting factors starting in 2002-03**, thus ensuring consistency of approach throughout the NHS and eliminating accusations of post code prescribing;*
>
> • *make clear that this is **conditional on the introduction of England-wide or, if possible, UK-wide contracting** to keep additional costs to a minimum;*
>
> • ***make specific provision in HA allocations, funded at the expense of some other priority or by pre-empting growth monies**, on the understanding that long-term phasing will spread these costs over a number of years.*

- If this approach is acceptable, we would develop a profile estimating growth of costs during the phase-in period." (Original emphasis).

4.62. Ministers responded on 26 February 2001.

4.63. Lord Hunt commented, *"I support phasing in the provision of recombinant although I think the pressure will be to deliver this before 2007/08. Unless we agree we will find ourselves continually pushed and always on the defensive."* **[WITN4505259]**.

4.64. Mr Milburn's private office indicated that the Secretary of State had said that, " … *we cannot make specific provision in HA allocations. The funding will have to be found at the centre, eg in the NBA or a similar area. Grateful for further advice on this point." [***WITN4505260***].* In light of this, I told Lord Hunt's Private Office that I had discussed the matter with Linda Percival (she was essentially a Divisional coordinator/programme manager) and that she would speak to David Hewlett (who was our Deputy Director / Branch Head) to see what funding might be found within the Health Services Directorate funding envelope **[WITN4505261]**

4.65. I attended the 65th meeting of SEAC on 21 February 2001, but only in relation to agenda item 5 – Current Health Issues. Part of the discussion on that item covered the consideration being given to an extension of recombinant products to all haemophiliacs (see minutes at 5.25) **[WITN4505262].** There was also mention of a wider group intended to be established to consider the feasibility of replacing all blood products by synthetic products in the future and the sort of research programme necessary to implement that.

4.66. On 6 March 2001 Dr King, put a submission to Lord Hunt, Yvette Cooper (Parliamentary Under-Secretary for Public Health) and the CMO Professor Donaldson on the implementation of a strategic approach for HCV **[WITN4505263]**. The submission invited Ministers to agree to the setting up of an ad hoc steering Group to oversee the development of the Department's

strategic approach to HCV, and to the announcement of the membership of the group. In the response from Lord Hunt's Private Office, it was indicated that Lord Hunt was content with these proposals but was interested in linking the announcement with that on recombinant products if there was any movement on that decision [**WITN4505264**]. Having discussed this with me, Dr King gave our joint view to Lord Hunt's office that it would be better to keep these announcements separate [**WITN4505265**]. The reasons were that: the extension of recombinants – if adopted – would apply to all haemophiliacs not just those with HCV; the Secretary of State had decided that the funding for recombinants would have to come from existing central funds and we were still seeking to identify what if anything could be dropped; while there was an urgency to the recombinant decision, it was unlikely to be made in the next two weeks.

4.67. Later in March 2001, Dr Hill of UKHCDO advised me that Bayer had suspended product release of its recombinant Koganate FS which would have a severe impact on the overall recombinant Factor VIII market given the shortage of supply [**DHSC0041238_004**]. I forwarded the information to colleagues in the Medicines, Pharmaceutical and Industry Group and the Purchasing and Supply Agency requesting that they urgently assess the supply position in view of the potential for NHS shortfall. I was copied into subsequent communications from UKHCDO on the management of this situation and attempts to mitigate the shortage of Recombinant Factor VIII supply. I also attended the meeting of the UK Haemophilia Centre Doctors' Organisation on 15 May 2001 limited to the discussion of this issue: see [**HSOC0005853; HCDO0000013_193; HCDO0000013_041; BART0000936_002; HCDO0000013_172; HCDO0000013_151**].

4.68. On 30 April 2001, Novo Nordisk wrote to me with their current position document on recombinant Factor VIIa. I had agreed in principle to meet with them [**WITN4505266**].

4.69. On 2 July 2001, I emailed the Private Secretary to Yvette Cooper, regarding PQs from Sandra Gidley MP **[DHSC0041379_179]**. I provided a copy of the earlier submission to Mr Milburn on recombinants. By this stage, I was noting that the position was that the Department could not justify re-prioritising within current funding envelopes. This would indicate that it had not been possible to find the money within the existing Health Services Directorate budget. Accordingly, I was by this stage in the course of putting together a bid for new funding for the Spending Review 2002.

4.70. I met with Dr Kennedy of Novo Nordisk on 2 July 2001, to discuss their Factor VIIa product, and she wrote to Dr Hay about our meeting **[HCDO0000013_023]**. In that letter, Dr Kennedy recorded, amongst other things, that I had expressed the view at the meeting that I " … *couldn't see how the Government can resist a move to recombinant products for all in the near future, although the implementation may have to be phased due to the ongoing shortages. Charles also agreed with our points in relation to current guidance, but was reluctant to make any changes at present until the whole issue of recombinant for all is addressed."* Dr Hay subsequently provided me with a copy of this letter (see Dr Hay's letter of 20 July 2001) **[WITN4505267]**. He made the point, of which I would have been well aware, that Novo Nordisk had a particular interest in looking to ensure that their Factor VIIa product was used for all patients with inhibitors, whereas Dr Hay considered that clinicians would prefer to have prescribing freedom. There was also a later follow-up letter from Novo Nordisk on 20 September 2001 **[WITN4505268]**. It was inevitable in my role that I was lobbied frequently by the pharmaceutical industry, either directly or through PR agencies. I was always aware of the need to be circumspect knowing that they were likely lobbying to gain a commercial advantage.

4.71. On 4 July 2001, Dr Winter in his capacity as Co-Chairman of the Haemophilia Alliance wrote to Yvette Cooper on the Alliance's recently drafted national service specification for haemophilia and related disorders **[WITN4505269].** Dr Winter sought a meeting to discuss the document with the Minister and, in that context, pressed the ongoing concern about use of plasma-derived blood

products for adults in England. He recognised that supplies would not permit all adults to be treated with recombinants but wanted the Department to accept the principle that subject to supplies, all patients should have access to recombinant treatment.

4.72. On 12 July 2001, I provided a revised note of bids for the Spending Review 2002 for Dr Pui-Ling Li who was coordinating bids for PH. This included the costs of a phased extension of recombinant treatment to all adult haemophiliacs **[WITN4505270]**.

4.73. On 24 August 2001, I put a submission up to Mr Milburn regarding the US plasma shortage and its impact on BPL / the supply of blood products to the NHS **[DHSC0008129]**. The shortage of US plasma had precipitated a race by commercial manufacturers to acquire all the independent plasma suppliers in the US for their own exclusive use. The most viable solution was for the Department to purchase a US supplier for BPL of which DCI was the largest remaining independent supplier. The world shortage of recombinant products was part of the background to this pressure on US plasma supply. The shortage of recombinant product increased the demand for plasma-derived products, a point addressed under paragraph 4 of Annex A to the submission in which I sought to give the detailed background.

4.74. As I have set out in paragraph 2.53, above, on 12 September 2001, the Private Secretary to the Minister of State, Mr Hutton, emailed Dr King and I with a summary of a meeting held that afternoon on compensation for those infected with HCV **[DHSC0004363_090]**. The summary noted:

> *"MS(H) doesn't think offering compensation is an option. However, he asked that you look in to providing a social care support package similar to that of the vCJD scheme e.g. exempting haemophiliacs from the charge regime.*
>
> *MS(H) was supportive of giving ?>16s? access to recombinant products. He asked that you investigate whether there is a way we can*

avoid paying tax on this cost by reaching an agreement with HMT. If necessary he will write to them.

MS(H) agreed to look at the PQs and POHs again. You agreed to check and send the standard line in light of this meeting."

4.75. On 4 October 2001, I emailed Dr Hill to pass on a comment I had received from BPL which had suggested that many patients were refusing treatment and criticising lack of any assurance provided by the Haemophilia Society [**HCDO0000014_487**]. I asked of Dr Hill,

"Is there any truth to the statement that many patients around the country are refusing treatment and that the Haemophilia Soc has "done nothing to have done nothing [SIC] to provide patients with assurance's during this period"? Both statements seem to me to be exaggerated but I would be grateful for your take on things. Should the department be pressing the Haemophilia Society to do more? This is such a sensitive area that I don't want to act on BPL's assessment unless there is some real substance to it."

4.76. Also on 13 November 2001, Dr King provided Mr Hutton with a draft speech for the forthcoming adjournment debate on HCV, ahead of a briefing meeting we were to hold that afternoon with the Minister [**WITN4505271**].

4.77. Amongst the flow of Parliamentary Questions at this time was one specifically on recombinant products from Mark Todd MP. The draft reply was composed by Robert Finch (HSD7) and approved for submission to the Minister by Dr King [**WITN4505272**].The suggested reply indicated that the Government was actively considering extending the provision of recombinant factors to all haemophilia patients in England when supplies allowed, and that currently the policy was to provide recombinants to new patients and children under 16. The background briefing noted that a bid for funds had been included for the 2002 Spending Review.

Recombinants developments in 2002

4.78. On 28 January 2002, I was one of several officials copied into a submission from Richard Lawes to HM Treasury officials regarding the plans to purchase Life Resources Incorporated (the parent company of DCI) in order to maintain an adequate supply of US plasma **[DHSC0008440]**. Richard was in the DH Commercial Directorate working to Peter Coates and part of the team with me negotiating the purchase of DCI. The background section noted that the use of non-plasma derived products was not a viable solution to the use of US plasma in BPL production because there were no such products available for immunoglobulins which were a major BPL product. And while there were recombinant Factor VIII and IX products, there were both in short supply and expensive. The submission noted that Ministers had not yet taken a decision around the future of recombinant products, but that even if such a decision were taken, the earliest the replacement by recombinant products could take place would be 2005/2006. Even then the current information was that there would still be patients unable to use recombinant products and therefore there would be a continued need for plasma derived Factor VIII and Factor IX products, albeit at reduced levels.

4.79. Amongst the ongoing PQs at this time was one from Laura Moffatt MP dated 8 February 2002, who asked specifically about treatment for patients with inhibitors, and whether the policy on treatment of under 16s with recombinants extended to them **[WITN4505273].** Novo Nordisk was based in Ms Moffatt's constituency. My suggested reply made clear that unlike haemophilia A and B patients, the Department had not issued advice on patients with inhibitors for whom treatment with recombinant Factor VIIa was one of a range of possible treatments. It noted that guidance on the overall treatment of such patients had been issued by the UKHCDO. There was also a PQ from Lord Morris asking about the sources of evidence for statements made about the efficacy and safety of recombinant and plasma-derived clotting factors **[WITN4505274]**. The draft reply with amendments read:

> *"It is generally accepted by UK clinicians that recombinant and plasma derived clotting factors are equally effective in treating clotting*

disorders. In guidelines produced by the United Kingdom Haemophilia Doctors Organisation, comparisons between the two types of product revolve around their relative safety, bearing in mind that no medicinal product can ever be completely free from risk. An advantage of recombinant products, where they are entirely free of human albumin, is that they eliminate the risk from blood borne viruses and the theoretical risk from vCJD. However, I am advised by the Medicines Control Agency that regulatory guidance has already been developed at the European level, If is aimed at minimising the risk of viral transmission from plasma derived clotting factors through a) the effective screening of donors and b) the incorporation of appropriate procedures into the manufacturing process designated to inactivate/remove vital contaminants. By ceasing to use UK plasma in the manufacture of blood products, the Government has already taken steps to reduce the unknown risks from vCJD.

The Government will make a full statement once we have completed our consideration of the Haemophilia Society's call to extend the provision of recombinant clotting factors to all haemophilia patients in England."

4.80. On 11 March 2002, I provided a briefing to Yvette Cooper ahead of the first Ministerial meeting with the newly formed All Party Parliamentary Group on Haemophilia [**WITN4505275**].Karin Pappenheim of the Haemophilia Society had indicated that the main focus of the meeting was likely to be on recombinant clotting factors. At this stage, the difficulty remained that while a bid for funding had been made in the 2002 Spending Review, the Department did not yet know the result of that bid, and hence we – and Ministers – did not know if the funds would be available to move towards the extension of recombinant products.

4.81. The briefing for the Minister [**WITN4505275**] included so called 'elephant traps', lines to take in the event of difficult questions. One surprised me on re-reading as it seems at first sight contrary to our very clear objective of securing funding

for recombinants through SR 2002 and includes a figure I don't recall using in any other circumstance. It reads:

> *"Difficult to justify the increased expenditure on recombinant clotting factors on cost benefit grounds; could be cost effective only in dire situations e.g. if vCJD were found to be transmissible through blood/blood products, and more than 10% of haemophiliacs died as a result".*

I think this has to be read in the context of a situation where the Department's case for funding recombinants was not based on a stark cost benefits argument, which would have included a calculation of cost per life year. Instead, our case focussed on the overriding need to protect people with haemophilia against any further risk from blood borne disease. The papers found by DH have not included the case I made for SR2002 funding, but from recollection my argument was based on the history of infection with HIV and HCV, the fact that vCJD could not be inactivated in blood and the unknown nature of any future blood borne risks. Given that purely synthetic clotting factors were available, or becoming available, I felt that there could be no justification for continuing with plasma based products any longer than necessary.

4.82. On 22 March 2002, I provided Yvette Cooper with information relevant to the correction of an earlier PQ answer on recombinants which had mistakenly referred to patients over 20 when it should have referred to patients under 20 **[DHSC0041332_291]**. I provided a draft letter of apology to the MP concerned (Jackie Lawrence MP) and a redrafted PQ reply.

4.83. On 25 March 2002, I received an interim business case from KPMG Corporate Finance as the Department's financial adviser for the proposed purchase of Life Resources Incorporated **[DHSC0004235_013; DHSC0004235_014; DHSC0004235_015; DHSC0004235_016].** I continued to be involved in the arrangements for this purchase through to its completion on 16 December 2002 (see the written Ministerial statement on 18 December 2002) **[WITN4505276]**.I will not further detail the developments in this statement because recombinant

products and vCJD risks – the issues the inquiry have raised with me - were essentially part of the background against which this purchase took place, rather than the motivation or reason for it.

4.84. On 29 April 2002, Dr Angela Robinson the Medical Director of the NBA forwarded me a paper from Vox Sanguinis on the use of recombinant Factor VIIa to treat persistent bleeding following dental extractions in two cirrhotic patients. She provided it as background information for me on where recombinant Factor VIIa was being used in light of recent PQs **[WITN4505277; WITN4505278].**

4.85. On 29 April 2002, Karin Pappenheim invited me to a meeting organised by the Haemophilia Society to consider the available data on the best cost-estimation for extending recombinant treatment [**DHSC0004285_045**].

4.86. On 15 May 2002, Dr King, Robert Finch and I attended in support of Yvette Cooper at a meeting with the Manor House Group **[WITN4505279].**The main items discussed were: self-sufficiency and the 'David Owen issue'; patients' right to have been informed of the risk of treatment; the moral issue/no fault compensation; ignored warnings/public inquiry and the stigma surrounding haemophilia and HCV. The group raised the availability of recombinant treatment under any other business. The Minister made clear that the Government were still considering the call to provide recombinant treatment for all and that a decision would be made later on in the year. She made clear that when the decision was made, the response would be provided through the All Party Parliamentary Group.

4.87. A number of PQs were tabled during the summer of 2002, seeking information on when the recombinant decision would be taken. The answers drafted indicated the same line, namely that a decision would be taken later in the year. See for example, the suggested reply drafted by Robert Finch and approved by me for submission to the Minister to a PQ from Mike Hancock MP in July 2002 [**DHSC0041332_183**]. The answering Minister was Hazel Blears, who had by

this stage succeeded Yvette Cooper as Parliamentary Under-Secretary for Public Health.

4.88. On 8 August 2002, Dr King provided a further submission to Dr Troop, DCMO, and Hazel Blears on the use of US fresh frozen plasma for neonates and children born after 1 January 1996 **[WITN4505280].** This provided further information at the request of the Minister following an earlier submission from me dated 25 July 2002 **[DHSC0017705]**. One of the issues addressed by Dr King in weighing up whether a pro-active announcement of this development should be made was the likelihood of it prompting comment from other groups on other issues. The Haemophilia Society and other groups' call for expansion of the recombinant treatment was raised in that context.

4.89. David Kemsley, Deputy Director of Commissioning for Hillingdon PCT, wrote to me on 31 October 2002 following a meeting of the Pan Thames Haemophilia Consortium Strategy Sub-Group on 28 October 2002 (at which I was not present) **[DHSC0045140_123]**; **[DHSC0004285_006]**. In anticipation of the pending Ministerial decision on extension of recombinants, he wanted to raise concerns about the distribution of funds being on a capitation basis as opposed to a usage basis, because of the disproportionately high number of haemophilia patients living in the London and SE consortium area. As part of this, he considered that by year five the recurring revenue consequences would be far in excess of the current estimate of c. £50m. He enclosed financial projections prepared by Prof. Savidge of St Thomas'.

4.90. On 7 November 2002, there was a stocktake on blood policy issues with Hazel Blears attended by Robert Finch and me **[WITN4505281]**. The briefing notes on recombinants for this meeting referred to the fact that the Department would be under pressure to make an early announcement once the outcome of the Spending Review Bid was known, and we wished to discuss with the Minister how she wanted to handle this.

4.91. On 27 November 2002, I emailed Brian Bradley in DH Finance. Brian was looking to reduce SR2002 bids. I gave up money on fresh frozen plasma but defended the other bids including for recombinants, while noting that £10m had already been cut from year 2 of the original bid, stating:

> *"Securing Recombinant Clotting Factors – Ministers have been under pressure for the past 2 years to provide these products for haemophiliacs, something Scotland and Wales do already and which N. Ireland is committed to doing. They are incredibly expensive and prices are likely to rise even higher in the new [sic] few years. The funding bid for already assumes a 4 or 5 year phasing process which will already be hard to justify. Year 2 has already been cut by £10m from the original bid. Haemophilia Commissioners are already expressing concerns that the global sum quoted by Ministers for the cost or recombinant is inadequate and that a decision to provide these products backed up with too little money will shift all the pressure on to PCTs."* **[DHSC0006156_030]**

4.92. Later in November 2002, Prof Savidge (via the Commissioning Secretary Hillingdon PCT) brought to my attention information about ReFacto, one of the leading recombinant Factor VIII products. His concerns were about warnings in the new German product information which had not been carried through into the English text version concerning the risk of immunogenicity and loss of efficacy, with a potential knock on effect on the costs of the expansion of recombinant products. **[WITN4505282]; [DHSC0004285_023]**. I forwarded Prof Savidge's concerns to Dr Tsang in the MCA, seeking information on whether there was any substance in Prof Savidge's concern that the product might be removed from the market by the MCA. On 11 December 2002, Dr Hill wrote to me on recombinant Factor VIIa but he also provided further information on the issue raised by Prof Savidge **[HCDO0000266_038].** See further the response I received from Dr Cook of the MCA on 17 December 2002 **[DHSC0004285_019]** which confirmed that the issues raised in Prof Savidge's

letter were already known to the licensing authority and were the subject of a variation to the license, approved by all EU states via the centralised procedure.

4.93. On 17 December 2002, I was alerted by Hazel Blears' Private Office to a call from Michael Connarty, Chair of the All Party Parliamentary Group on Haemophilia, who had advised of a report coming out putting England and Wales bottom of the table for the availability of recombinant products in 17 developed countries, and seeking an Early Day Motion on the issue **[WITN4505283]**.

4.94. On 18 December 2002, I hosted a meeting convened by the Department to discuss issues that could affect the cost of the extension of recombinant treatment. The other attendees were Mr Kemsley (Pan Thames Haemophilia Consortium); Ms Pappenheim (Haemophilia Society); Mr Stokoe (NHS Purchasing and Supply Agency); Prof Hill (UKHCDO), Dr Schonfield (Pan Thames Haemophilia Consortium) and Prof Savidge (Guys and St Thomas's and Kings College London). The minutes **[WITN4505284]** record that I closed the meeting with the following recommendations:

"•*a funding decision will be made in January 2003.*

• *should funding become available, recombinant factor VIII should be offered to the 21-30 year age group first.*

• *define the data required to facilitate the process and set in place appropriate steps to secure such data.*

• *ascertain appropriate market research and surveillance data.*

• *recalculate revalidated data on possible patient use of recombinant factor VIII, ensuring that consideration is given to those adult patients who do not wish to use the recombinant products.*

• *determine the position in Scotland and, if possible, secure their purchase figures.*

• *no date for a further meeting or its composition were arranged"*

I also provided a detailed note on this meeting for Dr King and Jill Taylor **[DHSC0004591_050]**. I noted that the figures used in the SR 20002 would now be out of date and required reassessment, although there were grounds to

consider that the costs would not be anything like as high as Prof Savidge's own figures. I was awaiting data on current usage from the UKHCDO and Dr Schonfield. I was keen to update the departmental calculations before any Ministerial announcement. I stressed the importance of solid data and forward modelling to the success of the phasing strategy. I noted the risks of the allocation of funds on a capitation basis but also the need to avoid the process of Trusts bidding for resources for recombinants as had happened in 1998/9. I made clear that the Department would set up an informal working party to work through the complexities collaboratively if the funding was made available to extend recombinant treatment. The extension of the decision into January 2003 would have been because the Spending Review outcome was not yet available.

4.95. On 17 December 2002, Jill Taylor from my team was asked to provide briefing for the Prime Minister's Office surrounding the purchase of LRI ahead of Prime Minister's Questions the following day, and I provided lines to take for a private notice question on haemophilia and recombinants. The Prime Minister answered a question from Jim Dobbin about recombinants. **[DHSC0004568_051; DHSC0004568_019; WITN4505285; DHSC0004568_050]**.

4.96. There was also an Independent on Sunday article which raised previous incidents in which LRI subsidiaries had had to withdraw plasma, and which argued for the wider introduction of recombinants. Commenting on the article to departmental colleagues, I advised of likely ongoing press interest and asked for the facts behind the specific recalls that had been mentioned in the piece **[DHSC0004568_013]**.

4.97. On 24 December 2002, Dr Winter (again in his capacity of Co-Chairman of the Haemophilia Alliance) wrote to the CMO, Sir Liam Donaldson, raising the distress caused to adult haemophiliacs by the concern over transmission of as-yet unknown infectious agents in plasma-derived clotting factors. He accepted that there should be phasing in over at least three years, and sought re-

assurance that a decision on this matter would not be further delayed [**DHSC0004285_009**].

Recombinants developments in 2003

4.98. At the start of 2003, we were involved in providing briefing to Lord Hunt for a starred PQ from Lord Morris on help for those infected by HCV from blood products. I noted to Dr King that there would be nothing new to announce in this area unless the decision on recombinants was made before the answer was due on 13 January 2003. [**WITN4505286; WITN4505287**]. There had also been letters to the Times during the Christmas break, one being from Dr Winter who argued that, "*Anything other than a rapid extension of recombinant to adults as well as children will represent an endorsement of postcode prescribing in its most shameful form.*" [**WITN4505288**]. In commenting that Dr Winter was "stirring things up" on recombinants, I made clear to my colleagues Dr King, Jill Taylor and Zubeda Seedat that the one thing we knew would not happen was a, "rapid extension of recombinants to adults". That was so for the dual reasons that funding would need to be phased, and because of the supply issue. Indeed, in his earlier letter to the CMO, Dr Winter himself had recognised that there would need to be phasing over a few years.

4.99. On 6 January 2003, I minuted Dr Troop responding to a minute from Peter Coates on the future of BPL [**DHSC0004381_022**]. I was supportive of the need for further strategic study of BPL. I noted that it was not "*…heading down the road of synthetics …"* with one exception and that, "*Even if the UK goes over to 100% recombinant F8 in the next 5 years or so, there will still be a considerable market for high quality plasma-derived products in many parts of the world. Other products in development are a Fibrin Sealant (2005) and a recombinant Anti D immunoglobulin which is about to enter early clinical trials. BPL's major contract fractionation deal to supply Fibrin Sealant for sale in the US also goes live in 2004.*"

4.100. On 9 January 2003, Sir Liam Donaldson replied to Dr Winter's letter of 24 December **[WITN4505289]**. I provided a draft reply and minute to the CMO in relation to this. With the Spending Review result being imminent, the CMO replied to Dr Winter that,

> *"I can assure you that the Department of Health is giving very careful consideration to this important issue and that a decision on funding will be made within the next few weeks. If funding is provided, we will involve the Haemophilia Alliance closely in decisions on a phased transition.*
>
> *I will write to you again when a decision is taken."*

4.101. In my minute to the CMO on this response **[WITN4505290]**, I noted that if the funding was provided, a good deal of work would be needed to agree a workable phasing strategy. I noted that:

> "3. *There is a bid for SR2002 central funding - for £13m/£22m/£53.5m - to provide recombinant clotting factors for all haemophilia patients. As far as I know this still survives. As the usage and price of these products are rising year on year, this funding will probably be insufficient to complete the transition by the end of 2005/06 and I strongly suspect that further funding to complete phasing will be needed in the next SR round.*
>
> *4. If funding is provided, a good deal of work will be needed to agree a workable phasing strategy and the appropriate allocation of resources to PCTs. To achieve this and to obtain full stakeholder support we will need to work closely with the Alliance, PASA and NHS haemophilia commissioners. Haemophilia commissioners are already struggling to meet existing haemophilia treatment costs and careful targeting of recombinant funding will therefore be essential."*

4.102. On 10 January 2003, I was sent a short letter with figures from the manufacturer Wyeth **[DHSC0004285_005]** suggesting (in contrast to Prof Savidge's calculations) that the Department's costing of the extension of recombinant treatment was reasonably accurate.

4.103. On 28 January 2003, Dr Hill wrote to all Haemophilia Centre Directors to survey the current treatment types and usage so that there could be better data to inform recombinant funding (if granted) [**WITN4505291**]. He wrote:

> "*Charles Lister at the Department of Health is anxious that we have accurate data in order to ensure that if the Minister of Health agrees to this funding, it will be sufficient to allow all patients who choose to have recombinant products, rather than plasma products, to have their choice provided. Such funding is likely to be phased and we must ensure that there will be no shortfall.*"

4.104. On 3 February 2003, I minuted Hazel Blears' Private Office [] [**DHSC0042275_075; WITN4505292**]. I noted that while a final decision on central budgets might still be a few days off, the areas where Mr Milburn had queries did not include recombinants, and that the amount of money granted for recombinants over the three years covered by the 2002 spending review was £88 million phased as £13m - £21.7m - £53.4m. Against that background, we were discussing the possibility of pressing ahead with the announcement on recombinants before final agreement on other areas of DH central budgets and before the Parliamentary recess, given the pressure from the All Party Parliamentary Group and the need to get working on the implementation stage. I provided a draft note for Hazel Blears to provide to Mr Milburn to raise this possibility, noting that the Department's credibility was wearing thin given that an announcement had earlier been promised before the New Year. The note was put to Mr Milburn whose office responded to the effect that the Secretary of State was content for the announcement to be made the following week.

4.105. I was then able to inform Dr King that the announcement would be made on 12 February and that Hazel Blears would be meeting Mr Connarty MP that day, noting also the need for us 'swing into action' with the planned implementation group. I noted to Dr King that I had held a meeting with the Haemophilia Commissioners which had been useful and who were grateful for the

collaborative approach the Department had taken [**DHSC0042275_073; WITN4505294; WITN4505295**].

4.106. As was usual for an announcement of this kind, there was then a lot of work with colleagues in preparing briefing and the mechanics of the announcement to ensure that interested groups and interested MPs were properly informed of the decision, see for example: [**WITN4505296; DHSC0020876_035; DHSC0020876_034; WITN4505297; DHSC0004591_022; WITN4505298; WITN4505299; WITN4505300**].

4.107. The formal announcement [**WITN4505301**] was then made on 12 February 2003 by Hazel Blears by a written Ministerial statement:

> *"I am pleased to announce today that the Government have invested an extra £88 million over the next three years to provide recombinant clotting factors for haemophilia patients in England. Haemophilia patients up to age 21 are already receiving these products. The extra funding will extend the availability of recombinant clotting factors to adult patients.*
>
> *Over the next few months the Government will work with key stakeholders, including the Haemophilia Society, clinicians and primary care trusts, to design a programme for rolling out access to recombinant products to older age groups. This roll out will take time to achieve because of the large volume of product involved. However, by March 2006 the vast majority of haemophilia patients should be receiving recombinant clotting factors.*
>
> *We have taken a number of steps to make clotting factors used to treat people with haemophilia as safe as possible. We hope this extra £88 million will ultimately give all haemophilia patients access to synthetic treatments, where these are recommended by clinicians."*

4.108. A similar announcement was made in the House of Lords in a written answer from the Minister Lord Hunt to Lord Morris. There was also a press release the same day **[WITN4505302; DHSC0020876_022]** and the decision was referred to by the Prime Minister in PMQs that day:

> *"Mr. Michael Connarty (Falkirk, East): I apologise to the Prime Minister for distracting him from international matters, but he is aware of the campaign that has been run by the all-party group for haemophilia and the Haemophilia Society to get recombinant treatment for all haemophiliacs in the United Kingdom. Can he inform the House whether the Government have reached a decision and, if so, what it is?*
>
> *The Prime Minister: My hon. Friend raises a very important issue, and he will be aware that the Government have now allocated just under £90 million for synthetic clotting factors to help those with the condition of haemophilia. That will be rolled out across the country in the months to come, and it will make a considerable difference to the treatment of that condition throughout the country."*

4.109. On the same day, 12 February 2003, Dr Hay in his role as Vice Chairman UKHCDO wrote to Haemophilia Centre Directors concerning the allocation of funding. He copied in a number of interested organisations including the Department (via me) and the Haemophilia Society **[WITN4505303]**. Dr Hay allowed me to see a draft of the letter and I had been able to provide some suggested changes **[DHSC0020876_047]** and **[HCDO0000109_038]**. This was indicative of the collaborative approach I adopted with the interested bodies (including the UKHCDO and the Haemophilia Society) to make the roll out work effectively.

4.110. In the finalised letter, Dr Hay wrote:

> *"You should, by now, have received a copy of the Department of Health press-release describing today's announcement to Parliament regarding the new funding for recombinant clotting factors in England.*

It has been decided to allocate £88M in total, over 3 years, to enable a staged change of English patients from plasma-derived to recombinant factor VIII and IX. This is very good news, but roiling out the changeover is likely to be complicated. The allocation is very much back-loaded. £13M will be made available in the financial year 2003/2004, £21.7M in the financial year 2004/2005 and £53.4M in the financial year 2005/2006. It is anticipated that most patients with haemophilia A and B will be using recombinant factor VIII/IX by March 2006. The D.O.H. anticipates that the complete roll-out will take at least four years.

The Department of Health recognises that £88M may be inadequate for all patients to make this changeover and it is likely that tough negotiation with purchasers will still be required before all patients are changed to recombinant factor VIII/IX. The D.O.H. also recognises that, once the allocation is distributed to P.C.T.'s, many of which are currently overspent, there is a danger that the money might be used for other purposes. They will therefore be giving careful thought to how the funds are allocated so that this risk is avoided.

A working party will be formed by the D.O.H. to devise an orderly strategy for changing patients over to recombinant This working party will include representatives from the D.O.H., UKHCDO, purchasers, the NHS Purchasing and Supplies Agency and the Haemophilia Society. It is anticipated that patients will be changed to recombinant FVIII/IX in age bands yet to be decided, but starting with those in their 20's as soon in the forthcoming financial year as possible. This working party will also consider increasing access to rVIIa (Novoseven, Nova). This working party will need to confer urgently because most centres are already at an advanced stage in their contractual negotiations for the next financial year, and will require further guidance to amend their contracts.

Although the broad details of this agreement have been widely anticipated, many patients will be disappointed because it is likely that

most patients currently using plasma derived FVIII/IX will not be changed to recombinant until 2005/2006. Patients should be made aware of this so that they have realistic expectations."

4.111. In discussing arrangements over the announcement, I expressed the view to Dr King that I was hopeful that the development over recombinant funding could be used to change the nature of the relationship with the Haemophilia Society **[DHSC0020876_019]**. I had certainly worked hard at building a relationship of trust with Karin Pappenheim who I met frequently. Again this was about DH adopting a more collaborative approach which had been welcomed by stakeholders including the Haemophilia Society. The idea of having a genuinely open discussion about policy on roll out, as opposed to decisions from the centre, was still novel and I remember the Haemophilia Society being surprised and delighted by this.

4.112. Dr Hay also emailed me on the day of the announcement stressing the importance for the working party to meet quite quickly (a concern I shared) and raising some of the issues that would need to be addressed, as he saw them **[HCDO0000109_042]**.

4.113. On 21 February 2003, Peter Stevens of the Macfarlane Trust emailed me **[DHSC0003282_013]**. Welcoming the news on recombinant treatment, he was concerned to understand whether the extra recombinant funding would have any impact on MFT funding. I was able to reply the same day, indicating that I had no reason to think that the recombinant decision would impact on MFT funding and that the Minister (Hazel Blears) was likely to treat them as separate issues.

4.114. On 5 March 2003, I sought the views of Gail Nolan as to which groups should be involved in the decision on how to allocate the new recombinant funds. **[DHSC0004591_010]**. Zubeda Seedat from my team sent out preliminary enquiries to potential working party members, see for example

[**DHSC0004295_134**], and later a draft remit for the group and agenda for the first meeting [**DHSC0004295_134; WITN4505305; WITN4505304**].

4.115. I then chaired the first meeting of the Recombinant Clotting Factors Working Group on 19 March 2003 [**WITN4505306**]. The other attendees were:

- *Chris Hodgson* *Haemophilia Society*
- *Karin Pappenheim* *Haemophilia Society*
- *Dr Frank Hill* *UKHCDO*
- *Dr Charles Hay* *UKHCDO*
- *Christine Harrington* *RCN Haemophilia Nurses Association*
- *David Kemsley* *London & SE Haemophilia Consortium*
- *Dr Susan Schonfield* *Croydon PCT*
- *Mick O'Donnell* *Haemophilia Commissioner — West Midlands*
- *Neil Brent* *South Gloucestershire PCT*
- *Mike Maunder* *Haemophilia Commissioner — North Tyneside*
- *Steve Davies* *NHS Purchasing & Supply Agency*
- *Howard Stokoe* *NHS Purchasing & Supply Agency*
- *Zubeda Seedat* *Department of Health*

My recollection is that we brought in one or two patient representatives for later meetings of the group, and I can see that GRO-A was invited to the second meeting, and attended the third meeting, in that capacity [**WITN4505307**] [**WITN4505308**].

4.116. The minutes summarise the overview and objectives for the meeting as follows:

> *"5. Charles Lister said the money announced in February was to provide patients with recombinant Factor VIII, IX and, where clinically indicated, VIIa. It was unclear whether the funding allocated would be sufficient to place all patients on recombinant by 2005/06 given rising usage and uncertainties around the pricing of third generation products. Any*

additional funding required from 2006/07 to complete the transition would need to be considered in the context of the next spending review.

6. The aim of the meeting was to identify the issues that needed to be resolved in order to arrive at a phasing strategy; to take at least a preliminary view on as many of these issues as possible; to identify data requirements and to agree an action plan. The final recommendations of the Group would have to be agreed with DH Central Finance and with Ministers."

4.117. On 27 March 2003, Zudeda Seedat from my team provided a short summary of Blood Policy Team issues for a planned meeting between the CMO and Hazel Blears. On recombinants, this stated that,

" … we are working with key stakeholders including the Haemophilia Society, clinicians, Primary Care Trusts and others to put in place a strategy to implement the availability of Recombinant Clotting Factors. An extra £88m is available over three years. The first meeting of the Working Group was on 19 March 2003".

4.118. On 9 April 2003, Zubeda Seedat circulated to the Working Group discussion papers on funding allocation options and patient priority order [pg. 850]; [**WITN4505309; WITN4505310**]. The second meeting of the Working Group took place the following day, 10 April 2003 (the minutes erroneously record 11 April) [**HCDO0000111_154**]. The meeting discussed patient priority order; national contracting; allocation of funds to PCTS; data collection; and the planned DH guidance. On 16 April 2003, in accordance with the discussions at the second meeting, I sought agreement from PASA to the use of the accelerated tendering process for a national contract for recombinants.

4.119. On 25 April 2003, there was a quarterly meeting between DH and Specialist Commissioning Groups [**WITN4505311**]. I reported on Haemophilia Services to this meeting and the minutes record:

"Charles Lister from the DH reported on the additional central funding agreed under the Spending Review for haemophilia services and specifically recombinant clotting factors (£13m in 2003/04, £21m in 2004/05 and £53m in 2005/06). Three issues had to be addressed: organising the prioritisation of patients to receive recombinant factors (ie from the youngest to the eldest); deciding on the criteria for allocation of funding to PCTs (ie capitation versus actual patient numbers in each PCT); and agreeing the purchasing mechanism for the clotting factors. Charles reported it has been decided that there will be national contracting via PASA in Years 1, 2 and 3 for clotting factors purchased by the additional funding and by Year 4 for all clotting factors; the additional funding will be included in PCTs' overall allocation; and funding will be on the basis of actual patient numbers. Consequently a data collection exercise is being carried out on existing caseload by PCT.

Paul Maubach from West Midlands SCG reported that PASA was conducting an audit of existing clotting factor contracts and their expiry dates to see if the programme for national contracting of all clotting factors could commence earlier than Year 4.

Commissioners agreed that they supported the national framework approach and asked to be involved in the validation of the data.

Commissioners were concerned about wastage of clotting factors and the need for measures to tackle this problem.

Agreed action:

To give lead commissioners' names to Charles Lister, so data collection can be validated by SCGs. (Julia Stallibrass)"

4.120. On 28 April 2003, Dr Hill wrote to me covering a report on the UKHCDO's case for requesting DH funding for the National Haemophilia Database [**HCDO0000111_064**]. The need for the database to address issues relating to the roll out of recombinants was part of the case being made by the UKHCDO for DH funding.

4.121. Also on 28 April 2003, I circulated to the Working Group a revised statement on patient priority order [**WITN4505312; WITN4505313**].

4.122. On 29 April 2003, I sent Drs Hill and Hay of the UKHCDO a note on the proposed national contract framework for recombinants, noting that the Special Commissioning Groups wanted to be able to validate the data provided from centres to the UKHCDO [**WITN4505314**].

4.123. The DH records include some handover notes [**WITN4505315**] which I prepared for my successor Richard Gutowski. On Recombinant Clotting Factors, my notes explained that:

> *"We have £88m over the next three years to roll out recombinant clotting factors for haemophilia patients still receiving plasma derived products (largely those over age 21/22). I have set up a working group with all the stakeholders to help the department agree a phasing strategy. This has met three times so far. You will need to take over the Chair of this. The next meeting would have been on 10 July but this clashes with the Commission's meeting on the Directive. Zubeda was trying to rearrange.*
>
> *Information on the group — remit, membership, minutes etc are on the DH website ….*
>
> *Again, it's probably easiest if I bring you up to date on where we have got to - and what needs to happen next - by phone."*

4.124. The Third meeting of the Working Group was held on 13 May 2003, and this was the last meeting I chaired before leaving my blood policy post [pg. 919];

[**WITN4505308**]. The minutes cover the various areas discussed, but one area raised was the funding of the UKHCDO database. The possibility was raised of the recombinant funds being used to fund a project manager post to enable UKHCDO to manage and audit the data required for the recombinant roll-out programme. Following up on this, on 14 May 2003, I indicated to Dr Hay that – subject to formal confirmation – DH could agree to fund the post for the next year (this would have been by top slicing from the recombinant budget) [**WITN4505316**].

4.125. On 15 May 2003, Dr Hill offered to put together some further short papers for the Working Group to help develop a framework on which to put timescales for achievement [**DHSC0004295_052**]. I also forwarded to Drs Hill and Hay a question that had been raised about confusion over how those who had missed the 16 year old provision in 1998 and were now 21 – 22 years old, should be prioritised in the roll – out of wider recombinant provision [**WITN4505317**].

4.126. On 19 May 2003, I moved to a new post so this was effectively the end of my involvement with recombinant issues in the Department.

CONTENTS

SECTION 5: THE ALLIANCE HOUSE ORGANISATIONS

5.1. Reflecting on the areas raised in the Rule 9 request, I have divided this section of my statement into:

- 5(A):The Working Relationship between the Alliance House Organisations and the Department
- 5(B): The Appointment of Trustees
- 5(C): Funding the AHOs
- 5(D): Department of Health Input into AHO Policy and Decision Making

5(A) THE WORKING RELATIONSHIP BETWEEN THE ALLIANCE HOUSE ORGANISATIONS AND THE DEPARTMENT

5.2. I am asked how I would describe the working relationship between the Alliance House Organisations ('AHOs') and the Department during my time there. I am also asked about the obligations on the AHOs to report to the Department, whether the Department considered the AHOs to be independent of Government, and whether it was acceptable to the Department for the AHOs to campaign for a change in government policy to benefit their beneficiaries.

5.3. One of my roles as Head of Blood Policy was to be the main contact in the Department for the AHOs. At the time this was mainly the Macfarlane Trust and Eileen Trust, although issues occasionally arose in relation to the Macfarlane (Special Payments) Trusts.

5.4. I would say the working relationship between the Department and the Trusts during my time there was very good to excellent. Ann Hithersay, the Chief Executive of both the Macfarlane and Eileen Trusts at the time, and I were in regular contact and maintained a cordial, professional relationship. I also had a very good relationship with Peter Stevens when he became Chair. My aim was for an open and collaborative relationship and I believe we achieved that.

5.5. However, relationships were strained at times, particularly during 1999 and 2000, when my team and I were under particular pressure and under resourced. At times, the needs of the AHOs regrettably took less priority than other more immediate and politically sensitive work. Other work when I first joined the blood team included issues addressed elsewhere in this statement such as measures arising from the then-theoretical risk of vCJD transmission through blood and the 'Better Blood Transfusion' initiative. We also faced the immediate risks of winter blood shortages (we launched the first TV adverts on giving blood around this time) and needed to work closely with the new Chair and Chief Executive of the National Blood Authority to agree priorities and restore Ministers' confidence in the service (as mentioned, the previous Chair had been dismissed by the Secretary of State in 1998 and a new CEO had just taken up appointment at the time I joined the blood team). I should add that I have not seen all the documents relating to the work I was engaged with at this stage, but my clear recollection is of an extremely busy period.

5.6. There were particular delays over the allocation of Section 64 ('S64') funding for the Macfarlane Trust in 1999 and later, which were entirely avoidable and are embarrassing to revisit. We were also very slow in responding to requests on the reappointment of trustees. These delays caused considerable administrative irritation for the AHOs. Later in this statement I have responded to Rule 9 questions that relate to these issues.

5.7. As far as I can recall there were no formal reporting obligations between the AHOs and the Department. There was nothing equivalent to the formal Annual Accountability Reviews we had with the National Blood Authority. However, there were regular meetings between my team, Ann Hithersay and the Chairman at which a range of issues were discussed. These meetings sometimes included others from the AHOs, such as the Finance Director. Discussions covered both the Macfarlane and Eileen Trusts as appropriate.

5.8. S64 grants, which I explain in more detail later in this statement, were subject to standard conditions. These included, for example, that the recipient of the

S64 grant must provide annual accounts to the Department and the Department could ask for further details about the expenditure of the grant, and that any S64 grant money not spent in the financial year for which it was awarded had to be notified to the Department.

5.9. My recollection, which I think is supported by the documents I have seen, is that the meetings were fairly ad hoc to begin with but in late 2001 or perhaps 2002 more regular catch up meetings were established. I recall that these massively improved communication and ensured that issues were not left hanging.

5.10. I have seen a note of a meeting between Departmental officials and the Macfarlane Trust on 14 June 1999, which records an intention that: *"Regular meetings to be held between Trust and DH three times a year and ad hoc as necessary. A year's meetings to be arranged shortly."* I now do not think the meetings happened in this regular way until later, when the slight increase in numbers on my staff team made this practicable [WITN4505318 and WITN4505319]. There are two very similar versions of this meeting note. I cannot explain why. I do not know who wrote the notes.

5.11. To the best of my recollection, meetings would have been minuted by my team. This was certainly the case from December 2001 because I recognise the 'house style'. The minutes prepared by my team would have been shared with the relevant Trust.

5.12. The Chair and Chief Executive of the Trusts also met Ministers from time to time, either at their request or ours. Those meetings would often have been preceded by a meeting with Department officials. There was no fixed process for scheduling meetings with Ministers. We had four different Ministers during the five years I was involved, so the process was inevitably rather ad hoc.

5.13. The deeds for the Macfarlane and Eileen Trusts gave the Trusts independence in how each exercised its charitable objects and also set out the discretionary powers of the trustees. Operationally they were independent of government and

I always viewed them as such. There was however, an accountability relationship with the Department as the sole funder of the AHOs. I recall this being fairly light touch.

5.14. I do not recall there being a framework document that set out the relationship between the Trusts and the Department. I am however happy to comment on it if one emerges. I will therefore try to describe the relationship as I understood it at the time.

5.15. First and foremost, as charities the Trusts were subject to regulation by the Charity Commission. As with any charity, it was the role of trustees to ensure compliance with its governing document (the Macfarlane and Eileen Trust Deeds), to comply with charity law and to act in the charity's best interest to manage the charity's resources responsibly and to be accountable to those with an interest in the charity, including beneficiaries and funders. The Charity Commission's publication '*The Essential Trustee: what you need to know, what you need to do*'[1] states (in the current edition) that charity trustee duties include:

> ***"9.2 Being accountable to people with an interest in the charity***
> *It's important to take account of what your members, beneficiaries, supporters and funders say. Use this information to inform decisions and improve the charity's services."*

5.16. As Ministers had established the Trusts, and as the Department was the sole source of funding, there was a natural accountability relationship between Ministers, officials and the senior leadership of the Trusts. As is apparent from the principles referred to above, it is both conventional and appropriate that a charity should take account of what its funders say, and here the government was sole funder. This is, I believe, an important part of background context to the relationship between the AHOs and government. Given the government's legitimate role and interest as sole funder, it would be wrong to view discussions and a degree of consultation between the AHOs and government as indicative

[1] WITN4505320

of a lack of independence. That is not to exclude the obvious importance of the charity's beneficiaries.

5.17. It was very much a two-way relationship. My aim was to achieve trust, openness and mutual support. Whether we always achieved that is another matter.

5.18. For me, the purpose of the relationship was to achieve assurance that the Trusts were carrying out their functions as intended, meeting their aims and being disciplined in the way they managed the 'top up' funding provided by the Department. I was also keen to understand the challenges being faced by the Trusts and to be as supportive as possible.

5.19. Underlying all of this was my awareness of the principles for managing public resources set out in the Treasury's document *Managing Public Money*[2] , the standards expected of all public services:

> *…honesty impartiality openness accountability accuracy fairness integrity transparency objectivity reliability carried out in the spirit of, as well as to the letter of, the law in the public interest to high ethical standards achieving value for money".*

I am quoting here from the current version, but these fundamental principles were very much in place during my time in the blood team.

5.20. As the evidence shows, one of my main concerns was to stress the need for the Macfarlane Trust to manage within the budgets set by the Department. These were based on the Trust's own estimates of future spend. Within that, decisions on how to spend the funds allocated were for trustees to take. I was occasionally asked for an opinion on proposed new areas of spend. But ultimately these decisions were for the trustees alone.

5.21. From my experience as a trustee on the board of other charities, any funder – whether in the public or private sector - will expect assurance that grants were

[2] WITN4505321

spent for the purposes intended and funders will often set performance or outcomes targets for the charity to meet. There will inevitably be some form of formal reporting requirement back to the funder. In my opinion and based on my experience as a board member of other charities, the Department was light-touch with the Macfarlane and Eileen Trusts.

5.22. Over the latter part of my involvement with the Trusts my concern was to give the Trusts greater clarity on future funding but within a cash limited framework. This was achieved by early 2003, with the announcement of the outcome of the 2002 Spending Review.

5.23. To my knowledge there was nothing to prevent the Trusts from campaigning/ or lobbying the Department for changes in government policy to benefit beneficiaries. On the other hand, the Trust's objects did not include any specific remit to campaign or lobby publicly.

5.24. I do not recall the Macfarlane or Eileen Trusts campaigning or lobbying for a change in government policy in my time. Nor did they raise with me any suggestion that they wished to campaign or lobby. It is impossible for me now to say what the Department's reaction would have been had either Trust done so. We certainly gave no direction or advice on this issue during my time.

5.25. The Trusts sought additional funding at various times and made a case for this, but that was not done publicly and did not amount to campaigning or lobbying.

5(B) THE APPOINTMENT OF TRUSTEES

5.26. I am asked what I knew about the appointment process for the AHOs during my time at the Department, what involvement I and the Department had in this process, how the Department selected the candidates it put forward as trustees, and whether those positions were advertised (and if so, where).

5.27. I no longer have any detailed recollection of the formal requirements for appointing trustees and so am relying on the documents I have seen.

Macfarlane Trust: General Provisions on Trustee Appointments

5.28. The Macfarlane Trust deed, dated 10 March 1988 [WITN4505322], provided for the appointment of ten trustees, "*…of whom four shall have been appointed by the Secretary of State for Social Services ("the DHSS Trustees") and six shall have been appointed by the Executive Committee ("the Society Trustees"). Of the DHSS Trustees one shall be a Haemophilia Reference Centre Director and one a Haemophilia Centre Social Worker*"

5.29. I am aware that the deed was varied on a number of occasions but I understand the above provision continued to apply over the period I am giving evidence about.

5.30. I have seen a document with the title "*APPOINTMENTS PROTOCOL for the appointment and reappointment of Trustees to the Macfarlane Trust Macfarlane Special Payments Trusts and Eileen Trust*" (the 'Protocol') which was agreed between the Department and the Macfarlane and Eileen Trusts in March 1996 [EILN0000009_099].

5.31. This was written and agreed before my time in the blood policy team but it appears the document seeks to set out, in one place, provisions that were contained in the relevant trust deeds, subsequent agreements between the Department and relevant trusts, and what happened in practice. I would have been aware of the Protocol at the time but do not now have any specific recollection of what it contained.

5.32. I can see the Protocol states that the Haemophilia Society may recommend names to the Secretary of State to fill the appointments which were "*…earmarked for a Centre Director and Centre Social Worker/ Counsellor*" and that, "*In exercising the option to make nominations…the Haemophilia Society by virtue of its regular contact with Centres will identify potential Trustees who*

may be able and willing to be appointed and will then pass the nomination to the Department of Health not less than 3 months before the date (re)appointment is due."

5.33. The Protocol also included:

"***Procedure for Appointment/ Reappointment***

The Macfarlane Trust has per se no responsibility or rights in this matter, but in the interests of smooth running of the Trust and continuity of control will monitor the programme and make suggestions or reminders, and will be happy to assist as needed."

To the best of my recollection, it was standard practice for the Trust to make suggestions and contribute to the process. One example of this, to which I will return below, is the Macfarlane trustees positively advocating for one of the Secretary of State-nominated trustees to continue to be a former civil servant, because they valued the experience that such trustees brought.

5.34. The Protocol (and the Macfarlane Trust deed) also stated that the tenure of trustees was "*Not exceeding two years at a time*" and that trustees could be re-appointed. However, the Protocol records the Secretary of State's intention that the Haemophilia Centre Director's and social worker's appointment should not exceed two terms except as an emergency measure and also that the appointments should be rotated around the areas of the UK. According to the Protocol this intention was stated in letters from the Department in 1995. The objective of rotating appointments around areas of the UK was not an issue I recall arising in my time but I was recommended to limit the number of reappointments to the position of trustee which in my experience was relatively standard practice.

5.35. The Macfarlane Trust Strategic Review interim report, dated July 1998, states that in practice most Haemophilia Society appointed trustees had served for at least two terms of office [MACF0000174_030].

5.36. The Trustees appointed a Chairman and Deputy Chairman.

Eileen Trust: General Provisions on Trustee Appointments

5.37. The Eileen Trust deed, dated 29 March 1993, provided that there should be five trustees and "*THE POWER of appointing new Trustees to complete the complement of five or to fill any subsequent vacancy shall be vested in the Secretary of State for Health who may exercise her power by writing under her hand.*" (cl 9(e)). [WITN4505323]

5.38. The Protocol stated, relying on a letter from the Department dated 29 March 1993, that:

> *"For as long as Eileen Trust is hosted by the Macfarlane Trust, 3 of the Trustees will be nominated by the Macfarlane Trust, and at least one of these will be a Secretary of State's appointee to the Macfarlane Trust."*

5.39. The Protocol also stated, relying on "*usage*":

> "*Normally all three of these nominees will be Macfarlane Trustees, thus ensuring common experience between the two Trusts. As a general rule, the second will be the Centre Director (to provide medical advice) and the third a Haemophilia Society appointee to the Macfarlane Trust.*"

5.40. The deed also stated: "*A TRUSTEE shall hold office for a period not exceeding three years but shall be eligible for reappointment.*" (cl9(b)). This was supplemented by the Protocol which suggested that the Macfarlane Trust trustees sitting also as Eileen Trust trustees should be re-appointed on a two year basis to coincide with their Macfarlane Trust tenure.

5.41. Thus, the Secretary of State appointed all five trustees to the Eileen Trust. Three of those five were nominated by the Macfarlane Trust and the other two were nominated by the Department/ Secretary of State. This was in contrast to the Macfarlane Trust deed, under which the Secretary of State appointed four trustees and the Haemophilia Society appointed six trustees.

Macfarlane (Special Payments) Trusts: General Provisions on Appointment of Trustees

5.42. For completeness, the Macfarlane (Special Payments) Trust provided that:

> "*10. (a) THE number of Trustees hereof shall insofar as may be practicable be maintained at five in number of whom two shall be appointed by the Secretary of State for Health ("the DH Trustees") and three shall be appointed by the trustees for the time being of the said charity known as the Macfarlane Trust ("the Macfarlane Trustees")*" [MACF0000003_058].

5.43. The provisions for the Macfarlane (Special Payments) (No. 2) Trust were the same, see cl 31 [MACF0000083_004].

5.44. In relation to both the Special Payments Trusts the Protocol added:

> "*Historically all Trustees were appointed from the Trustees of the Macfarlane Trust, and although not a legal requirement this should probably be regarded as best practice.*
> *Historically also the same Trustees have served both Trusts and this remains good practice since there is a degree of overlap in the terms of eligibility which have to be proved by potential beneficiaries, and hence, for any new cases arising, work of both Trusts can often be done in parallel.*"

Process of Appointment

5.45. I was aware of the appointments process while I was in role. I was involved in the identification of candidates and making recommendations to Ministers on potential appointments. The chronology below explains my role further, along with the involvement I and the Department had in the process for appointing trustees.

5.46. I would have known how the appointment process worked at the time, as I and my team were responsible for the administrative side of appointments within the Department. I do not now have a good recollection of how the Department selected the candidates it put forward as trustees for the AHOs. However, I prepared a submission for the Parliamentary Under-Secretary, Lord Hunt, dated 27 March 2000 on the appointment of trustees to the Macfarlane and Eileen Trusts. The submissions assists with the position at that time. [DHSC0003434_004 and WITN4505324]. I wrote then:

> "*We are aware that Ministers wish trustee appointments to be made in line with Nolan principles, including the advertising of vacancies. However, in the case of the Macfarlane and Eileen Trusts, this has not been done to date for reasons of proportionality:*
>
> • *trustee appointments are part-time and are unpaid apart from expenses;*
>
> • *two of the four appointments to the Macfarlane Trust have to be a Haemophilia Centre Director and social worker, which limits the field considerably. By convention, we consult the Haemophilia Society on these appointments;*
>
> • *the other appointments to the Trust have been retired senior civil servants. The Trust has recently said that they would like this arrangement to continue, as they value the experience these people can bring. The Cabinet Office maintains a list of retired civil servants interested in serving on public bodies, and we propose to continue using this list to identify potential trustees, if you are content.*"

5.47. I am referring here to the fact that vacancies were not advertised publicly so did not meet the principles of openness and transparency.

5.48. I have not seen a response to this submission from Lord Hunt.

5.49. I have seen a note of a meeting between the Department and the Macfarlane Trust on 5 April 2001. This note was prepared by the Macfarlane Trust and

appears to have been for the trustees. The note states at paragraph 3 'Trustee Appointments': [MACF0000006_019]

> "*Charles Lister explained that all potential candidates for trustees would need to be screened using Nolan Committee principles. Letters had been sent to all recently retired senior civil servants including those who had taken early retirement.*"

5.50. I have also seen a copy of minutes from a meeting of the Macfarlane Trust board on 24 April 2001 [MACF0000006_003]. This refers to the Department's meeting with the Trust on 5 April 2001 and at paragraph 01.18 says:

> "*The issue of new Trustees was also raised and Charles Lister…had explained that Nolan principles were to be used in making Trustee appointments in future. Notification of the need for two new Trustees had been circulated to recently retired senior Department staff. The appointment process would include panel interviews with short-listed candidates. The Chairman had been invited to participate in the interview process and be a panel member.*"

5.51. The apparent contradiction between my statement about Nolan principles in the submission to Lord Hunt and the record above of my conversations with the Trust is explained by the fact that I was talking to the Trusts about the application of wider Nolan principles aimed at ensuring appointment on merit, for example the inclusion of an independent element on all selection panels. 'Nolan' refers to the recommendations of the Committee on Standards in Public Life (the Nolan Committee) relating to public appointments in July 1995. These were later summarised in the 2002 Code of Practice for Public Appointments published by the Commissioner for Public Appointments (OCPA).

5.52. To the best of my recollection, we did not publicly advertise Trustee vacancies during my time, believing that to do so would be disproportionate for such circumscribed roles. Although I agreed this position with Ministers at the time, I suspect that current standards might require full advertising of the post notwithstanding the narrow pool of candidates. This point was flagged again

with Ministers in a submission of 8 May 2002 by which time the OCPA guidelines had been published [*paragraph 5.91*].

5.53. My submission to Lord Hunt dated 27 March 2000 [DHSC0003434_004], also refers to the Macfarlane Trust wanting the trustees appointed by the Secretary of State to include retired senior civil servants. The same submission says:

> "*5. Of Secretary of State's four appointments to the Macfarlane Trust, the Trust Deed requires one to be a Haemophilia Centre Director…; and one a Haemophilia Centre social worker…The other two are generalists and, at the request of the Trust, have so far been retired senior civil servants…*"

5.54. In preparing this statement I have asked myself whether I ever considered if appointing former Departmental officials meant they may not exercise independence in the interests of the charity or whether there might be the appearance of a lack of independence from the Department. It was certainly not an issue that occurred to me at the time and was never raised by others as a concern, at least not with me. The Chair of the Macfarlane Trust was clear in his preference for former civil servants because of the skills they brought and there was never a suggestion that those we appointed acted other than in the best interests of the charity. I would have been extremely concerned had any such evidence come to light.

5.55. My role in identifying candidates from among former civil servants was to the best of my recollection to simply to elicit expressions of interest. I did this by writing to individuals who had held the right level of seniority (i.e. Deputy Director and above) from a list maintained by the Cabinet Office of retired civil servants looking for public appointments. I conducted no other selection or scrutiny. Those who chose to apply were then subject to a formal selection process, with a shortlisting and final interview. My role was then confined to ensuring that a selection panel was convened and putting the panel's recommendations to Ministers for approval. I cannot recall any circumstance

where Ministers declined to appoint a recommended candidate, whether a Macfarlane Trust nomination or a Secretary of State appointment.

5.56. I give more detail on this below in the chronology.

Difficulties Appointing Trustees

5.57. I am asked about difficulties appointing trustees during my time at the Department. I am referred to a report prepared by the Macfarlane Trust Chief Executive for a board meeting on 3 October 2000 [MACF0000006_060]. That report, which was not written by me (and would not have been seen by me) includes:

> *"7.**Appointment of new Trustees***
> *There remains one vacancy to be filled by The Department of Health, following the appointment of Elizabeth Boyd recently. Charles Lister reported considerable difficulty identifying suitable candidates able to accept the appointment and said that all those approached from a list discussed earlier in the year had not proved possible to appoint. We have suggested a suitable candidate to The Department and have forwarded a CV to Charles Lister this week."*

5.58. I cannot recollect the events leading up to October 2000, in any detail and am reliant on the documents I have seen to try to put together a chronology. The documents I have seen do not explain the reference in the Macfarlane Trust's minutes to difficulty finding suitable candidates. It may well have been that none of those we approached were interested in the role. The wording "*…not proved possible to appoint*" implies that candidates had come forward but had been rejected for some reason. However, that cannot have been the case as we did not to the best of my knowledge, sift candidates before setting up an appointments panel. All I can say, looking back, is the process took longer than it should have done.

5.59. I can see from the documents that on 14 June 1999 I and other Departmental officials met with the Macfarlane Trust. This was in advance of a planned

meeting between the Macfarlane Trust and the Minister on 17 June 1999. As explained above, it appears there are very similar notes of this meeting [WITN4505319 and DHSC0003212_004]. The note at [DHSC0003212_004] records that the Macfarlane Trust expressed concerns about the lack of contact and other issues but was "*reassured this was due to pressure of work rather than politics.*"

5.60. On trustees, the note records: [DHSC0003212_004*]*

> "*Trustee replacements – Pat Winterton – DH to consider whether SoS would be content with a reappointment. Ken Bellamy – DH to obtain names and consult Ministers. Time commitment is about 3 days a month. 4 Trustee meetings a year, plus working groups on strategic review, etc. Proximity to London was important, and Grade 5 calibre needed….*
>
> *Trust Social Worker, Tim Hunt, DH nominated, to become Wales Regional Director of MIND. Need another nominee, propose Elizabeth Boyd from Royal Free. DH to consult Social Work colleagues."*

5.61. Clearly, the Macfarlane Trust was here raising with the Department the need for the Secretary of State to identify and appoint two replacement trustees. I believe Ken Bellamy was a former official. The reference to "*grade 5 calibre needed*" is to the old grade 5 in the civil service, i.e. a retired senior civil servant (nowadays a deputy director). I cannot now say if it was the Macfarlane Trust saying that "*Grade 5 calibre*" was needed but the structure of the note suggests that might have been the case - the Trust would have specified the likely time commitment and that proximity to London was important. Tim Hunt was a social worker.

5.62. On 17 June 1999, Macfarlane Trust representatives met the Parliamentary Under-Secretary, Baroness Hayman. Baroness Hayman wrote to the Macfarlane Trust on 1 July 1999 [DHSC0006162_006] and her letter included:

"There are some residual issues, including full notification of the S.64 grant and the appointment of Trustees, which officials will be completing and discussing with you, consulting Ministers as appropriate."

5.63. On 23 August 1999, Ann Hithersay wrote to me referring to a brief meeting we had the previous week and sending me a specimen job description for a Macfarlane Trust trustee and other information for potential candidates for the Macfarlane and Eileen Trusts [DHSC0006162_077].

5.64. There was a meeting between the Department and the Macfarlane Trust on 12 October 1999. Ann Hithersay wrote to me on 28 October 1999 and her letter included: [DHSC0003209_009]

"(vi) Trustee Replacement

We discussed the replacement of Kenneth Bellamy, who retired last May, and the replacement of Tim Hunt, who resigned with effect from 19th October 1999.

It was agreed that The Department would seek to replace Mr Bellamy with a similarly qualified retired civil servant. Two names were suggested as possible replacements for Tim Hunt.

We look forward to learning who the new Trustees will be and when they are likely to be able to take up their appointments.

(vii) Retirement of the Chairman
The Reverend Alan Tanner, Chairman of the Trust, advised you that he would be retiring with effect from the end of March 2000. The Chairman introduced Mr Peter Stevens as his replacement. Mr Stevens was formally elected Vice Chairman at the Trustees Meeting on 19th October 1999."

5.65. On 4 November 1999, Ann Hithersay wrote to me about the appointment/ re-appointment of Eileen Trust trustees [WITN4505325]. She referred to the provisions of the Protocol and stated that the Macfarlane Trust may nominate three trustees to serve as Eileen Trust trustees, the Secretary of State should nominate the other two, and then the Secretary of State should appoint all five trustees. She explained the present position:

- That the Macfarlane Trust had agreed to nominate Peter Stevens to be the new Chairman of the Eileen Trust (replacing the Reverend Alan Tanner);
- That Dr Winter was also a Macfarlane Trust nomination on the Eileen Trust and had served as such since March 1996. However, he had not been re-appointed in March 1998 (as he should have been) and was due either for re-appointment or retirement in March 2000;
- That "*If Miss Winterton were now to be regarded as a 'Macfarlane nominee', she should be re-appointed from March 1999 to March 2001".* She had been appointed to the Eileen Trust in 1993*;*
- Mrs Susan Phipps had also been a trustee of the Eileen Trust since 1993. She was reappointed in 1996 to serve until 24 June 1999. However she had not received a letter of re-appointment. She was willing to be reappointed with effect from 24 June 1999 to 24 June 2002;
- Mr Kenneth Bellamy had resigned as an Eileen Trust trustee in May 1999 but had yet to be replaced by the Secretary of State.

Therefore Ann Hithersay was raising two distinct issues about the Eileen Trust trustees, namely that some trustees needed to be appointed or formally re-appointed, and that a new trustee needed to be identified by the Department.

5.66. By letter dated 21 January 2000, Ann Hithersay wrote to me about appointments/ reappointments for both the Macfarlane and Eileen Trusts [WITN4505326]. On the Eileen Trust she essentially repeated the information in her letter of 4 November 1999. On the Macfarlane Trust she wrote that:

- Mr Kenneth Bellamy had retired in April 1999 but that vacancy had yet to be filled by the Secretary of State;

- Mr Tim Hunt had resigned in October 1999 and that vacancy should be filled by a Haemophilia Centre Social Worker or counsellor, if at all possible (that vacancy clearly had also not been filled);
- Miss Patricia Winterton's role as a trustee should have been renewed in March 1999 if the Secretary of State wished her to continue as a Macfarlane trustee, Miss Winterton was willing to be reappointed until March 2001;
- Dr Mark Winter should have been reappointed in March 1998 and had not been. The Secretary of State needed to ratify his reappointment to cover the period from March 1998 to March 2000 and then to reappoint him to serve as a trustee from March 2000 to March 2002.

5.67. She also explained that the Secretary of State would need to appoint a replacement trustee for the Macfarlane (Special Payments) Trusts, as Mr Alan Palmer wished to stand down. Ann Hithersay ended her letter with, "*I hope it will be possible for you to advise us on new appointments to all these vacancies before the end of March 2000, please*."

5.68. On 26 January 2000, I met Ann Hithersay. Ann wrote to me about a number of issues on 27 January 2000. Her letter raised serious concerns about the trustees who had been serving on the Macfarlane and Eileen Trust boards but had not been formally re-appointed by the Secretary of State, and included: [DHSC0003211_004].

> ***"Re-appointment of Trustees – Macfarlane and Eileen Trusts***
>
> *When you called, I mentioned that the Eileen Trustees had asked for a view from Paisner & Co about their position as Trustees, in view of their non-appointment to continue as Trustees when their terms of office had expired. I told you that Paisner's view of the situation was that for as long as Trustees continued to carry out their duties as Trustees, they would be deemed under Charity Law to be Trustees, but that public indemnity would probably no longer apply to them, since they had not*

been formally appointed to act as Trustees in accordance with the Trust Deed.

The Trustees were very concerned to learn of this view, and asked me to instruct Paisner & Co to write to the Department immediately to say that assurance must be received that the Department would indemnify the Trustees if public liability did not, when acting as Trustees of either Macfarlane or Eileen Trusts.

The Trustees also asked Paisner & Co to say that if they had not each received re-appointment letters within 14 days of the Department's receipt of such a letter, they would deem themselves no longer appointed to act as Trustees.

I do hope that you will be able to ensure that re-appointment letters are sent to Miss Winterton, Dr Winter and M/s Sue Phipps as quickly as possible, please.

It is also necessary for the Secretary of State to ratify the change of Chairman of both Trusts, for as you know, Alan Tanner will retire at the end of March, and Mr Peter Stevens will become the new Chairman with effect from 1st April 2000."

5.69. On 27 March 2000, I put a submission to Lord Hunt, the Parliamentary Under-Secretary, inviting him to appoint/ ratify the appointment of four trustees of the Macfarlane and Eileen Trusts, "…*three of whom have been exercising this role for some time without being formally appointed*." I have already referred to this submission at §5.46 and §5.53, above. [DHSC0003434_004]

5.70. In the submission, I informed Lord Hunt that:

"4. The Trusts' solicitors have drawn our attention to the fact that the appointment periods of three Eileen Trust trustees – Patricia Winterton, Susan Phipps and Dr Mark Winter – ended as far back as March 1998 without being reappointed or having their reappointments

ratified by the Secretary of State. However, they have continued to carry out their trustee duties. This is a highly regrettable state of affairs which breaches the terms of the Trust Deed and needs to be remedied urgently. Indeed, we have been informed that unless appointments are confirmed by the end of this month, the three will cease to regard themselves as trustees of the Eileen Trust."

(The reference to the end of this month, i.e. March 2000, suggests there probably was further communication with the Trusts about this issue after Ann Hithersay's letter dated 27 January 2000).

5.71. I informed Lord Hunt that Peter Stevens had been nominated as Chair of the Macfarlane and Eileen Trusts and invited him to ratify this.

5.72. I also referred to two vacancies on the Macfarlane Trust board, to replace Mr Kenneth Bellamy and Mr Tim Hunt and wrote, "*...we need to appoint a Haemophilia Centre social worker and a former civil servant. We have identified a candidate for the former post and will be consulting with the Haemophilia Society on this shortly, and we have asked Cabinet Office for a list of suitable candidates for the other.*"

5.73. There was clearly no requirement in the Trust deeds or the Protocol for a "*former civil servant*" to be appointed. When I wrote that I would have been relying on the Macfarlane Trust's express wish to have a former senior civil servant on the board, as the submission states that "*...the other appointments to the Trust have been retired senior civil servants. The Trust has recently said that they would like this arrangement to continue, as they value the experience these people can bring."*

5.74. Lord Hunt approved the proposed reappointments and issued appointment letters immediately. He also wrote to Peter Stevens to appoint him as Chair of the Macfarlane and Eileen Trusts.

5.75. Lord Hunt met with Macfarlane Trust representatives on 18 April 2000. A briefing in advance of that meeting focused mainly on funding for the Trust and the changing needs of registrants but also informed Lord Hunt that there were two trustee vacancies that needed to be filled by Department nominees and officials would be putting a submission to him shortly with recommendations for those appointments [DHSC0003487_005; DHSC0003264_004; DHSC0032415_051; DHSC0003232_007; DHSC0003487_004].

5.76. I have seen a report prepared by Ann Hithersay for the Macfarlane Trust board, dated 23 June 2000, [MACF0000006_102], in which Ann wrote:

> "*We have been advised that it is likely that Elizabeth Boyd from the Royal Free Hospital is likely to be appointed to the 'Social Work' vacancy shortly. Charles Lister has a list of possible retired civil servants to approach about the second vacancy. I have made it clear that we are expecting this vacancy to be filled before the October Trustee Board Meeting.*"

5.77. Elizabeth Boyd was appointed to the Haemophilia Centre social worker trustee role in around September 2000. I can see from [MACF0000006_060] that Ann Hithersay reported to the Macfarlane Trust board on 3 October 2000 that:

> "*There remains one vacancy to be filled by The Department of Health, following the appointment of Elizabeth Boyd recently.*"

(This is the same report as I have been referred to by the Inquiry in which it is recorded I reported considerable difficulty identifying suitable candidates able to accept the appointment).

5.78. This report also referred to the Macfarlane Trust taking advice from the Charity Commission on appointing 'user trustees'. It states:

> "*The Trust has also advised The Department of Health of the likely appointment of user trustees. We have been advised informally that there would be no objection to this, but have requested a statement to this effect in writing.*"

5.79. I don't recall being asked for a view on the appointment of user trustees. Indeed, the wording of the report says that we were advised that this may be happening, not asked for a view. The note that the Department's informal advice was that "*there would be no objection to this*" should not be read as suggesting that the Department might have objected. If I had been asked directly whether the Department would object, I would naturally have said "no" as this was a decision for the Trustees to make within the scope of the Trust Deed. I cannot say why the Trust felt they needed this in writing and I have not seen evidence of whether this was provided.

5.80. As part of the relationship between the Trusts and the Department, I would have expected the Trust to tell me about decisions such as this, so that we were fully informed about changes in the governance of the charity. There was no expectation on my part that the Department should be asked for a view on matters which were within the Trusts' remit to decide. However, I did not see a problem when they occasionally did. I took this as the Trust seeking extra assurance and I did not see providing this on occasions as undermining the independence of the Trust.

5.81. My review of the documents tells me that the outstanding vacancy had not been filled by January 2001. I have seen a copy of Macfarlane Trust board minutes from 23 January 2001 [MACF0000006_013] which record that seven out of ten trustee places were filled at that time. There were two trustee vacancies to be filled by the Haemophilia Society. One of these would be filled by a 'user trustee'. The minutes continue:

> "*The current Government appointed vacancy had existed since the resignation of Mr Bellamy in April 1999. As Miss Winterton was due to stand down as a trustee at the end of March, the Department had been alerted to the need for two suitable trustees to be appointed as a matter of urgency. The Chairman had made a number of suggestions to our contact at the Department, and had pointed out the importance of at least one of the Government appointments being a recently retired senior civil servant…*

Trustees were concerned that the situation should not arise where the Trustee board was 'inquorate'. The Chief Executive was asked to identify the quorum specified in the Trust Deed. [The Trust Deed states that Trustees have the power to make, vary and revoke regulations for the purpose of the time, place, method of calling and quorum of Trustee Board meetings. There is no other reference made to a quorum in the Deed or the Trustees Aide Memoire.]"

5.82. On 5 April 2001, there was a meeting between the Department and the Macfarlane Trust. I was present. I have seen a copy of Ann Hithersay's note of that meeting [MACF0000006_019] which includes:

"3. Trustee Appointments

Charles Lister explained that all potential candidates for trustees would need to be screened using Nolan Committee principles. Letters had been sent to all recently retired senior civil servants including those who had taken early retirement.

An interview panel would meet at the end of May and early June to select two trustees. The panel would include an 'independent assessor'. Peter Stevens was also invited to join the panel. Charles Lister asked the Trust to suggest some alternative names to be included in the selection of a 'non- Department' appointment. Both new trustees would be appointed to serve on the boards of both the Macfarlane and Eileen Trusts."

5.83. I can see from the documents that unfortunately the interviews did not take place as planned. I cannot tell why from the documents I have seen, other than perhaps pressures of work and staff shortages.

5.84. I have seen a copy of Ann Hithersay's report to the Macfarlane Trust Board, dated 15 October 2001, [WITN4505327] which says there had been no progress in appointing two new trustees to fill vacancies which had existed since

1999 and February 2001. The Chairman had agreed to sit on an appointments panel but before that could happen applications needed to be processed and appointments arranged. As mentioned above, I cannot now explain the cause of the delay.

5.85. As explained elsewhere in this statement my team moved to the Blood and Healthcare Associated Infections Unit (PH6.6) headed by Dr Vicki King in July 2001. On 5 December 2001 the new team, including me, met with the Macfarlane Trust. Minutes of that meeting record again that:

> "*DH needed to appoint 2 Trustees to MFT and 2 to Eileen Trust (same applicant could be appointed to both posts if agreed). CL apologised for the delay.*
>
> ***Action: DH to send out letters to interested parties by end of 14 Dec and would keep the Trust's informed thereafter."*** [DHSC0003256_004].

5.86. On 14 December 2001, I wrote to a number of former Department senior civil servants who we had previously contacted to ask if they were still interested in applying to become trustees of the Macfarlane/ Eileen Trusts. I set a deadline of 1 February 2002 for applications. A draft letter is at WITN4505328.

5.87. Interviews were arranged for April 2002. It was decided that all six applicants for the trustee role should be interviewed. Dr Mary O'Mahony, PH6's Branch Head, was to chair the interview panel along with Peter Stevens and an independent assessor, Ronald Brooks. For reasons I now cannot recall, Dr Vicki King ended up chairing the interviews.

5.88. On 13 March 2002 (so before the interviews took place) the Department met with the Macfarlane and Eileen Trusts. I attended this meeting. The minutes record: [DHSC0003255_004]

> ***"Trustee appointments***
>
> *11. The process of appointing two trustees to each trust was ongoing. Applications had been received and dates in late April had*

been sent for interviews. Peter Stevens (PS) was very pleased with the quality of applicants who had applied.

12. The issue of Dr Mark Winter's tenure as a trustee was also discussed. He will have completed three terms at the end of March and was happy to continue. In the past the trust has recommended serving only two terms. CL agreed to speak to Mark Winter and get his views and seek Ministerial approval if he was keen to stay on.

Action: DH to speak to Mark Winter and then seek Ministers approval of two year extension."

5.89. Robert Finch in my team prepared a submission for the Parliamentary Under-Secretary for Public Health (now Yvette Cooper) on 8 May 2002. This set out the outcome of the interview process and asked her to approve the appointment of two new trustees, Mr Roger Tyrell and Mr Patrick Spellman, to the Macfarlane and Eileen Trusts and to confirm Dr Mark Winter as a trustee to the Macfarlane Trust for a fourth term [WITN4505329].

5.90. When Robert Finch joined the blood team, I recall giving him a liaison role with the Macfarlane Trust as part of his job description. This was now possible with a larger team. This role was taken on by Zubeda Seedat when she succeeded Robert in the role. I see from the records that, from this point on, a member of my team usually attended Macfarlane Trustee meetings as an observer. Along with the quarterly DH/Trusts liaison meetings, this would have vastly improved communication between the Department and the Trusts.

5.91. The submission included:

"***The appointment exercise***

4. We are aware that Ministers wish trustee appointments to be made in line with OCPA guidelines, including the advertising of vacancies. However, in the case of the Macfarlane and Eileen Trusts, vacancies have not been advertised publicly for reasons of proportionality:

> • *Trustee appointments are part-time and are unpaid apart from expenses;*
>
> • *The non professional appointments to the Trust have been retired senior civil servants. The Trust has recently said that they would like this arrangement to continue, as they value the experience these people can bring.*
>
> *5. The appointment process was carried out alongside the criteria set down in the DH Guidance on the Appointment of Chairs and Members of SHAs, NDPBs, and other Public Bodies. A letter was sent to those who had expressed an interest in taking on a role of this sort and who had a significant baseline of experience in public administration. Six applications were received and all candidates were invited for interview.*"

5.92. In response to this submission, the Minister commented that she was content that Dr Mark Winter should be re-appointed. However she was concerned about the process for the proposed new trustees. Her view was that it *"seems a bit like an 'old boys network"* and she noted that the individuals were all male (in fact, one candidate was female). She also asked who within the Trust had stated that "*they would like the reliance on retired civil servants to continue*." [WITN4505330].

5.93. On 21 May 2002 Robert Finch responded to the Minister's private secretary. He wrote:

> "*…Both the Chairman of Trustees (Peter Stevens) and the Chief Executive (Ann Hithersay) have said that they are very keen to have former civil servants as trustees as they provide specific experience that complements the backgrounds and expertise of other trustees.*
> [Robert then set out the names and backgrounds of the existing trustees].

…Although the mix of experience and expertise blends well, both the trusts and the Haemophilia Society (who appoint the other 6 trustees for the Macfarlane Trust) are aware of the shortage of women as trustees and wish to encourage more women applicants of the right experience and qualifications. The Haemophilia Society will have between 3-4 vacancies to fill over the next 12 months and will do all it can to encourage female applicants.

In the meantime, as the two Trustee posts are currently vacant, the Trust is anxious to have them filled as soon as possible. The candidates came forward from a mailing of all recently retired senior DH and NHS employees. All those who expressed an interest were interviewed. Unfortunately, this only included one women who did not perform well at interview." [WITN4505330]

5.94. The Minister's Private Secretary responded the same day, saying: [WITN4505330]

"PS (PH) is still concerned about the process behind these appointments (though not the individuals concerned). Who decide that these posts should be recruited from former civil servants? Is there any standard guidance? Is Nigel Crisp's office content that due process is being followed?"

5.95. In response to this, I suggested to Robert that he should speak to Chris Hope in the Appointments Unit for any guidance before we took a decision on speaking to Nigel Crisp's office (Nigel Crisp, now Lord Crisp, was the Department's Permanent Secretary at the time).

5.96. On 24 May 2002, Robert Finch emailed Peter Stevens to apologise for the delay in appointing the trustees and to explain the Minister was concerned that "*its all a bit cronyistic to have ended up with two ex DH civil servants.*" He asked Peter Stevens to summarise why he was keen to have this type of experience for trustees [WITN4505331].

5.97. On 25 May 2002, Peter Stevens replied. He said he was also aware that "the minister was concerned about the absence of women on the shortlist." He did not see this as an issue. He wrote: [WITN4505331]

> "*As far as the choice of former civil servants is concerned, it is precisely their departmental experience that we seek (and have missed since the departure of the two most recent departmental appointments of that nature). What they bring that we find especially valuable are*
>
> *- understanding of how the Department and the Ministers think and operate so that we can act and report in the most efficacious way, bearing in mind that there will always be an element of tension between the Trust wanting more money and the Department not having any for us*
> *- experience of making difficult decisions between equally demanding options when unavailability of money is a major issue; a number of trustees (and most of the staff) tend to have backgrounds that lead them to favour saying "yes" to every request unless there are others who know how to combine objectivity with compassion*
> *- understanding of the administrative processes that the Trust needs to adopt, again a sort of experience that is not necessarily shared by all Trustees.*"

5.98. On 28 May 2002, I put a submission to Nigel Crisp, explaining the background, the appointments process and the Minister's concerns [WITN4505332]. I expressed the issue for consideration as, "*We have recently completed interviews to fill two trustee vacancies at the Macfarlane and Eileen Trusts. At the Trusts' requests, the new appointees are former DH officials. PS(PH) has concerns about cronyism and would like to know if you are satisfied that due process has been followed."* I summarised the reasons Peter Stevens gave for wanting former civil servants in these trustee roles and explained that the "…*Chair and Chief Executive of the Trusts were therefore keen to maintain this kind of experience within the Trustee base and asked us specifically to appoint*

former DH/ NHS officials to the two vacancies. We felt this was a reasonable request provided the appointment exercise was as fair and open as possible."

5.99. I explained the appointments process and concluded:

"10. We are confident that:

- *the decision to limit candidates to former senior civil servants was reasonable given the request from the Chair and Chief Executive of the two Trusts;*
- *the candidates were selected in as fair an open a way as possible eg by issuing an open invitation to apply to all eligible candidates…;*
- *the appointments process was carried out in line with the relevant DH guidance on appointments to public bodies.*

Are you content to advise PS(PH) that, on the basis of the evidence presented to you, the exercise was fair and proper, that due process was adhered to and that, in your opinion, there is no obstacle to the appointment of the two recommended candidates?"

5.100. At paragraph 5.54 of this statement I reflected on whether we might have achieved a more fair and transparent process by advertising the roles publicly. From the standpoint of today, (even from a narrowly circumscribed pool) writing to eligible candidates would probably not be regarded as acceptable. However, at the time, we concluded that we had met OCPA guidelines, and I do not recall having any doubt in the matter.

5.101. On 5 June 2002, Ruth Wetterstad, Nigel Crisp's private secretary, responded:

"Nigel Crisp was grateful for your submission dated 28 May. He is content that, on the basis of the evidence presented to him, the exercise was fair and proper, *that due process was adhered to and that, in his opinion, there is no obstacle to the appointment of the two recommended candidates."* [WITN4505333]

5.102. By this point, Yvette Cooper had left the Department and was replaced by Hazel Blears as Parliamentary Under-Secretary for Public Health. She was informed

about Ms Cooper's concerns and that Nigel Crisp was content the process was fair and appropriate to the posts. Ms Blears approved the appointments [WITN4505334]

5.103. On 19 June 2002, Hazel Blears wrote to Roger Tyrell and Patrick Spellman inviting them to be trustees of the Macfarlane and Eileen Trusts [WITN4505335]

5.104. Also on 19 June 2002, Ann Hithersay wrote to Robert Finch in relation to the appointment of trustees to the Macfarlane (Special Payments) (No. 2) Trust, pointing out there were vacancies for two Department nominated trustees and asking that the new appointees to the Macfarlane/ Eileen Trust trustee positions should also be appointed as trustees for the Special Payments Trust. Ann also stated that the Macfarlane Trust nominated Gordon Clarke to fill another vacant trustee role and asked that the Secretary of State appoint him. [DHSC0002960_009]

5.105. It appears from the documents that Mr Tyrell and Mr Spellman agreed to being appointed as trustees to the Macfarlane (Special Payments) (No. 2) Trust as on 23 December 2002, Zubeda Seedat (who had replaced Robert Finch on my team) invited the Parliamentary Under-Secretary for Public Health, Hazel Blears, to:

> *" i. reappoint Elizabeth Boyd* [a Haemophilia Centre welfare rights advisor] *to a two year term as trustee to the Macfarlane Trust; and*
> *ii. appoint Patrick Spellman and Roger Tyrrell, who were appointed as Trustees to the Macfarlane and Eileen Trusts in June 2002, to the Macfarlane (Special Payments) (No. 2) Trust."* [WITN4505336]

5.106. By email dated 14 January 2003 the Minister confirmed she was content to makes these appointments [WITN4505337].

5.107. By email dated 30 January 2003, Peter Stevens wrote to me about the process for appointing a new CEO for the Macfarlane and Eileen Trusts, to replace Ann Hithersay. His email included: [WITN4505338]

> "*…Basically the questions are:*
>
> *- How directly, if at all, should the DoH be involved?*
>
> *- What Nolan-type procedures should be followed?*
>
> *I am sure that Ann was appointed solely by my predecessor and his Deputy following an advertisement…and an interview by those 2 chaps, maybe with 1 or 2 other Trustees involved. I doubt that there was any consultation with either the* [Haemophilia] *Society or the Department…*
>
> *I would be quite happy that you and I could confer should that be necessary, as we already have done. But your participation might need to be more overt.*
>
> *I would certainly include on the interviewing panel one of the recent DoH appointments – would that be sufficient "protection" of the Department's position?*
>
> *Would it be necessary, desirable or simply a matter of our discretion to have an independent assessor on the panel?..."*

5.108. I responded the same day (30 January 2003) [DHSC0002958_001] to say:

> "*I don't think that DH needs to be involved directly in making the appointment. It would be helpful, however, if we could agree on the type of individual we would like to fill the post and, if you intend reviewing it, the remuneration package. From our earlier conversation I don't think this will be a problem.*
>
> *Your suggestion of including either Roger Tyrell or Pat Spellman on the selection panel is welcome. If you could also consult us on the job spec for the CEO, I think that would meet our needs.*
>
> *Thinking about the process, I would recommend that you operate in the spirit of Nolan but nothing too onerous, i.e. advertise the vacancy (ideally in the national press) and include an independent assessor on the selection panel…*"

5.109. Looking back, this exchange with Peter Stevens was a good indication of the good working relationship we had established. However, on balance, it probably went too far on this occasion in commenting on matters for the Trust to determine. At the time, I quite rightly stepped back completely from any suggestion that the Department should be directly involved in the appointment of the CEO. However, I also recall at this time, I wanted the Trust to be more conscious of managing its expenditure within the spending limits set in the 2002 Spending Review, so in commenting on *"the type of individual"*, I hoped the Trust would appoint someone who understood this.

5.110. I do not think I had further involvement in this (as supported by Peter Stevens' email to Richard Gutowski dated 8 August 2003. [WITN4505338]

5(C) FUNDING THE AHOs

5.111. There is significant overlap in the questions that I am asked about the funding of the Macfarlane Trust and Eileen Trust and the factual evidence I can provide to answer these questions. Therefore to avoid answering similar questions twice I have combined my answers.

5.112. I am asked to set out the process by which the Department of Health provided funding to the MacFarlane Trust. Linked to this I am asked:

- Whether this changed over the time I was involved;
- If so, how?
- Whether there problems with this process;
- If so, what they were and what were the consequences?

5.113. I am asked what I knew about how the Government set the budget for the Macfarlane Trust and what input I had or should have had into this process. I am also asked whether Government took account of representations made by the "*relevant AHO*".

5.114. I am asked to describe my involvement in considering requests for further funding for the Macfarlane Trust and about any decisions and

recommendations I made. I am also asked what actions I or the Department took in order to address the AHOs' need for increased funding.

5.115. I am asked to explain the annual 'top-up' process and asked, by reference to the Macfarlane Trust's Chief Executive's report dated 23 June 2000 [MACF0000006_102], how the sum of £2m was calculated.

5.116. I am also asked whether the Department granted the requested top-up of £2.5m in response to the Macfarlane Trust's financial projections and if not, why not.

Overview

5.117. The Department provided two types of funding to both the Macfarlane and Eileen Trust:

- 'Top-up' payments which were intended to fund the grants made by the Trusts to beneficiaries. Initially these 'top-up' payments were ad hoc but as time passed the Macfarlane Trust payments were made on a more regular basis; and
- Section 64 grants (under the Health Services and Public Health Act 1968) which were intended to fund the Macfarlane and Eileen Trust's administrative costs. S64 funding could also be used to provide funding for the administrative costs of specific projects. Examples are S64 funding of approximately £51,000 paid to the Macfarlane Trust in March 2000 for IT equipment and S64 funding paid to the Macfarlane Trust in 2003/2004 to fund the Long Term Review.

5.118. In addition to 'top-up' payments and S64 grants I also bid each year for a budget as a contingency fund in case there were new applications for lump sum payments from people who had not previously applied. This was £100,000 per annum, reduced to £50,000 per annum from 2001/2002.

5.119. Since I have been asked specifically about S64 funding in other parts of the Rule 9 request, I will focus this part of my statement on 'top-up' or capital funding for the Macfarlane and Eileen Trusts.

'Top-Up' Payments to Macfarlane's Trust Fund

5.120. When I took over sponsorship of the Macfarlane Trust, it was making three sorts of payments. These were made from the Macfarlane Trust's fund, which was set up initially with a grant of £10m from the Department and then supplemented with further lumps sums over the years:

- Regular monthly payments paid to registrants, infected intimates (as was the term used then), widows with children and disabled widows;
- Single grants for specific one-off costs, e.g. household goods and repairs; and
- Winter payments.

5.121. At the time the Trust maintained at least £4m of its Trust fund in investments. The income from these enabled the Trust to provide additional support to beneficiaries over and above the payments made by the Department. The convention was that the Department would top up the Trust fund when it dipped close to £4m.

5.122. Before I joined the blood policy team, the Department had provided £3m of 'top-up' funding to the Macfarlane Trust in 1997/1998. During my tenure, the funding provided can be summarised as:

- 1998/1999: nil [MACF0000045_018]
- 1999/2000: £2m [MACF0000045_018]
- 2000/2001: £2.5m [MACF0000006_009]
- 2001/2002: £2.25m [MACF0000045_015]
- 2002/2003: nil [MACF0000009_127]
- 2003/2004: £3.1565m [MACF0000045_013]

5.123 As can be seen from the chronology below, different potential 'top-up' sums were discussed at various points, based on requests from the Trust. This can make the chronology seem quite confusing at times. It may therefore help at this point if I provide some explanation about how Department of Health funding worked at that time. This is not a definitive explanation but is based on my memory of what happened during my time in the blood policy team.

5.124 In common with all government departments, the Department had to work within a Departmental Expenditure Limit (DEL). This is the annual spending limit imposed on a government department arising from its agreed, longer-term financial settlement with the Treasury. Most of the Department's spending was directed towards the provision of front-line NHS and personal social services. There were also a wide range of activities funded from the Department of Health's spending programmes whose only common feature was that they received funding direct from the Department and not via Health Authorities. Some of these services were managed directly by Departmental staff, others were run by non-departmental public bodies, or other separate executive organisations. The 'top up' funding for the Macfarlane and Eileen Trusts fell into this category.

5.125. Some central budgets were covered by the Spending Review (SR) process (the discussions with Treasury that usually take place every two to four years and set limits on departmental spending) and some were outside of this. The first Spending Review took place in 1998 and covered expenditure for the years 1999 to 2002. When I joined the blood policy team, the 'top-up' funding for the Macfarlane Trust was a non-SR central budget. I cannot explain why this was, and I am not sure I knew at the time. Nor did we include it in SR 2000 (covering 2001 to 2004) for reasons I cannot now recall. I therefore included funding for the Trust in SR 2002 which covered the period 2003-2006. From here on, there was a regular annual budget for the Trust.

5.126. So, prior to 2003-04, 'top-up' funding for the Trust came from non-SR centrally funded services. I recall that this was subject to an annual bidding process and

decisions on budgets were taken after everything else was settled. Ministers always wanted as much money as possible to go to NHS front line services, so a very strong case had to made for any money held back to be spent centrally and the process was very competitive. Final decisions on spending priorities were taken by Ministers. There was no funding held back for contingencies.

5.127. If we received in-year requests for central funding that had not been anticipated at the bidding stage, the only means of finding this was from underspends on other centrally held budgets within the Department. In practice, budget holders usually only declared underspends in the last quarter of the financial year, so requests for unanticipated funding from budget holders to Department finance were usually dealt with then.

5.128. Given the uncertainties inherent in this system for the Trust and the clear need, following the Strategic Review, for annual tops up to the Macfarlane Trust's fund, inclusion in the Spending Review was a logical move.

5.129. With the outcome of the 2002 spending review, the Trust were given a clear commitment to annual funding for the three years ahead, namely £3m in 2003/2004, £3m in 2004/2005 and £3.05m in 2005/2006. At this point the Department's expectation was that requests for further funding for the Macfarlane Trust would need to be made through a proper business case which the Department would consider in line with future spending reviews.

5.130. As stated above, there is a significant overlap in the questions the Inquiry has asked me about funding for the Macfarlane and Eileen Trusts and so I have sought to set out a chronology of events which, I hope, will assist with several of those questions. I have done my best with the records available to me, although I do not think they are complete. However the records I have seen give a reasonable picture of my involvement.

5.131. When I started in role in October 1998 funding for grants for the Macfarlane Trust and Eileen Trust was not provided on an annual basis. At this time funding

to enable the Macfarlane Trust to make payments to beneficiaries was 'topped up' periodically. The Eileen Trust had received £500,000 when it was established and had not been 'topped up' since then. As explained above, funding for administrative or core costs was provided annually to each Trust under S64 and the Trusts could apply for additional S64 funding for specific projects.

Macfarlane Trust 'Top-Up' Funding: Chronology in 1999

5.132. As stated above, I am aware that in 1997/1998 the Department provided 'top-up' funding of £3 million to the Macfarlane Trust. No 'top-up' funding was provided in 1998/1999. This would have been because, as recorded in their 1997/1998 Annual Report and Accounts, the Trust Fund balance was a healthy £9.3m (rounded) at 1 April 1998 and was at £7.7m by 31 March 1999. *[MFT annual report and accounts for yr end 31.3.98: MACF0000045_020 and MFT annual report and accounts for yr end 31.3.99: MACF0000045_018]*

5.133. In January 1999 the Macfarlane Trust completed a "*Strategic Review*" (the "Review") [MACF0000045_019]. The Review stated that it had "*identified changing patterns of needs and expectations of registrants who are benefitting from more effective treatments which increase life expectancy*". The Review made a number of recommendations to Ministers and the Department of Health. The key recommendation was that "*Ministers/ Department of Health should recognise the changing patterns and increasing financial demands and expectancies of registrants. They should provide policy guidance and priorities and furnish the required level of resources*" (page 5).

5.134. I understand from the documents that this Review had been in train for some time and an interim report was submitted to the Minister of State for Health, Baroness Jay, in July 1998. The Department provided funding to the Macfarlane Trust to complete the Review - £23,000 was provided under a section 64 grant in the financial year 1999/2000 (this was in addition to the section 64 funding

for the Macfarlane Trust's core administrative costs) (MFT annual report and accounts for year end 31 March 2000 [MACF0000045_017].

5.135. On the financial support required, the Review concluded that the financial support requirements of registrants were unlikely to diminish over the next 3 - 5 years and the current high level of needs would continue. It also noted that as the numbers of registrants reduced, so the needs of widows and dependent children increased. The Review stated that £10m would be required to cover expenditure from 1999 – 2004, if support to registrants was to continue at a similar rate to that provided over the past 10 years. If wider needs were met that would lead to an increase in the resources required. The Review stated that to "*support these levels it would be necessary for the Government to provide further 'top-up' payments to the Trust in 2000 and again in 2003*" (pg 18).

5.136. On 12 April 1999 Gwen Skinner (an official on the blood policy team who reported to me) put a submission to Lady Hayman. It explained that:

> "1. …*We have needed to consider the recommendations of the Macfarlane Trust's Strategic Review, which was funded from S.64 monies. The Trust wished to establish the right direction for itself, as circumstances have changed in the management of haemophilia and the treatment of people with HIV….*
>
> *3. Essentially, the Trust recommends that it continues expenditure at about £2 million a year. This would require top ups to the Trust every two to three years of several million pounds to maintain its annual disbursement. Although there are fewer registrants with the Trust, their needs have changed and the items of expenditure are different. The main difficulty is that the financial support for HIV infected people with haemophilia might be considered over generous, eg help with house purchase and furnishings. There would also be a widening gap between this and the self help ethos which we are encouraging for those with hepatitis C….*

> *6. … £2 million a year continues to be disbursed, and the payments are expected by the Trust to continue at this level – lesser numbers, but higher payments.*
>
> *…*
>
> *12. We recommend that the Macfarlane Trust's suggestion of a meeting to discuss the review is accepted…*" [DHSC0032142_007]

5.137. I do not now recall what considerations Ministers and officials gave to the Strategic Review other than recognising the changing needs of registrants and the consequential funding implications.

5.138. On 17 June 1999 a meeting took place between the Minister of State in the Lords, Baroness Hayman, and the Macfarlane Trust. Following the meeting Baroness Hayman wrote to the Reverend Alan Tanner at the Macfarlane Trust on 1 July 1999. I drafted this letter on her behalf, which reiterated that the presentations delivered at that meeting had left a "*much more lasting impression than correspondence ever could*". The letter continued:

> "*I can give you my assurance that we are fully supportive of the Trust's work and have great admiration for the thought and energy which you give to it. We will of course continue the commitment to provide the finances which you need for the Trust Fund. We will also continue to fund the efficient administration of the Trust and we will meet the costs of appropriate information technology needs.*" [DHSC0006162_006].

5.139. On 7 July 1999 Ann Hithersay wrote to me in relation to the Macfarlane Trust, saying: [WITN4505339]

> "*So sorry I omitted to let you know how much money will be needed in 2000/2001 to 'top up' the Trust fund. Working on the principle that the fund should never drop below £4,000,000, we shall need £2,000,000 fairly early on in 2000.*"

5.140. I also recorded the outcome of the meeting on 17 June 1999 in a minute to Sue Adams, dated 7 July 1999 [DHSC0006162_003]. This included that Baroness

Hayman had undertaken to provide £2m to top up the Macfarlane Trust fund in 2000/2001. I wrote:

> "*There is an ongoing commitment on the part of the Department to give periodic top-ups to the Trust Fund. Unfortunately, we did not realise when the BPRs were being written that a further sum would be needed in 2000/2001. By the end of the financial year, the Trust Fund is expected to be down to £5m or under. At least £4m of this is kept in capital investments in order to maintain payment levels, and grants from the fund current total around £2m pa. It is therefore clear that a top up will be needed in 2000/2001 and the £2m suggested by the Trust seems reasonable. A further sum is likely to be needed in 2002/2003.*" [DHSC0006162_003].

5.141. I can no longer remember what "BPR" stood for, but from the context it appears to have been a return submitted to the Department's Finance department on budgetary requirements.

5.142. In the same minute to Sue Adams, I raised a further undertaking by Lady Hayman to provide £52,000 to the Macfarlane Trust in 1999/2000 to cover the cost of new IT equipment, software, staff retraining and year 2000 compliance:

> "*This is the request for funding, I wrote to you about on 17 March and which was first raised by the Trust some 18 months ago. The money has already been spent by the Trust and is mentioned in their 1998/99 accounts as an overspend against their management budget. The Trustees have taken the view that it is inappropriate to take this money out of the Trust Fund, a view supported by Lady Hayman. As there is no money through S64 for year 2000 compliance, we have told the Trust that the best we can hope for is to find the money out of any end of year underspend. I would be grateful therefore if you could flag this up as a potential call.*"

I have not seen the minute of 17 March but I assume it covered much the same ground. Nor have I seen a reply to my minute of 7 July.

5.143. By letter dated 4 October 1999 Ann Hithersay sent to me a list of issues the Macfarlane Trust wished to discuss at the forthcoming meeting between the Department and the Trust on 12 October 1999. Under the heading "*Outstanding issues from June Meetings*", that list included:

> "*Top-up Requirements - General Fund*
> *Confirmation that the Trust has asked for two top-up payments over the period 1999 – 2004 and these amounts have been agreed in principle by the Department as:*
> *£2 million in 2000 and £3 million in 2002.*" [WITN4505340]:

5.144. I have not seen documents showing that the Department had, prior to 4 October 1999, agreed these sums in principle and think this may refer to an agreement that Ann Hithersay was seeking.

5.145. I have not seen the minutes from the Department's meeting with the Macfarlane Trust on 12 October 1999. However, Ann Hithersay wrote a follow-up letter to me on 28 October 1999 which states I was present at the meeting. That letter included [DHSC0003209_009]:

> "*We pointed out at the meeting that the Strategic Review had identified that in order to meet current levels of payments to those registered with the Trust, top up of £2 million would be required in 2000, and a further £3 million in 2002.*"

5.146. The letter also referred to further funding that would be required if the Trust was to honour its commitment to meet needs related to living with HIV and to continue to support dependent children. It said the Macfarlane Trust was doing work to identify the cost of additional or increasing payments to beneficiaries.

5.147. So, at this point in time the Macfarlane Trust had requested £2 million in 2000/2001 and £3m in 2002/2003, with an indication that further funding beyond this may be requested to meet the growing or changing needs of beneficiaries. As explained elsewhere in this statement £2m was provided in 1999/2000, £2.5m in 2000/2001 and then £2.25m in 2001/2002.

5.148. On 13 December 1999 I authorised the payment of £2 million to the Macfarlane Trust for 'top-up' funding for the financial year 1999/2000. I notified the Macfarlane Trust about this on the same day. I can see this 'top-up' payment is contained in the Macfarlane Trust annual report and accounts for year end 31 March 2000 (i.e. the financial year 1999/2000). [MACF0000045_017]

Macfarlane Trust 'Top-Up' Funding: Chronology in 2000

5.149. On 18 April 2000 Ann Hithersay, Dr Mark Winter and the new Chair of the Macfarlane Trust (Peter Stevens) met Lord Hunt. Dr McGovern was also present. I prepared a briefing in advance of the meeting which informed Lord Hunt that the Macfarlane Trust wished to discuss the changing needs of Trust registrants and the Trust's resulting financial requirements. On the latter point the briefing stated that the Macfarlane Trust was now:

> "*…proposing to increase payments to registrants and dependents from around £2m pa in 1999/2000 to £2.5m in 2000/2001 (against a planned spend in 2000/2001 of £2.3m), rising to nearly £3m in 2005/2006. This increase in payments would need to be funded by the Department.*" [WITN4505341]

5.150. The briefing for Lord Hunt also provided information on the payments made by the Macfarlane Trust and stated:

> "*…At 31 March 2000, the fund stood at £7.9m. Of this, the Trust maintains at least £4m as investment capital, yielding income at approximately 4.25% pa. When the fund dips close to £4m, it is topped up by the Department. We provided £2m in 1999/ 2000 and were expecting to have to make a further payment in 2002/2003 of around £3m (this need was identified in the Trust's strategic review).*"

5.151. The briefing then set out the Trust's proposed changes to payments from September 2000 and stated,

> "*This would increase annual payments to £2.4m in 2000/2001 (against £2.3m planned), rising to £2.6m in 2001/2002 and £2.7m in*

2002/2003….As a result the Trust are asking for a top up payment of £4m in 2001/2002, a year earlier than planned and of a greater sum than anticipated. At present there is no provision to make any payment to the Trust in 2001/2002 and there is no contingency funding that year."

5.152. The briefing says that these proposals had first been discussed with officials on 6 April 2000. It reflects the fact that at this stage, the funding was dependent upon non-SR centrally funded services (as I have addressed at paragraph 5.126-5.128, above), and was not subject to the same levels of advanced and set funding and budgeting to which we later sought to advance.

5.153. The briefing advised that there was no reason to doubt the financial position of the Trust's registrants was worsening and that the outlook for people co-infected with HIV and hepatitis C was not good. It also agreed that the Trust's proposals to increase regular payments and cut back on certain discretionary payments was the correct response. The briefing stated, "*[i]t is hard to resist the Trust's request for additional funding to meet the needs of registrants when the Trust is acting within the terms of its remit as laid down in the Trust Deed.*" However, it also raised some concerns about the proposals, the long term costs, and also the increasing gap between those with HIV and those with hepatitis C. The briefing recommended that the Department should commission an independent review of the Trust's activities before committing additional funds (assuming funds could be found in 2001/2002).

5.154. Part of the issue, as identified in the briefing, was that top-up funding had not been set aside for the Trust in 2001/2002 as it was expected that the need would arise in 2002/2003, based on earlier information and requests from the Macfarlane Trust. The Macfarlane Trust was also now proposing a 'top-up' of £4m rather than £3m. There was no contingency budget for 2001/2002.

5.155. I am aware that when Peter Stevens gave evidence to the Inquiry on 23 February 2021 and was asked about this briefing and the meeting with Lord Hunt, he said that the Trust was not given additional funding, commenting that:

> "*Yes.It's kick it into the long grass, or kick the can a bit further down the road. It's a fairly standard process for Government departments.*"

I do not agree with that characterisation. In fact we arranged for the £2m set aside for the Trust in 2002/03 to be paid early in 2001/02 with an additional £225,000 [WITN4505342].

5.156. On 18 April 2000 Lord Hunt met representatives of the Macfarlane Trust. I have been provided with minutes from the Macfarlane Trust board meeting on 2 May 2000 [MACF0000013_031] which record that the meeting was "*positive but inconclusive*". It had been curtailed by individuals from the Macfarlane Trust arriving late and Lord Hunt having a subsequent engagement. The minutes also record that the Chairman advised Lord Hunt of the need to increase payments to registrants from September 2000 and Lord Hunt's response had been neither positive nor negative. Lord Hunt had indicated that he expected to have a further meeting with Trust representatives later in the year.

5.157. Given that all Departmental budgets would have been allocated by the time of the meeting with Lord Hunt, it would not have been possible for the Minister to make commitments to provide additional funding. Instead, the action would have been for me to take this forward with the Department's Finance department, as I did.

5.158. I have also seen, for the first time, minutes from a Partnership Group meeting on 22 May 2000, attended by Peter Stevens [MACF0000088_024] which reported on Peter Stevens' impression of the meeting with Lord Hunt. Some of Peter Stevens' explanation appears to be focussed on managing beneficiary expectations. After explaining that Lord Hunt had said that finding more money might cause problems for the Department as no contingency fund existed but that "*he would find a way to provide funds needed*", Peter went on to say that *the impression had been gained that Department civil servants had not been monitoring the work of the Trust as closely as Lord Hunt would have liked. There was a sense of the 'whip being cracked'. We all need to be aware that the Macfarlane Trust was not like fund raising charities*

and not at liberty to spend funds as it pleased. It was necessary to remember that our funds were not unlimited and that all funds came to us directly from the Government".

5.159. I do not recall Lord Hunt 'cracking the whip' at officials to monitor the work of the Trust more closely (as appears to have been Peter Stevens' impression of this meeting) and that is not something the record shows us as doing. However, we did continue to expect the Trust to stay within budget and deliver good value from public money.

5.160. Of course, all charities must balance income and expenditure. The difference with the Macfarlane and Eileen Trusts was that the Department was the sole source of funding. The Department was not attempting to say how or on what the Trust should spend its money provided they stayed within the scope of the Trust Deed. However, we wanted the Trustees to maximise the value to beneficiaries, for example by not using Trust Funds for items that might be equally well funded by health and local authorities or the benefits system. We also wanted them to stay within an agreed budget.

5.161. I have not seen papers to suggest that a further meeting took place with Lord Hunt – I am fairly certain there was not one - but am happy to reconsider this if documents show that there was. The next meeting between the Trusts and Ministers was on 27 February 2003 and is discussed at paragraph 5.196 below.

5.162. After this meeting with Lord Hunt, I followed up on the Macfarlane Trust's recent funding proposal. On 8 May 2000 I emailed Sue Adams in the Finance department as follows (there were clearly other conversations preceding this):

"…I'll be letting you have a note shortly. We will be looking for top-up funding for the Trust in 2001/2002 (not 2000/2001), which I think, from my conversation with Ian, is equally difficult.

I am working on forecasting the Trust's funding needs for the next five years or so. I don't think that the ad hoc way we have funded the Trust in the past is sustainable and have come to the conclusion we should

have a proper budget set up for maintaining the Trust fund. The fact that we don't at present probably contributed to this commitment being overlooked at the time of spending review.

It looks at the moment as we are going to have to find around £2m a year for the Trust for the foreseeable future, and possibly more as time goes on, to match the level of payments they are giving out – all of which are in line with Ministers' commitment to the Trust.

I am pursuing, as I think I mentioned, the idea of an independent review of the Trust and the needs of its registrants. I am particularly keen to explore the extent to which the Trust are funding services which should be properly provided by health and local authorities…" [DHSC0003490_015]

5.163. I had put a marker down with Sue Adams in relation to £2m of 'top-up' funding in 2000/2001 in my minute to her of 7 July 1999 referred to above.

5.164. On 23 May 2000 I further wrote to Ian Fleming in the Department's Finance Department providing more detail on funding for the Macfarlane Trust. I explained that ongoing funding to the Macfarlane Trust would "*not only be an inescapable commitment for some years to come but that the level of funding required may well increase over the next 5 years*". I wrote, "[i]*t seems clear to me that what is needed, ideally, is a new budget to support this commitment. However, as any such proposal should have been covered in the Spending Review 2000, I am not sure where we go from here and would be grateful for your advice…" [DHSC0003487_002] for part of the document and [WITN4505343] for second part of document].*

5.165. I have explained the background to these issues above and the reasons for wanting to achieve greater certainty for the Trusts through the SR process.

5.166. I cannot now say what Ian Fleming's response was but subsequently (in June 2000 I think) I submitted a formal budget request for an annual payment of £2m to the Macfarlane Trust, from 2001/2002 – 2003/2004 inclusive. That request

entailed a projected reduction in the Trust fund balance down to £4.389m by the end of 2003/2004 [WITN4505344].

5.167. This budget request did not include a 'top-up' payment in 2000/2001. However, as explained in this statement such a payment was in fact made.

5.168. My commentary to this budget request included:

> *"£2m – The need for this budget is expected to continue for a number of years – for the lifetime of the Trust's 437 surviving registrants (which, with advances in treatment for HIV, is hard to predict) and their dependants (the Trust's payments to widows with dependent children continue until the children complete full-time education). The proposed budget of £2m a year for the next three years is less than the Trust's net annual expenditure, and will therefore need to increase in subsequent years if the balance of the Trust fund is to be maintained at £4m or above."*

I do not now recall the reasons for bidding for £2m a year and not more. It may have been that this was limited by pressures on Departmental budgets at the time. That would explain my flagging up the point to Finance colleagues that the budget would have to increase in subsequent years. In practice, we were able to do better than that.

5.169. On 6 September 2002, I was copied into a minute from Malcolm Harris to Dr Adam summarising the Health Services Directorate's non-SR central budgets from 2000/01 to 2003/04. This included a budget line headed "*grants in respect of haemophiliacs*" (i.e. the Macfarlane Trust) showing:

- 2000/01 budget level: £50,000
- 2001/02 proposed budget: £2.05m
- 2002/03 proposed budget £2.05m
- 2003/04 proposed budget £2.1m. [WITN4505345]

These are the sums I bid for with an inflationary element added. The £50,000 for 2000/01 is the sum to reimburse the Trust for year 2000 compliance costs, mentioned in my minute to Sue Adams on 7 July 1999.

5.170. I can see from minutes of the Macfarlane Trust board meeting on 3 October 2000 that I reported to the Macfarlane Trust that I had made a budget application and that I was hopeful the proposal would be approved. [MACF0000006_032].

5.171. In fact, as set out in this statement, the funding for the Macfarlane Trust over the following years was not £2m per annum. The Trust received £2.5m at the end of the 2000/2001 financial year, £2.25m in 2001/2002, nil in 2002/2003 (because the payment planned for 2002/2003 was brought forward to 2001/2002) and then approximately £3.15m in 2003/2004. Later in this chronology I will detail the discussions that led to these change

5.172. Other than this, the documents I have seen show that in late September 2000 I raised the possibility of asking consultants to look at how the Macfarlane Trust supported its registrants and whether there was scope for making better use of the resources allocated to the Trust. I address this consultancy study, which was done in 2001, below in my statement at §5.426. I also suggested that the Department should take a fresh look at its financial commitment to the Trust and whether it was happy to continue with the policy of enabling the Trust to hold at least £4m of its fund in investments [*see* DHSC0003486_013].

Macfarlane Trust 'Top-Up' Funding: Chronology in 2001

5.173. On 5 March 2001 Sue Adams emailed me and asked:

> "*Could you let me know if it would be justifiable to "top-up" the Macfarlane Trust with £2M in this financial year if we have the funds available? Also if more than £2M were available could we justifiably pay more ie £3M?...*" [DHSC0003485_003]

5.174. I replied the same day: [DHSC0003486_004]

> "*I think we need to discuss what constitutes a justification for giving the Trust £2-3m this year. As we have always funded the Trust ahead of need so that they can keep at least £4m in investments, I guess the criteria are a bit less strict than they might be…*
> *Would this be instead of the £2m they are down to get in 2001/02?*"

5.175. It has not been possible to locate a response to this email. However, I must have discussed the Macfarlane Trust funding with Ian Fleming as I emailed him on 22 March 2001 to say: [DHSC0003485_002]

> "*As discussed, I understand that you are able to give the Macfarlane Trust £2m at this time to meet the 2001 financial commitment. As you know we have a longstanding arrangement with the Trust that they receive regular top ups to their Trust fund in order for them to maintain as much as possible (and not less than £4m) in investments. The Trust Fund currently has a balance of £6m and expected expenditure is about £2.7 - £2.8m pa. It would therefore be reasonable to provide the money now rather than wait until later in the year.*
>
> *I have just been asked by the Eileen Trust (same management as the Macfarlane Trust) if we could top up their trust fund this year. I am not sure when this was last done, if ever. The Eileen Trust fund has a current balance of around £300K and a spend of £80 – 90K pa.*
>
> *If additional funds are available this financial year, may I propose that £2.8m is given to the Macfarlane Trust (roughly in line with their projected annual spend) and £0.2m to the Eileen Trust…*"

5.176. Ian Fleming emailed me on 23 March 2001:

> "*…It is clear that expenditure by the Trust is continuing to increase annually. I also note that the review of how the Trust manages its finances is underway* [that is a reference to the consultancy study]…

For the present I am willing to make available £2.5m, this year, for the Macfarlane Trust. This payment would be likely to meet most of their annual costs.

[He also replied about the Eileen Trust – see below.]

If you are content to authorise a payment of £2.5m to the Macfarlane Trust it will need to be paid within the next few days. Please let Sue Adams know if you wish to go ahead and she will confirm the availability of funds…." [WITN4505346]

5.177. I replied on the same day to confirm that £2.5m should be paid to the Macfarlane Trust. [DHSC0003485_001] I can see from the Macfarlane Trust annual report and accounts for year end 31 March 2001 that the payment was made in the 2000/2001 financial year.

5.178. I am asked if the Department granted the Macfarlane Trust's requested top-up of £2.5m in response to the Trust's financial projections. The Inquiry has referred me to a letter from Gordon Clarke to me [MACF0000011_023] to answer this question. The question I am asked does not give a date and the letter from Gordon Clarke is also undated. I think, but cannot be sure, the letter dates from April 2001, following a meeting I had with the Macfarlane Trust on 5 April 2001. I also cannot now be certain if this letter was sent to and received by me – the copy provided to me is also unsigned, as well as undated.

5.179. I have seen a copy of Ann Hithersay's note of our meeting on 5 April 2001 which includes: [WITN4505347]

"***Future funding of the Trust:***

Additional top-up funding of £2.5m had been paid to the Trust at the end of March. Further payments of £2m would be made in 2002/03 and 2003/2004. Charles Lister hoped this would lead to a three year rolling programme of funding for the Trust."

5.180. As already mentioned, this was the plan at that stage. However, as the chronology will show, it was later amended so that the £2m planned for 2002/03

was instead provided earlier, in 2001/02, and increased to £2.25m. There was therefore no payment in 2002/03. 2003/04 was the first year of SR 2002, and the beginning of the three year rolling programme. The Trust received approximately £3.15m that year.

5.181. As stated, I think Gordon Clarke's letter at [MACF0000011_023] was sent after this meeting. His letter says I had asked for some financial projections for the Trust. My reading of this document is that these projections assumed no top up in 2001/2002 (which fits with Ann Hithersay's note referred to above) and then £2m in 2002/2003 and then £3m per annum thereafter. I think it was in this context that Gordon Clarke wrote, "*with no further top-up provision until March 2003, the capital balance would fall to the previously agreed minimum* [i.e. £4m in the investment fund]. *Consequently, the financial years 2002/03 through 2005/2006 would be very difficult. It would seem prudent, therefore, to argue for a top-up of £2.5m in 2002/03 with subsequent annual provision of £3m*".

5.182. Looking at it now, I think there are a number of points to make about this. First, it is a proposal, made in (I think) April 2001 about funding for 2002/2003. It is premised on no funding in 2001/2002 as that would take the Macfarlane Trust fund close to £4m (around £4.2m in the projections). However, as explained above, funding of £2.25m was provided in 2001/2002.

5.183. In any event I will have used this information to support by bid for funding for the Macfarlane Trust in the 2002 Spending Review (for funding from 2003/2004).

5.184. The consultancy study, which I refer more to below at §5.426, took place in mid-2001. The resulting report I have seen does not appear to have a date on it [MACF0000006_010].

5.185. The report's recommendations included that the Macfarlane Trust should have business planning processes, should submit an annual business plan to the Department which provided, as far as possible, an early indication of pressures

arising in subsequent financial years, and should provide a business case for where additional funds can be identified.

5.186. On 5 December 2001 the Department met with the Macfarlane Trust. I attended this meeting. This was also the first meeting after the move of my blood team to PH6 and Dr Vicki King, the head of the team, attended [DHSC0003256_004]. The minutes of the meeting (now written by my team) reflect what had happened in the intervening period. On funding, there was now a suggestion that there would be a likely 12% increase in the Macfarlane Trust's expenditure and that expenditure was now exceeding funding from the Department. The minutes recorded:

> "*The current Trust fund status stood at £5.5m after winter 2001 payments, however this would go down to £4m by mid 2002 reaching the agreed critical break point. Although the Trust hoped that the increase would not be as high as 12%, payments were increasing, in particular for issues that would not have been foreseen when the organisation was set up (such as marriage break-ups, relocation costs).*
>
> *Finance – future capital expenditure*
>
> *Charles Lister (CL) said that DH needed to know the projected spend for the Macfarlane Trust over forthcoming years, considering expenditure was now higher than income. It was expected that the Macfarlane Trust would receive funding of £2m in the next financial year. DH hoped to increase the budget from 2003/04. CL said it was important that DH had some idea of projected future spend up to 2006/07 so that the Department could prepare to adequately fund the organisation…*
>
> *It was agreed that with some idea of future requirements DH could look into how the funding structures, currently in place, could be changed to suit both parties better. Section 64 funding for administration costs no longer seemed appropriate.*
>
> ***Action: Macfarlane Trust/ Eileen Trust to provide DH with projected spend where possible up to 2006/07. DH then to pursue different funding options.***"

Macfarlane Trust 'Top-Up' Funding: Chronology in 2002

5.187. On 13 March 2002 there was a further meeting between the Department and the Macfarlane and Eileen Trusts, which I attended. The note records: [DHSC0003255_004]

> "***Financial status of both Trusts***
>
> *…Regarding the future funding of both Trusts the DH spending review was the time to consider such a change, however, bids had been completed and the next opportunity to consider changing the financial structures of both organisations would come in 4 years time….*
>
> *As requested the Trusts had provided expenditure forecasts, however, AH* [Ann Hithersay] *pointed out that the projections do not reflect increased expenditure due to changing needs. This would be possible after Kat Mcfarlane finished her work…*"

5.188. I have seen a document that, I think, contains the Macfarlane Trust's cash flow projections sent to me around this time [WITN4505348].

5.189. On 13 March 2002, Ian Fleming emailed me to say [WITN4505349]:

> "*At present we can probably lay our hands on some £1m+ of which I am aware but Sue is still chasing and we will know better later in the week. At present I know of no other use for such spare funds but I will need to clear any such use within the CDT.*
>
> *For the present, I suggest you say that it may well be possible to make a payment this year to both but it will be next week before we can be certain.*
>
> *In light of our discussions on the rate of depletion of the Macfarlane Trust, would there be any justification for pying[sic] more than £2m if it was available this year?"*

5.190. Unfortunately, the record here is incomplete. But I had clearly asked Ian Fleming if there was any end of year uncommitted money that might be given to the Trusts. This is the discussion that led to the decision to give the Macfarlane

Trust £2.25m in 2001/02 instead of £2m in 2002/03. It also yielded £0.5m for the Eileen Trust.

5.191. On 28 March 2002, I emailed Peter Stevens to say [DHSC0003251_013]:

"*As I hoped when we last met, we have been able to make end of year payments to both Trusts. These total £2.75m:*

£2.25m for the Macfarlane Trust Fund. This replaces the £2m you were due to receive from the Department in 2002/2003.

£0.5m for the Eileen Trust fund.

A decision will be taken later this year (probably in the Autumn) about the levels of payments to the Macfarlane Trust Fund from 2003/2004"

5.192. On 11 April 2002 Peter Stevens wrote to me expressing: [WITN4505350]

"*...considerable gratitude that the Department's coffers yielded something, especially for the Eileen Trust. And thank you, personally, for the work that these payments reflect.*"

5.193. Returning to Gordon Clarke's unsigned and undated letter to me (see § 5.176 above) [MACF0000011_023] and the Inquiry's question about whether £2.5m was provided to the Macfarlane Trust in 2002/2003 (as Gordon Clarke suggested in that letter), the answer is that it was not. Gordon Clarke's financial projections were based on no funding being provided in 2001/2002 whereas the Department in fact provided £2.25m in that financial year as a replacement for the 2002/2003 funding. That was more than had been budgeted by the Department.

5.194. I/ Department officials continued to meet with the Macfarlane Trust regularly in 2002/2003. Funding, including section 64 funding, would have been discussed.

Macfarlane Trust 'Top-Up' Funding: Chronology in 2003

5.195. Decisions on the 2002 Spending Review were not taken until early 2003. From 2003/2004 there was a commitment from the Department to provide capital funding of £3.050m in 2003/2004, £3.053m in 2004/2005 and £3.1m in 2005/2006. £50K of this funding in each of the three years was for the Department to hold back in case a person with haemophilia and HIV emerged who had still not received their lump sum payment from the Department. There had been a case in 2000 of someone living in New Zealand who had previously been unaware of their entitlement, so it seemed prudent to retain this small contingency fund.

5.196. Prior to that commitment being made, the Parliamentary Under-Secretary, Hazel Blears, held a meeting with Peter Stevens, Ann Hithersay and Dr Mark Winter on 27 February 2003. The meeting was originally planned for 22 January 2003. I prepared a briefing in advance of this meeting *[see DHSC0003280_007 and DHSC0042275_051].* However the meeting had to be postponed because the Minister was giving evidence to Committee. It was re-scheduled for 27 February 2003. I can see from the papers that I sent an updated briefing on 25 February 2003 [WITN4505351 and WITN4505352] and [DHSC0003279_012]

5.197. The updated briefing for the meeting now to be held on 27 February included, in relation to the Macfarlane Trust [DHSC0003279_012]:

> *"**Macfarlane Trust – Overview***
>
> *…*
>
> *2. In 1988 none of the 1,240 registrants infected with HIV were expected to survive for long. Today, 408 are still alive, 238 with families. Three-quarters are in the 25-50 year age range. All are co-infected with hepatitis C. The Trust also supports 38 widows or partners infected with HIV through intimate contact, 288 other widows and 438 children, 220 of whose fathers have died.*
>
> *3. Despite continued uncertainties about health, many registrants are becoming more optimistic about life expectancy and the ability to live a more normal life. They want to get back to work, marry, start families etc. Many of those who were young boys when the Trust was*

set up now have partners and young children. This means that, for the future, the Trust 'community' is likely to grow.

4. This long-term survival and change in expectations places demands on the Trust's resources, and there is a resulting tension between the expectation of registrants, the Trustees assessment of what it is reasonable to support and the Department's wish to keep Trust spending within agreed budget limits. We are managing this tension at present because of the close and amicable working relationship between the Trust and officials (we have a particularly good relationship with Peter Stevens who appreciates the Department's wish not to let costs spiral) but this may get harder as the expectations of registrants increase. To take one example, the Trust has been pressed by some registrants to support the cost of assisted conception techniques to avoid transmission of HIV. The Trustees have decided not to help with the cost of treatment but to assist with expenses such as travel and hotel accommodation close to the hospital providing the service.

5. The Trust started life with a £10m fund which, until a couple of years ago, was topped up by the Department on an ad hoc basis. We now have an annual budget for the Trust of £2m. This is inadequate as the Trust currently spends close to £3m pa (although, for this year, the Trust Fund balance is large enough for this not to matter). You will be able to tell Peter Stevens that further funding for the Trust has been obtained through SR2002 giving them £3.050m in 2003/04; £3.053m in 2004/05 and £3,100m in 2005/06. This will allow the Trust to meet current costs but does not give them any room to increase provision beyond that. In addition, we meet the Trust's administrative costs through Section 64 payments. These will reach £287K pa by 2004/05…

…

DH Support for the Trust

8. Over the past couple of years, we have focused on:

- *providing annual top-ups to the Trust fund that match the Trust's spend as far as possible whilst allowing the Trust to maintain a reasonable balance in investments;*

• supporting the Trust in developing its financial management systems. This was accomplished through an initial DH review to identify scope for improvement, seconding a NHS finance trainee to the Trust for 6 months to set up new financial and operating systems and funding a new financial assistant to maintain these systems.

• ensuring they have a full complement of well qualified Trustees;

• Meeting Peter Stevens and Ann Hithersay quarterly to review progress and discuss issues.

9. Looking forward:

• we have sought advice from DH solicitors on the extent of the Department's financial obligations to the Trust under the terms of the Trust Deed. We wanted to be sure that we were on safe legal grounds in capping the Trust's expenditure. SOL has advised that we have no legal obligation whatsoever to provide further funding. The deed simply sets out what the trustees must do as regards the money that comes into their possession.

• we need to work with the Trust to establish how best to meet the needs of registrants within funding constraints. We have agreed to support the cost of 3 yearly assessments of registrants' needs and the strategy to meet them…..

• …

• both we and Trustees recognise that some of the support provided by the Trust would be more appropriately provided by statutory bodies…The Trust argue that the service provided by local authorities is slow, insufficiently comprehensive and lacking in confidentiality (the stigma of HIV remains an issue among Trust registrants)…".

5.198. I return to this briefing in relation to other aspects later in this statement. At present I think it is useful to explain that the reference to advice that the Department had no legal obligation to provide further funding did not amount to a suggestion that the Department intended to stop funding the Macfarlane Trust. What I was seeking to establish was whether there was any legal obligation on the Department to match the funding it provided with the increasing sums being

requested by the Macfarlane Trust. That is why I referred to "*capping the Trust's expenditure*". This also links with the point I made in the briefing that the Department wished to keep Trust spending within agreed budget limits.

5.199. Following the meeting between the Minister and the Macfarlane and Eileen Trusts on 27 February 2003, Peter Stevens wrote to the Parliamentary Under-Secretary, as follows [DHSC0042275_042]:

> "…*We were greatly heartened to receive the assurance of the Government's continued commitment to the Trusts, and I know that all my fellow Trustees will also greatly appreciate the kind words you said about them. The certainty of the financial commitment over the next 3 years will also enable us to plan with greater confidence the development of our support for our registrants and their families.*
> *As I said at the meeting, we have found Charles Lister and his team consistently helpful and patient; having now had the pleasure of meeting you, I can fully understand why this working relationship between The Department and the Trusts has become so straightforward."*

5.200. Confirmation of a payment of £3m for 2003/2004 was sent to the Macfarlane Trust on 9 May 2003 [DHSC0003273_014]. The reason why the payment made was £3m and not the £3.05m allotted in SR 2002 was that £50k was held back as a contingency in case new Macfarlane Trust registrants were identified.

5.201. I note from the Trust's accounts for the year ending 31 March 2004, that the sum provided by the Department was in fact £3.1565m. This must be because the Trust agreed an additional payment with the Department after I left the blood team or it may simply be an inflationary element added by the Department. [EILN0000016_050]

Eileen Trust: 'Top-Up' Funding

5.202 The Eileen Trust also received top-up funding and S64 funding. From 1998/1999 – 2003/2004 the Eileen Trust received £500,000 of funding in

2001/2002 (plus sums paid to the Eileen Trust to provide lump sums for new registrants).

5.203 On 22 March 2001, I emailed Ian Fleming and raised the possibility of top-up funding for the Eileen Trust: [DHSC0003485_002]

> "*I have just been asked by the Eileen Trust (same management as the Macfarlane Trust) if we could top up their trust fund this year. I am not sure when this was last done, if ever. The Eileen Trust has a current balance of around £300k and a spend of £80-90k pa.*
> *If additional funds are available this financial year, may I propose that… £0.2m [is given] to the Eileen Trust*".

5.204. I do not have any independent recollection but, based on the documents I have seen, I do not think the Eileen Trust had requested a 'top-up' prior to this, while I was in my role. Of course, I am happy to reconsider this if documents show that earlier requests for 'top-up' funding were made.

5.205. I cannot now say whether the Eileen Trust representatives asked for a specific sum as a 'top-up'. In addition, I have not seen any Eileen Trust board meeting minutes that might assist with this. If the £200,000 potential 'top-up' figure was one I came up with, it would have been based on the amount left in the fund and the Trust's annual spend. Looking back, it feels like a reasonable sum to have suggested. I later revised this figure upwards to take account of new developments.

5.206. On 23 March 2001 Ian Fleming replied. I have already referred to this email. In relation to the Eileen Trust he said: [WITN4505346]

> "*I note what you say about the Eileen Trust. However, their existing assets seem sufficient to meet their liabilities for the foreseeable future and it would not seem prudent to make a further payment at this time. However, we will note this possible requirement next year and look again later.*"

5.207. I replied to this email on the same day but did not say anything about funding for the Eileen Trust in that reply.

5.208. In preparing this statement I have seen a copy of minutes from the Eileen Trust board meeting on 19 October 2001 [DHSC0003057_003]. Those minutes record:

> "*It was clear that Eileen Trust funds would be exhausted within the next 18 months and therefore very important to provide The Minister responsible for 'blood issues' with a forecast of future financial needs so that the Trust Fund could be topped up in 2002/2003. The Chairman said that he hoped a meeting with M/s Yvette Cooper, Minister of State for Health, could be arranged for early in 2002.*"

5.209. As set out above, in fact, further funding of £500,000 was provided to the Eileen Trust late in the financial year 2001/2002.

5.210. I have already referred in this statement to a meeting between the Department and the Macfarlane Trust on 5 December 2001 [WITN4505353]. The note of this meeting states I said it was important that the Department had some idea of the Macfarlane Trust's projected future spend up to 2006/2007 so that the Department could prepare to adequately fund the organisation and that:

> "*The same problem existed with the Eileen Trust…*
> ***Action: Macfarlane Trust/ Eileen Trust to provide DH with projected spend where possible up to 2006/07…***".

5.211. On 20 February 2002, I picked up the issue of funding for the Eileen Trust again with Ian Fleming: [DHSC0006569_059]

> *"At 31 March 2002, the* [Eileen] *Trust Fund is forecast at £129,554. Total forecast payments in 2002/03 are £109,635. At the present level of payments, therefore the Trust doesn't start running out of money until 2003/04. However, the margin is too low for comfort. A new Eileen Trust registrant has emerged and, if the Trust do what they usually do and back-pay the registrant to the point where the HIV infection was identified, they will run out of funds before the end of 2002/03. I'd be grateful therefore whether you could see if there is any money available this year to give the*

Trust to ensure this does not happen? A payment of £350K or £400K would see the Trust into 2006/07 but a smaller one would address the immediate problem."

5.212. On 13 March 2002 there was a meeting between the Department and the Macfarlane and Eileen Trusts [WITN4505354]. I was present. The minutes of this meeting record that we discussed the amount of capital held by the Eileen Trust and I said I was hoping to ensure a payment to the Trust in this financial year from the Department's underspend. The minutes also state that the Trusts (Macfarlane and Eileen) had provided expenditure forecasts although Ann Hithersay pointed out these projections did not reflect increased expenditure due to changing needs.

5.213. I have already referred above to Ian Fleming's email to me dated 13 March 2002 [WITN4505349]. In that email he stated that there may be funds that could be allocated to the Macfarlane and Eileen Trusts (i.e. in that financial year, 2001/2002). He advised me I could inform the Trusts that it may well be possible to make a payment year to both Trusts in that year but it would be next week before that could be certain.

5.214. On 28 March 2002 I emailed Peter Stevens and informed him that the Department would be able to make an end of year payment of £500,000 to the Eileen Trust [DHSC0003251_013]. This sum was in line with the case I put to Ian Fleming on 20 February 2002. Having regard to the funds left and forecasted payment (paragraph 5.208), £500,000 would have taken the Eileen Trust back up to £500,000 of holdings and gave it the certainty of being able to make payments for some years further.

5.215. Peter Stevens replied on 11 April 2002 (referred to above) to express gratitude that the "*Department's coffers yielded something, especially for the Eileen Trust...*" [DHSC0003251_013]

5.216. I have seen the Eileen Trust annual report and accounts for the year end 31 March 2002 [WITN4505355]. This records,

> "*Consequent upon the unusually high increase in the rate of disbursements during the year, which was largely due to causes that are not expected to recur, there would have been a marked depletion of the Trust Fund had the Department not provided a supplement to the Fund of £500,000. The Trustees are most grateful for this, not simply because it enables them to maintain their support of registrants and their dependants but also because it is tangible evidence of the long-term commitment by Her Majesty's Government to this small but uniquely damaged group of people.*"

5.217. I have also seen the Eileen Trust annual report and accounts for the year end 31 March 2003 [EILN0000016_051]. This refers to the 'top-up' of £500,000 at the end of the 2001/2002 financial year and says, "*the additional funding was received after the Trust had warned the Department that the level of the Fund was approaching £100,000, consequent upon a number of exceptional calls on it. In view of the assurance of continuing support from the Trust evidenced by the additional funding and reinforced at a recent meeting with the Government the Trustees believe that the Trust does not need a reserves policy.*"

5.218. I am aware this expression of confidence in continued financial support from the Department was repeated in the annual report and accounts for year end 31 March 2004 [EILN0000016_050]. This suggests that the Eileen Trust considered, at this time, that capital funding for the Eileen Trust from the Department was secure.

5.219. I think the reference to a "*recent meeting with the Government*" in the Eileen Trust accounts for year end 31 March 2003 is likely to refer to the meeting on 27 February 2003 between representatives of the Macfarlane and Eileen Trusts and the Parliamentary Under-Secretary, Hazel Blears. The briefing I prepared for that meeting (see §5.196, above) informed the Minister that, so far the Eileen Trust had made payments of £730,000, that the Department had provided the

first 'top-up' to the original fund in 2002, and that the Trust's current funds were £550,000, "*sufficient to keep it running until at least 2006/07*." I wrote that the "*costs are low and we have no difficulty given an unequivocal commitment to supporting the work of the Trust*" [sic]. [DHSC0003279_012]

5.220. I have not seen documents that show that the Eileen Trust sought a further 'top-up' before I left the blood policy team in May 2003. Again, if I am wrong about this then I will review the relevant documents and assist as best I can.

S64 Grants: Level of Funding

5.221. I am asked what factors the Department took into account when determining the level of S64 funding to the AHO. I am separately asked the same question about the Eileen Trust.

5.222. At the time covered by this statement, the Section 64 General Scheme of Grants (S64 of the Health Services and Public Health Act 1968) was the main way for the Department to make grants to voluntary organisations in England whose activities supported the Department's policy priorities. The grants were discretionary and terms and conditions agreed by Ministers and HM Treasury were applied. Competition for the available funds was always very strong.

5.223. In 1997, Ministers took the view that S64 grants should concentrate on innovative project funding. This led to those S64 grants that were inescapable long-term commitments for the Department (such as those for the Macfarlane and Eileen Trusts) being identified and separated off, although they remained S64 grants. This meant that grants for the Trusts for core administrative costs at the level approved by Ministers were not in competition with other bids for S64. However, as Simon Jones from the S64 team explained in a minute to Jonathan Stopes-Roe in DH Finance dated 29 July 1999 (into which I was copied) [DHSC0038637_047]:

> "*The possibility for additional core funding [for the Trusts] is always there but, like any other applications, must join the existing waiting list and is subject to the availability of funds.*"

5.224. Furthermore, any requests by the Trusts for S64 funding for projects, for example for the bereavement project discussed later, were in competition with other applications. Consequently, funding could be declined notwithstanding the merits of the case, even if supported by the blood team, because of competition for available funds from bids in other areas assessed to be even stronger. As I will address below, the nature of section S64 funding was allocation of funds from an overall 'pot' of a (strictly) fixed amount.

5.225. These factors, including the fact that Ministers wanted the overall amount awarded for S64 to diminish over time, made S64 a poorly suited vehicle for funding the Macfarlane and Eileen Trusts' administrative costs. Simon Jones' minute of 29 July 1999 went on to say:

> *"You will have noted from the figures that MT's core funding has been rising over the years instead of tapering in line with normal core grant policy. MT is almost unique in the S64 General Scheme in being wholly dependent on the Department for its administrative costs (the Eileen Trust is another very similar and related example).....given the facts that the money is needed but being included within the General Scheme budget might always be subject to other pressures. I have long thought that it would have been better to create a separate subhead for all MT's funding (and the Eileen Trust's)."*

However, no alternative to using S64 for the Trust's core administration costs, was identified during my time on the blood team.

5.226. My recollection is that S64 grants over £100,000 per annum required additional approval from the Department's S64 grants team. In addition, no organisation was notified about its S64 grant until Ministers made decisions on all grants. That meant organisations were sometimes not informed about their S64 grants until after the start of the relevant financial year.

5.227. S64 grants were replaced by the Department in 2008 by the Innovation, Excellence and Strategic Development (IESD) Fund.

5.228. It may help if I describe briefly how decisions on the award of S64 grants were taken in the Department, to the best of my recollection, and how decision on grants for the Macfarlane and Eileen Trusts fitted into this process.

5.229. The total sum available for S64 grants within the Department was agreed by Ministers. Each Directorate within DH was then given its own set allocation, which was divided between the Branches. In practice, this meant that the two branches that hosted the blood team – HS2 and then PH6 – has a maximum amount available to award to voluntary organisations within its policy areas. I was not involved in this allocation process so cannot say how these decisions were taken, but we were strictly cash limited.

5.230. Inevitably, we received many more requests for S64 grants than could be afforded within our Branch and Directorate allocations. Once the inescapable commitments, such as funding for the Trusts, were deducted, that left even less funding for other organisations. As addressed later, this became a particular issue when the blood team moved to PH6 bringing our S64 commitments with us.

5.231. Each year, Branches were required to submit an annual expenditure plan for approval by Ministers. This included details of grants recommended for award, including existing commitments and those recommended for rejection. As I will discuss later, recommendations for rejection often included applications that we would have liked to fund had more funding been available. I would have been involved in the decision making process on which grants to recommend to Ministers for acceptance or rejection.

5.232. As set out above, there were two kinds of S64 funding that the Trust's accessed under the S64 general scheme of grants. The first was core S64 funding which

was for the running or administrative costs. For the Trusts this was awarded on a three year cycle. For example:

- The Macfarlane Trust's core S64 budget from 1999/2000 – 2001/2002 was:
  - 1998/1999: £181,000
  - 1999/2000: £187,000
  - 2000/2001: £192,600
  - 2001/2002: £198,200
  - 2002/2003: £252,200
  - 2003/2004: £279,000
- The Eileen Trust's core S64 budget from 1999/2000 – 2001/2002 was:
  - 1998/1999: £23,000
  - 1999/2000: £24,000
  - 2000/2001: £25,000
  - 2001/2002: £26,000
  - 2002/2003: £30,200
  - 2003/2004: £32,500

5.233. The second kind of S64 funding were project grants. These were not for the general 'running costs' of the Trusts, but was intended to be for particular projects or financial requirements that arose from time to time. The Trust (or other organisation) would apply for this, and the application was separate from the application for core S64 funding. *Examples* are an application the Macfarlane Trust made for a bereavement project (that application was not successful – see below) and an application the Macfarlane Trust made for funding to update IT equipment (which was successful – also see below).

5.234. When it came to the core S64 funding for the Macfarlane and Eileen Trusts, the level awarded was determined by the Trusts' own assessment of its funding needs. I have seen a copy of a S64 checklist for the Macfarlane Trust S64 grant from 1999/2000 – 2001/2002. This was a form that had to be completed by officials for all S64 grant awards that were recommended to Ministers [WITN4505356]. I completed this particular form, probably in around

September/ October 1998. It shows the S64 grant applied for by the Macfarlane Trust in each financial year and the amount recommended to Ministers. These amounts are the same, i.e. the Macfarlane Trust put in a bid for funding in each year and I recommended the full amounts it requested.

5.235. A question on that S64 checklist reads, "*is the* [voluntary organisation's] budget administrative expenditure greater than that of the previous two years?" I have ticked yes, which according to the form should prompt further consideration of the appropriateness of a S64 core grant. I have then written on the form "*ministerial commitment to meet full admin costs so money provided for special payments + hardship can all go to affected individuals. Increase in budget reflects annual pay/ price increases + is reasonable.*"

5.236. I have also seen a submission prepared by David Hewlett, my branch head, to Dr Adam and the Parliamentary Under-Secretary, Lady Hayman, dated 21 December 1998. The submissions addressed HSD1's bid for S64 funding. There was a section on *"Ministers' funding principles*" which includes [DHSC0006162_066]:

> "*…Renewed core grants to the Macfarlane and Eileen Trusts, and a project bid from the Macfarlane Trust, are recommended. Both Trusts receive core grants for the costs of administering the special payment schemes established by the Government to make special payments to those infected with HIV through treatment with blood or blood products…Given the nature of the Government commitment to the schemes, we plan to examine alternative vehicles for covering the administrative costs, but for the coming year they are unlikely to have been identified.*
>
> *In addition, the Macfarlane Trust has submitted a bid for a project grant to complete a strategic review of their work. They were invited to submit the bid by Lady Hayman, after a request for additional funds in 1998/99 could not be met within the S.64 budget. The strategic review has been prompted by a significant change in the death rate and consequent life expectancy of the remaining HIV registrants, following the introduction*

of new treatments. Those infected with HIV through blood or blood products are living longer, but have to deal with different, psycho-social, problems, which may affect the way in which the Trust can best help them.

It would be publicly embarrassing if the administrative costs of the two Trusts were not to be covered. Equally, it would not seem sensitive to turn down the project application when some encouragement has been given, and when the project is a practical one designed to make the best use of the monies which the Trust receives and disburses."

5.237. The submission recommended approving the S64 core grants applied for by the Macfarlane and Eileen Trusts and also the Macfarlane Trust's S64 project grant.

5.238. As mentioned above, the general scheme of grants awarded under S64 was very popular and so there were competing demands on funding. A good illustration of this can be seen in PH6's annual S64 branch expenditure plan of 8 March 2002 submitted by Dr Mary O'Mahony [WITN4505357]. This shows that, in addition, to applications from the Macfarlane and Eileen Trust, my team had received S64 bids from the Haemophilia Society, the British Liver Trust, Mainliners Ltd, Friends of Life, the Anthony Nolan Bone Marrow Trust, the British Liver Trust and the Haemophilia and Hepatitis C Fund.

5.239. When it came to S64 funding for specific projects rather than core administrative costs, Trust applications were considered alongside other demands on the S64 budget and potentially wider budgets. I have seen a minute from Geoff Barrett in DH Finance to Lord Hunt's private secretary, dated 2 August 1999. Lord Hunt had taken over from Baroness Hayman as the Minister in the Lords. The minute was in the context of seeking to identify a further £52,000 for the Macfarlane Trust to reimburse the Trust for money it had already spent updating IT equipment. It said: [DHSC0038637_029]

"*… While, therefore, there is a good cause for making an additional grant to the Trust for up to £52k, as you know the Department's expenditure programme is under a great deal of pressure at present in*

particular because of the need to make available funds for the meningitis vaccine. The present position is that MS(H) has decided that we should not make any new expenditure commitments unless we are contractually bound to do so until at least the end of August when Ministers will be in a better position to assess the costs of the meningitis vaccine. We should, of course, not broadcast this embargo.

We shall not, therefore, be able to consider any additional grant to the Trust until the end of August and even then, given the pressure on the s64 general scheme budget, Ministers will presumably wish to consider the Trust's needs alongside the many other applications for funds.

I should be grateful if you would let me know if PS(L) is content with this position."

5.240. On 10 August 1999 Lord Hunt's private secretary replied to say he was content. [WITN4505358]

5.241. Prior to this, at a meeting between the Macfarlane Trust and Baroness Hayman on 17 June 1999, Baroness Hayman had informed the Trust that the Department would cover the cost of new IT equipment. I had drafted a letter dated 1 July 1999 on her behalf to the Macfarlane Trust which included: [DHSC0006162_006]

"*I can give you my assurance that we are fully supportive of the Trust's work and have great admiration for the thought and energy which you give to it. We will of course continue the commitment to provide the finances which you need for the Trust Fund. We will also continue to fund the efficient administration of the Trust and we will meet the costs of appropriate information technology to meet today's needs.*"

5.242. There were various efforts to try to identify funds to reimburse the money the Macfarlane Trust had spent (spent before the meeting with Baroness Hayman). Ultimately money was identified in end-of-year underspend but it could only be

paid through a S64 grant [DHSC0038637_004]. Therefore on 23 February 2000 [WITN4505359] the Macfarlane Trust completed a S64 application for £51,302 for the costs of the IT equipment.

5.243. On 25 February 2000 I put a submission to Lord Hunt [WITN4505360] seeking his agreement to award a one-off S64 grant of £51,302 to the Macfarlane Trust in 1999/2000. This was in addition to its existing core grant.

5.244. In the submission I explained that:

> *"3. …The administrative costs of the Trust are met through a Section 64 core grant as an ongoing commitment. The grant awarded to the Trust this year is £187,000. However this grant does not allow for one-off items of expenditure which the Trust may unavoidably incur from time to time in order to ensure the efficient running of their service.*
>
> *4. Until recently the Trust maintained its records on a computer system installed in 1988…Replacement of the software was therefore essential to enable the Trust to continue its work….*
>
> *5. The Trust originally approached the Department in 1998 to fund the cost of the new system, but no source of funding could be identified at the time. The Trust therefore purchased the system using money from the Trust Fund, which they have asked the Department to reimburse (we have agreed as a general principle that the Trust Fund should be used only for the benefit of the Trust's registrants and not to cover administrative expenses). The Trust raised this issue with Lady Hayman when they met in June 1999, and Lady Hayman's follow up letter promised that "we will also continue to fund the efficient administration of the Trust and we will meet the costs of appropriate information technology to meet today's needs.*
>
> *6. Sufficient funding is available this year through Section 64 to enable us to award a one-off additional core grant to fully reimburse the Trust..."*

5.245. Lord Hunt agreed to this payment and it was authorised on 13 March 2000. [WITN4505347]

5.246. That was quite an unusual decision making process for S64 funding. A more typical example of a S64 project grant decision-making process can be seen in response to the Macfarlane Trust's application for S64 funding in October 2002 (so as part of the 2003/2004 funding). The application was for funds for a long-term review, "*to carry out a 'user focused' review of Trust registrants and the dependants of those who have died in order to plan for their long-term support from the Macfarlane Trust and to identify the level of long-term commitment that will be required from Government.*" [WITN4505361]

5.247. Ann Hithersay's covering letter to this application said: [DHSC0003244_012]

> "*Re: Project Application – Macfarlane Trust – Long Term Review*
> *I enclose our application form for the above Project Grant, which has been prepared at the request of Charles Lister of the Blood and Healthcare Associated Infections Unit…*"

5.248. I provide more information on the Long-Term Review later in this statement.

5.249. On 18 December 2002, Dr Mary O'Mahony, the branch head at PH6, submitted PH6's S64 bids for 2003/2004 to the Parliamentary Under-Secretary, Hazel Blears. The submission listed the previously approved S64 core funding for the Macfarlane and Eileen Trust (in annex A). It also listed applications for new or renewed grants that were recommended for approval (in annex B) and recommended for rejection (in annex C). [DHSC0046745_062]

5.250. The submission included a section on "*Ministers' funding principles":*

> "*S64 awards concentrate primarily on project funding but Ministers have also recognised that core funding may also be necessary for works which fit strategically with Departmental objectives and for which measurable outputs and achievements are possible. Any core grant*

applications recommended in Annex B have been required to demonstrate this as follows:-

(1) proposed new core grant – the innovative work that would be funded; and

(2) proposed renewal core grant – why and how continued funding would help achieve Departmental aims, and the outputs and achievements a grant would produce."

5.251. The Macfarlane Trust's application for funding for its bereavement project was listed in annex C, i.e. recommended for rejection. I had encouraged the Trust to submit this application, which aimed to establish mutual support networks and counselling for bereaved families of haemophiliacs with HIV, so I was particularly disappointed that it had to be rejected on grounds of "*insufficient funding*". This was not the first year that we had tried and failed to find S64 funding for this project. We also turned down applications from other bodies for worthwhile projects that year because funding was not available. I will go on to say more about this below.

Delay in Section 64 Funding to the Eileen Trust

5.252. I am asked why there was a "*long delay*" by the Department of Health in sending the first quarter payment of the S64 grant to the Eileen Trust in 1999. I am referred to EILN0000010_110, a letter from Ann Hithersay to me, dated 5 July 1999, in which Ann wrote, "*Obviously, the long delay in making the First Quarter payment of Section 64 grant for the year means that our cash holding is very low at present…*"

5.253. The Eileen Trust sent its application for S64 core funding on 25 September 1998. Ann Hithersay described it as a "*late submission*" and it appears there had been a problem with application forms [WITN4505362]. In any event, an extension to the deadline had been allowed. This application was passed on to the S64 grants unit on 28 September [WITN4505362A]. The Eileen Trust's application was for a S64 core grant of £24,000 (for 1999/2000).

5.254. In November 1998, I wrote to Linda Percival in HSD's central unit about my understanding that, in the absence of a decision from Ministers on the 1999/2000 S64 allocation, the plan was that each Branch in HSD should assume the same allocation as in 1998/99. I pointed out that this was not straightforward for HSD1, including in relation to the Macfarlane Trust [WITN4505363]. I cannot now say why Ministers had not reached a decision on S64 funding allocations for 1999/2000. I also cannot say whether this had any impact in the delay to the Eileen Trust receiving its first quarter S64 funding.

5.255. The Department met with the Macfarlane Trust on 14 June 1999, in advance of the Trust's meeting with Lady Hayman on 17 June 1999. I attended this meeting. As explained above there appears to be two very similar notes of this meeting. One version includes: [WITN4505319]

> "*S64: Eileen Trust core grant and Macfarlane Trust project grant letters given to Trust. Macfarlane Trust core grant letter being prepared. First quarterly payments to be made as soon as possible.*"

5.256. I had written a letter to Ann Hithersay on 14 June 1999 notifying her of the S64 grant award for the Eileen Trust: [DHSC0006162_065]

"We have now considered the request for a grant in your application to us dated 25 September 1998. I am writing on behalf of the Secretary of State to offer the Eileen Trust a grant up to a maximum of £24,000 for 1999/2000 and, provisionally and subject to the availability of funds approved by Parliament, up to a maximum of £25,000 in 2000/2001 and £26,000 in 2001/2002. Please accept our apologies for the delay in sending you this notification."

5.257. Unfortunately I cannot now provide further explanation of the delay up until this point.

5.258. In preparing this statement I have also seen a letter from Ann Hithersay to me, dated 19 August 1999 [WITN4505364]. The letter is primarily about delays in paying the Macfarlane Trust's S64 funding. However, the end of the letter says "*I must remind you that we are also awaiting payment of the Project Grant for*

the Strategic Review, and for the first two quarterly instalments of the Eileen Trust Core Grant for 1999/2000."

5.259. I sought authority to pay the Eileen Trust S64 core grant that day, on 19 August 1999 [WITN4505365]. This was granted and the first and second quarter's instalments were due to paid shortly after 6 September 1999 [DHSC0027392]. I have seen no documents to suggest this did not happen.

5.260. Again, unfortunately, I cannot say what caused this ongoing delay.

Continuation of Section 64 Funding

5.261. I am asked about the minutes of the Macfarlane Trust board meeting on 24 November 1998 which recorded that "*Mr Lister indicated that he felt that the Macfarlane Trust was a special case for continued Section 64 funding and he would not recommend that funds for the administration of the Trust came from any other Department budget*" [MACF0000017_065]. I am asked to explain the context of this statement, in particular, why the Macfarlane Trust was a "*special case*" and the alternatives to S64 funding that were being considered.

5.262. The relevant minutes record:

> ***"Department of Health Contact***
>
> *The Administrator reported that Mr Charles Lister had taken over from Christine Corrigan, the Trusts's [sic] most recent previous point of contact with the Department of Health. Mr Lister had visited the Trust to learn more about it's [sic] work and to discuss the recent Section 64 Application and request for funds to meet the costs of the Strategic Review. Mr Lister indicated that he felt that the Macfarlane Trust was a special case for continued Section 64 funding, and he would not recommend that funds for the administration of the Trust came from any other Department budget."*

5.263. I did not see these minutes at the time and cannot now comment on the accuracy of what was attributed to me. However, if the comment attributed to

me not recommending that funds came from anywhere other than S64 is correct, this can no doubt be explained by my newness in the role. As discussed above, it would quickly become clear to me that S64 was not in fact an ideal way of funding the Trusts' administration costs.

5.264. I have already explained that in 1997 Ministers decided that S64 grants should concentrate on innovative project funding and the Macfarlane Trust's administrative costs did not fall into that category. However, the Department had committed to funding these costs and so funding continued to be provided and, for many years, this continued to be done via a S64 core grant. At the time there was, I think, no other means of funding the Trust's administrative costs (or at least none had been identified).

5.265. I have already referred to a submission by David Hewlett to the Parliamentary Under-Secretary, dated 21 December 1998, seeking agreement to the S64 bids proposed by HSD1 for 1999/2000 [DHSC0006162_066]. That submission included bids for the Macfarlane and Eileen Trusts. I would have contributed to drafting it. The submission states, *"Given the nature of the Government commitment to the schemes, we plan to examine alternative vehicles for covering the administrative costs, but for the coming year they are unlikely to have been identified."*

5.266. The wording of the submission suggests that alternative vehicles had not yet been considered but that was something for the future. This continued to be raised over the following years but by the time I left the blood policy team the Macfarlane and Eileen Trusts' administrative costs were still being funded via S64 core grants.

5.267. As mentioned already, the S64 general scheme budget was naturally subject to other pressures, including competition for S64 grants. However, as explained above in this statement, it was recognised that the Trusts' S64 core grant was an inescapable commitment. Funding via the S64 core grant process also

meant that unpredicted or unbudgeted costs had to be sought separately, as happened with funding for the Macfarlane Trust's IT equipment (see above).

5.268. I can see that from the documents that I emailed Ian Fleming on 27 September 2000 as follows: [DHSC0003486_010]

> "*Can we discuss the possibility of funding the admin costs of the Macfarlane & Eileen Trusts through S64 specific grants. Given the function of these bodies and the fact that they have many years of life ahead of them, this does sound appropriate. But I don't know much about specific grants and whether adding to them at this time is a realistic prospect.*
> *We could look at this alongside our general review of our long-term commitment to the Trusts.*"

I cannot now recall what a S64 'specific grant' was or why I thought this might be a possible solution and none of the papers available to me help with this.

5.269. It seems this did not come to anything (although I do not recall the detail). I can see from the documents that Ann Hithersay reported to the Macfarlane Trust board meeting on 6 April 2001 (after a meeting with me on 5 April 2001) that: [WITN4505347]

> "*Charles Lister said that despite recognition that Section 64 funding was not really an appropriate vehicle for funding of the Trust's administration, no alternative had been found. Further applications for Section 64 Core funding for both Macfarlane and Eileen Trusts would need to be submitted in July 2001.*"

5.270. On 5 December 2001 I attended a meeting between the Department and the Macfarlane Trust. There are several references in the minutes to S64 being unsuitable for funding the Macfarlane Trust's administrative costs, including: [WITN4505353]

> "*CL explained the problems in obtaining adequate Section 64 funds to support not only the Macfarlane and Eileen Trusts' costs but also other*

projects by both Trusts and other organisations in this field. PS stated that if it would be more helpful to the DH to have just one budget then the Macfarlane Trust deeds would not disallow this and they would be happy to accept and separate the payments once they have been received."

I cannot now explain why the Department made no real progress on this issue while I was in the blood policy team. I do not recall this being an issue under discussion after 2001.

5.271. I mentioned above the issues caused by the Section 64 commitment imported into PH6 when the blood team moved from HS2. On 7 January 2002 I raised this concern with my new branch head, Dr Mary O'Mahony. In moving across to PH6, I had brought with me a substantial S64 funding commitment which outstripped PH6's total S64 allocation in 2001/2002 [DHSC0004032_047]. Having explained the situation, I suggested that Dr O'Mahony would need to:

"...argue for a much larger share of the PHCQ pot than last year. You may also wish to press for a transfer of S64 monies from Policy Directorate given the disproportionate burden on PHCQ's resources of taking on the blood team's S64 commitment."

5.272. On 22 January 2002 I emailed Peter Jones, in PH6's central unit to say: [WITN4505366]

"Clearly the lack of funding for the existing commitments and renewals imported by the blood team is very serious and needs to be addressed. The organisations we support should not be disadvantaged because of Departmental restructuring. The best outcome would be if we can get funding for all these plus Friends of Life but, failing that, FoL is our lowest priority bid and I wouldn't want them to have funding at the expense, say, of the Macfarlane Trust..."

I believe that this shows my concern that organisations previously dependent upon the Health Services Directorate for their S64 funding might be disadvantaged by mere departmental re-structuring. But it also evidences that I

saw the Macfarlane Trust as a high priority for such funding, even amongst a group of highly deserving bodies.

5.273. On 28 January 2002, Catherine Pearson from PH1 Emailed branch heads in the Directorate to confirm branch S64 allocations [WITN4505367]. In doing so, she added:

> *"…it seems there is no possibility of finding extra funding for the 'blood' bids for PH6. I'm afraid I've had to revise the branch allocations to take account of this, as well as the extra commitments which have been sent since. This means losing a total of around £900,000k from the overall amount requested in the draft branch expenditure submissions. I've tried to do this as fairly as possible across branches…..but it does mean that everyone will to cut back further."*

5.274. On 29 January 2002, Peter Jones emailed Dr O'Mahony with a summary of the implications of this for PH6 [DHSC0004032_039]. Taking account of unavoidable/priority commitments, he commented that we were left with *"a paltry £45,300 to spend on the remaining applications."*

5.275. On 8 March 2002, after further discussions on priorities, Dr O'Mahony sent a submission to the Minister setting out PH6's S64 bids [WITN4505357]. For the Macfarlane Trust this recommended S64 core funding of £252,200 in 2002/2003 as against a request for £266,000. It recommended the full amount requested in 2003/2004 and 2004/2005 (£279,000 and £287,000 respectively). The recommendations for the Eileen Trust were as per the amounts requested in all three years.

5.276. On 13 March 2002 the status of the S64 bids was discussed at a meeting between the Department and the Macfarlane and Eileen Trusts [DHSC0003255_004]. The minutes record I informed the Macfarlane Trust that decisions were awaited from Ministers, that the move of blood policy to PH6 (the public health directorate) had not brought an improvement in budget

allocation, and the core funding for the Macfarlane Trust may be reduced in year 1 but it was hoped years 2 and 3 would be granted in full.

5.277. The minutes also record:

> *"Regarding the future funding of both Trusts the DH spending review was the time to consider such a change, however, bids had been completed and the next opportunity to consider changing the financial structures of both organisations would come in 4 years' time. CL stated that it sounded sensible to change the financial position from Section 64 funding and said that DH would keep this as a medium term objective."*

5.278. On 22 March 2002 the Parliamentary Under-Secretary's office (Yvette Cooper) responded to PH6's S64 funding bids. She approved the recommended funding for the Macfarlane and Eileen Trusts [DHSC0006569_049].

Guidelines on Use of S64 Funds

5.279. I am asked whether the Department provided clear guidelines to the Macfarlane Trust on the use of S64 funds.

5.280. I think the answer to this question is probably yes, although I can only comment on this for the time in was in role.

5.281. It may assist here to expand slightly on the introduction to the S64 funding process which I set out above. First, when the relevant organisation made an application for S64 funding the specific form used for that purpose asked the organisation to identify the Departmental objective(s) that a core grant would further and the specific objectives to be achieved with a S64 grant. For example, the Macfarlane Trust's application in 1999/200 stated that *"It was agreed at the outset that administrative expenses would be met by Section 64 grant. Accordingly the objective of the core grant is to maintain the administrative infrastructure of the Trust in a manner compatible with the most effective use of the financial resource…made available by the Department…*". [WITN4505368]

5.282. I have not seen copies of earlier applications by the Macfarlane Trust.

5.283. After a decision had been made on the level of S64 funding to be provided, funding offers were made in writing to the Macfarlane and Eileen Trusts (and other organisations). The written offer included a statement of the purpose of the grant (i.e. what it was for) and included a series of standard conditions that attached to the grant offer. It could also include additional conditions that applied to the grant.

5.284. The recipient of the letter was asked to confirm he/ she had read and understood the contents of the letter and accepted the conditions, and to indicate this by signing a copy of the letter and returning it to the Department. That had to be done before grant money was provided.

5.285. I have provided an example of a S64 grant offer letter issued to the Macfarlane Trust in December 1999 [WITN4505369] and a letter issued to the Eileen Trust in June 1999 [DHSC0006162_065]. The December 1999 offer letter to the Macfarlane Trust stated: "*the grant is to meet the administrative costs in distributing the funds made available by the Government for people with haemophilia and HIV infection and their dependents.*" [WITN4505369]

5.286. I do not think there were significant changes to the standard conditions over the years that I was in the team.

Macfarlane Trust's Ex-Gratia Payment

5.287. I am asked to explain why an ex-gratia payment of £4000 was made to the Macfarlane Trust's administrator using S64 funding. I am referred to the minutes of a Macfarlane Trust meeting on 3 October 2000 [MACF0000006_032] and a report on a meeting with the Department dated 6 April 2001 [MACF0000006_019].

5.288. This question relates to events that occurred before I was in the blood policy team. I therefore cannot explain from first-hand experience why the Macfarlane Trust chose to make this payment. However, I will do my best to assist with setting out documents that appear to be relevant to this question.

5.289. As far as I can tell the payment of £4000 to mark the retirement of the Trust's administrator was made in the financial year 1998/1999 (see below). If that is correct it was made from S64 funds that were provided in the round of S64 funding from 1996/1997 – 1998/1999. I have seen a letter from the Department to the Macfarlane Trust, dated 6 February 1996 [DHSC0038637_061]. That letter offers the Macfarlane Trust S64 funding over this three year period. It is an earlier version of the offer letter I have described above. It states, "*This grant is to meet the administrative costs in distributing the funds made available by the Government for people with haemophilia and HIV infection and their dependants.*" It contains a series of conditions. Like later S64 offer letters it states that signing and returning the letter confirms acceptance of the conditions. I have not seen a signed return from the Macfarlane Trust but I anticipate this must have happened for the Trust to have received the S64 grant.

5.290. I have seen a document sent by Derek Dudley to Christine Corrigan (Christine was my predecessor on the blood policy team), dated 9 February 1998 [DHSC0003190_004]. This states that Mr Grinstead, deputy Chairman of the Macfarlane Trust, met with Mr Dudley on 5 February 1998. One of the issues raised was the Macfarlane Trust's wish to provide a payment to its former administrator to mark his "*sterling work*" while the Trust had not been providing any pension contributions for him. The Trust wished to explore ways of doing this.

5.291. Mr Dudley wrote:

> *"Given my own extensive experience of s64 policy I said that I had not come across such a novel use of S64 before and I doubted very much whether such a vehicle would be a possibility, even if we could overcome the procedural and timing difficulties. Looking at the Trust*

Deed with Mr Grinstead, I suggested that article 6(x) seemed to provide for such a situation….Although Mr Grinstead…would be reluctant to see Trust money used for other than direct patient benefits, we agreed that he would write to me with details of their modest proposals on which RMF-EAC2 would be happy to advise."

5.292. I have also seen a letter from Mr Grinstead to Mr Dudley, dated 16 February 1998 [DHSC0003190_003]. That letter referred to a conversation between Mr Grinstead and Mr Dudley and set out the Macfarlane Trust's proposal that £4000 should be paid to the former administrator and that "*it would be proper for the source of funding of the award to be the S.64 grant…*". The letter concluded "*I look forward to hearing from you*."

5.293. I can see that Sue Adams from DH Finance wrote to Mr Dudley on 4 March 1998 to say that the use of S64 would not be appropriate to provide a one-off payment to a former administrator and if Trust funds were to be used, there was a need to be satisfied this was permitted under the Trust deed [DHSC0038637_053].

5.294. On 13 July 1999, an individual from the National Audit Office spoke to me about the £4000 payment from the Macfarlane Trust's S64 funds. The same day I emailed Marian Awuley in the S64 grants unit as I was seeking to establish whether the payment was an appropriate use of S64 funds [DHSC0038637_052]. I asked Ms Awuley for her view on this. I also informed her that the Trust raised the issue of the payment with the Department in February 1998. I wrote that there was a minute on our files which set out the position, but there was no further paperwork. I am now not sure which minute this refers to. I wrote, "*sadly, we don't appear to have communicated our decision to the Macfarlane Trust in writing either.*" [DHSC0038637_052] I asked Ms Awuley if she had any documents to indicate what decision was taken at the time.

5.295. I cannot now say what documents/ files I looked at but it would appear I had done some kind of review or search and did not locate a letter from the Department saying the S64 funds could or could not be used for this purpose.

5.296. Ms Awuley responded on 14 July 1999, saying this was a "*novel and contentious use of S64 money…The fact is there is no evidence to suggest that we agreed to the payment and therefore the Trust may have to refund £4K…*". [DHSC0038637_050].

5.297. By email dated 20 July 1999, Simon Jones, the head of the S64 grants unit, informed me that they had provided advice that such a payment would be an inappropriate use of S64 funds [DHSC0038637_049]. Mr Jones now agreed with that view, writing that "*S64 General Scheme grants are not awarded to voluntary organisations to enable them to make ex-gratia payments, however worthy the cause. Such expenditure must be the responsibility of the trustees from other funds at their disposal – whether they have the right to do so under the terms of their trust deed I cannot say…*" He recommended that I consult with Department lawyers before replying to the National Audit Office and the Macfarlane Trust.

5.298. On 30 March 2000, Sue Adams emailed Geoff Barrett: [DHSC0003491_006]*:*

> *"I believe you are putting together a reply to NAO letter re grants. One area mentioned was a payment to an ex-employee of MacFarlane Trust. I was involved as we do FLP work for the Trust Fund budget part of MacFarlane.*
>
> *I saw a copy of the original letter from C Grinstead at the Trust to Derek Dudley (HSD) proposing this payment. Following some discussion about the use of S64 (of which I am no expert) I wrote to Derek on 4/3/98 saying that as Section 64 was inappropriate that all I could suggest was that HSD ask SOL if the Trust Fund deeds allow payment of such an item to be made from Trust Funds. This was the last I heard until an e-mail from Charles Lister (HSD) to Marian Awuley (S64) on 13/7/99 saying that MacFarlane appeared to have used their S64*

money for such a payment. I copied my previous advice to both Charles and Marion. Simon Jones (S64) agreed that S64 was inappropriate and that use of Trust funds for other than their intended purposes should involve SOL…"

5.299. I have seen minutes of a Macfarlane Trust Board meeting on 2 May 2000 [MACF0000013_031]. To be clear, I did not attend that meeting. The minutes record that:

"The Chief Executive's Report was noted. The issue of the Ex-gratia payment to GRO-A made in 1998 and the subject of a challenge from the National Audit Office that the payment should not have been made from Section 64 funding, was discussed It was agreed that the Chairman would seek a meeting with a senior officer of the NAO to discuss that contents of Clifford Grinstead's letter of 16.02.98 to Derek Dudley of the NHS Executive. Charles Lister had agreed to identify an appropriate person within the National Audit Office for the Chairman to approach the matter. Trustees were not prepared to accept the Department's decision to withhold £4,000 of the Section 64 grant for the current year on the basis of unclear and insufficient information from the Department".

5.300. I am aware from the documents that the issue was raised again at the Macfarlane Trust Board meeting on 3 October 2000 [MACF0000006_032]. The minutes refer to a meeting with me and record:

"The Chairman had asked Mr Lister for further information about who to pursue in the National Audit Office with regard to their statement that the Trust should not have used Section 64 Core Funds to make an ex-gratia to John Williams, the Trust's first Administrator in 1998. Mr Lister had promised to identify a name, and also mentioned that the Officer who had met with Mr Grinstead about the matter in 1998, had not made notes of the meeting and could not now recall their conversation. No letter had been sent to the Trust to advise that Section 64 Core funds should not be used for the purpose."

5.301. The Macfarlane Trust's annual report and accounts for year end 31 March 2001 [MACF0000006_009] state that the Trust was reviewing, with the Department, the applicability of S64 funding to a £4000 ex gratia payment made in 1998/1999.

5.302. I have seen an extract from a document with the title "*Ex-gratia payment made by the Macfarlane Trust to a retiring officer*" [DHSC0033332]. The document is incomplete and undated but appears to be an extract from a NAO management letter to the Department. It sets out the background to the issue I have described above and states:

> ***"Observation***
>
> *2.4.1 In February 1998 a senior employee from the Macfarlane Trust approached the Department with a suggestion to use Section 64 grant monies to fund a tax-free, ex-gratia award of £4000 to a retiring officer. The Department advised against the use of Section 64 grant monies, however, from liaison with the Macfarlane Trust's contact at the Department, we established that this payment was made against the Departmental advice.*
>
> ***Implication***
>
> *2.4.2 Payment of an ex-gratia sum to a retiring member of staff of a recipient body does not contribute to the Department's objective or meet the conditions under which Section 64 grants are made. The fact that the Department was not able to ensure that the Macfarlane Trust followed its advice also raises a concern as to the ability of the Department in practice to ensure that grant conditions are adhered to.*
>
> ***Recommendation***
>
> *2.4.3 When concerns regarding contentious payments by sponsored bodies are identified, it is essential that adequate measures are adopted to dissuade sponsored bodies from making such payments, including sanction to reduce future payments to recover such amounts.*"

I was the Macfarlane Trust's contact at the Department referred to in the first paragraph.

5.303. There is a response to this extract that was prepared by Simon Jones, head of the S64 grants unit [DHSC0033332]. It states:

> "*Recommendation 2.4.3 – Accepted. Action will be taken to recover this money. I should comment, however, that –*
>
> *(1) the approach in 1998 was from the Deputy Chairman of MT's trustees, not a "senior employee". MT is in the almost unique position within the S64 General Scheme, having been created by the Department to administer a trust fund solely to benefit those affected by contaminated blood products. The S64 grant is given for MT's core administrative costs. MT has no source of voluntary income and only a few employees. The trustees wished to mark the retirement of the MT's first Administrator, who had done so much to set up the organisation, but could not use the non-S64 money under the terms of their trust deed,*
>
> *(2) internal Departmental advice was certainly against MT using its S64 funds in the way proposed. The failure was in not passing this advice to MT – it is misleading to say "this payment was made against Departmental advice", and*
>
> *(3) in the opinion of the sponsor section, it would have been totally out of character for MT to have ignored Departmental advice had it been given.*"

I would have contributed to this response. Although, it's hard to recall the detail given the passage of time, I am confident that this response will have accurately reflected the conclusions I reached after reviewing the evidence.

5.304. I can see from the Macfarlane Trust's report of a meeting with the Department on 5 April 2001 [MACF0000006_019] that the payment continued to show as a 'contingent liability' on the Trust's accounts because the National Audit Office's view was that the payment should not have been made from S64 funding. The report states, *"[i]t was important that this matter was resolved in time for the auditors to delete the liability from the Trust's accounts for the financial year 2000/2001.*"

5.305. I have seen no further mention of the payment in subsequent accounts relevant to my time in the role, nor can I recall the outcome.

5(D) DEPARTMENT OF HEALTH INPUT INTO AHO POLICY AND DECISION MAKING

Macfarlane Trust Strategic Review

5.306. I am asked about my knowledge and involvement with the Macfarlane Trust Strategic Review (the 'Strategic Review').

5.307. In general terms, my recollection (aided by the documents) is that my own main involvement in issues raised in the Trust's Strategic Review was in the eventual achievement of a commitment to long term funding of the Trust with a greater degree of certainty of such funding achieved through its inclusion in the Spending Review process. I have addressed this in Section 5(C) above and uncertainty around future funding was the highest priority of those issues arising for the Department from the Trust's Strategic Review. As well as the continuance of funding, there was also a measure of increased funding which reflected (within funding restraints) what the Review had identified about the changing patterns and increased demands / expectations of registrants.

5.308. Ann Hithersay wrote to me on 23 October 1998, shortly after I joined the blood policy team, to update me on the progress of the Strategic Review. [WITN4505370].She explained that the Strategic Review was occasioned by the improved life expectancy of Macfarlane Trust registrants as a result of new treatments for HIV/AIDS. An interim report had been submitted to the Parliamentary Under-Secretary, Baroness Hayman, at the end of July 1998, with a request for further S64 funds to complete the review.

5.309. Ann Hithersay informed me that, on 8 September 1998, the Department had advised the Macfarlane Trust that there was no money available to fund completion of the Strategic Review in the current financial year (the Department had provided some S64 funding for this in the 1998/1999 financial year). At the

Minister's suggestion, the Macfarlane Trust had applied for S64 project funding but, rather than wait for a decision, the Trust had pressed ahead with the aim of completing the review by the agreed deadline of November 1998. The Trust was therefore projecting an overspend on its administration costs of £11,505. Ann's letter to me concluded with a suggestion that we meet after her return from leave on 3 November 1998.

5.310. I do not recall the meeting I had with Ann Hithersay in any detail, but I can see from the documents that, at the Macfarlane Trust Board meeting on 24 November 1998, she reported [MACF0000017_065]:

> *"Mr Lister had visited the Trust to learn more about its work and to discuss the recent Section 64 application and request for funds to meet the cost of the Strategic Review"*

5.311. As referred to above, on 21 December 1998, David Hewlett, my Branch Head, submitted recommendations to the Parliamentary Under-Secretary for S64 funding for 1999-2000, including for the Macfarlane Trust [DHSC0006162_066] I or my team will have contributed to the submission and were on the copy list. The submission recommended that Ministers agree project funding for the Strategic Review:

> *"They [the Trust] were invited to submit the bid by Lady Hayman, after a request for additional funds in 1998/99 could not be met within the S.64 budget. The strategic review has been prompted by a significant change in the death rate and consequent life expectancy of the remaining HIV registrants following the introduction of new treatments. Those infected with HIV through blood or blood products are living longer but have to deal with different, psycho-social, problems, which may affect the way in which the Trust can best help them…*
>
> *…it would not seem sensitive to turn down the project application when some encouragement has been given, and when the project is a practical one designed to make the best use of monies which the Trust receives and disburses."*

5.312. I understand this was approved and up to £23,000 was awarded. The Macfarlane Trust Board meeting minutes, dated 28 April 1999, record this [MACF0000017_067] I issued the formal award letter on 14 June 1999 [WITN4505371].

5.313. The Macfarlane Trust submitted the Strategic Review [MACF0000045_019] to the Parliamentary Under-Secretary, Baroness Hayman, at the end of January 1999 [MACF0000045_019]. A corrected version was resubmitted on 18 February 1999 with a covering letter from Ann Hithersay who proposed a meeting to discuss the findings [DHSC0032142_010].

5.314. The Strategic Review contained a number of recommendations which were directed at the Macfarlane Trust and to Ministers/ the Department of Health. The recommendations to Ministers and the Department of direct relevance to the work of my team were at §10.3 [MACF0000045_019], *section 10.3, pgs 90 and 91]*:

> *(i) "Ministers/ the Department of Health should consider the changing patterns and increasing financial demands and expectancies of registrants. They should provide policy guidance and priorities and furnish the required level of resources.*
>
> *(ii) To ensure ongoing funding to Macfarlane Trust to enable continued support to Trust registrants to meet existing and emerging needs, and with the Trust to review types and extent of provision required.*
>
> *(iii) To continue to fund an efficient administration of the Trust…*
>
> *(xv) To consider proposals for development of information and support services specifically for people with haemophilia and HIV to be presented by the Macfarlane Trust in partnership with the Haemophilia Society."*

5.315. Other recommendations concerned wider government policies on services for people with HIV.

5.316. On 12 April 1999, Gwen Skinner in my team provided advice for Lady Hayman on Ann Hithersay's invitation to meet the Macfarlane Trust and on the content of the Strategic Review. This was copied to me and Mike McGovern. Gwen wrote: [DHSC0032142_007]

> "*I am sorry there has been a delay in responding to this invitation. You sent an interim reply in March. We have needed to consider the recommendations of the Macfarlane Trust's Strategic Review, which was funded from S.64 monies. The Trust wished to establish the right direction for itself, as circumstances have changed in the management of haemophilia and treatment of people with HIV.*"

5.317. This submission also raised a concern about the gap between support for haemophiliacs infected with HIV and people infected with hepatitis C, which I have addressed in section 2 of this statement, dealing with HCV compensation This potential difference in support was expanded in the submission:

> *"10. A potential difficulty is the focus which the report* [i.e. the Strategic Review] *(perhaps unintentionally) brings to the balance between the relatively generous help for those who contracted HIV through blood products, and the absence of any special payment scheme for those infected with hepatitis C in the same way. This is especially noticeable in the case of young people, where those with HIV have help in setting up home, and those with hepatitis C have the Youth Information and Support project.*
>
> *11. The Haemophilia Society have been encouraged to promote the forward looking, positive thinking, self-help route for those with hepatitis C. The exceptional circumstances leading to the past introduction of the HIV scheme have recently been requoted in a significant number of PQs – the widespread public fear of the disease at the time, when infection was rapidly fatal and associated with sexual transmission. The HIV scheme has been justified on the basis of past circumstances, but in effect the difference today in the circumstances of*

a haemophiliac severely affected with hepatitis C and one infected with HIV is not so great."

5.318. The submission recommended that the Minister should meet with the Macfarlane Trust and said:

"12. …Officials would provide briefing on all the issues beforehand, plus a pre-meeting if you wish. It might be possible, for example, to explore with the Trust whether they see any scope for project work to encourage a move towards self help, and to put to the Trust the potential imbalance between the "recompense" for those with hepatitis C and to seek their advice on how this might be addressed within existing resources."

5.319. I am asked about the administrator's report to the Macfarlane Trust board meeting [MACF0000007_265] which states that a letter was written to me, "*to express our concern at the continuing lack of response or acknowledgement of our Report*." The administrator's report to which I am referred is undated but I understand it was prepared for a Macfarlane Trust board meeting which took place on 28 April 1999. I am asked to explain how I responded to the letter from the Macfarlane Trust and why there were delays in acknowledging the Strategic Review.

5.320. I do not recall whether or how I responded to the Trust's letter, and searches have not yet revealed copies of this correspondence. However, by the time of the board meeting on 28 April 1999, it is clear from the documents that the Macfarlane Trust had received a letter from Baroness Hayman accepting the Trust's invitation to meet to discuss the Strategic Review. At the board meeting there was a discussion about the meeting with Baroness Hayman, including the agenda for that meeting [MACF0000017_067].

5.321. I can see from documents that Baroness Hayman wrote to the Reverend Alan Tanner at the Macfarlane Trust on 19 March 1999 [WITN4505372]. The letter said:

> "*I am very sorry that you have not received an earlier acknowledgement to your letters of 29 January enclosing the final report of the Trust's Strategic Review and of 18 February enclosing an amended copy. Officials are looking at the report now, and we will be in touch with you very shortly for discussion.*
> *I hope you have not been too inconvenienced by the delay.*"

5.322. I have already referred to Gwen Skinner's submission to Lady Hayman, dated 12 April 1999, which began with, "*I am sorry there has been a delay in responding to this invitation. You sent an interim reply in March. We have needed to consider the recommendations of the Macfarlane Trust's Strategic Review…*". [DHSC0032142_007]

5.323. Based on the documents I have seen I cannot comment further on the administrator's report. There appears to have some delay in officials considering the recommendations in the Strategic Review. An interim response was sent in March 1999. Advice was given to Lady Hayman on 12 April 1999 and a meeting took place on 17 June 1999. Over 20 years later, I do not think I can say more about the specifics of this but am happy to comment on any further documents provided to me.

5.324. There was a meeting between officials and the Macfarlane Trust on 14 June 1999 (minutes at [WITN4505318]. An agenda for the meeting with the Minister was provided by the Macfarlane Trust [MACF0000017_067] and my team provided a written briefing for Lady Hayman in advance of the meeting [WITN4505373].

5.325. The briefing states that the Macfarlane Trust was content to reserve the latter part of the agenda for discussion with officials. On the Strategic Review, the briefing included:

> "*There are recommendations for:*
> …
> *for Ministers/ the Department.*

A key recommendation is for a firm assurance of continued funding. Registrants have said they feel anxious about the commitment, and they seek a specific assurance, with funding established on a more permanent basis. The wording of the commitment to continued funding has been "to keep the future requirements of the Trust under review." In practice this has resulted in the provision of funds (from CFS budget) to meet the Trust's requests."

5.326. I have not seen minutes of the meeting with Baroness Hayman. However, I have already referred to the letter sent by Baroness Hayman, dated 1 July 1999 [DHSC0006162_006].

5.327. I have also seen minutes of the Macfarlane Trust Board meeting on 12 July 1999, which state: [MACF0000017_068]

*"**Report of a Meeting with Baroness Hayman, Minister of State for Health***

…It had been an excellent meeting with each Trust representative presenting their piece, and Lady Hayman carefully listening to all that was said, showing real interest in each presentation. The atmosphere had been good, and the team came away well satisfied with what had taken place. A subsequent letter from Lady Hayman had been circulated to all Trustees, and a further meeting with Civil Servants was planned for the Autumn."

5.328. Lord Hunt took over as the Minister in the Lords after Lady Hayman left the Department on 29 July 1999.

5.329. I have already set out a chronology in relation to the Macfarlane Trust's funding thereafter.

Meeting with the Macfarlane Trust on 12 October 1999 and associated issues

5.330. I am asked about a meeting held on 12 October 1999 between the Department and the Macfarlane Trust and a number of documents related to that meeting [DHSC0003209_010, DHSC0003209_011 and DHSC0003209_009]. I am asked how regularly meetings like the one on 12 October 1999 took place and whether minutes were kept. I am also asked about the cause of delays to the Macfarlane Trust's core (or S64) payments in 1999, whether I or the Department supported the Macfarlane Trust's administrative expenditure from the General Fund, and how the loss of interest was remedied.

5.331. I have already explained my recollection that there were ad hoc meetings between the Department and the Macfarlane (and Eileen) Trust, but by late 2001 these were made more regular. I have reviewed notes of meetings held on December 2001, March 2002, June 2002, September 2002, December 2002 and March 2003, which show that we did eventually succeed in our intention of holding quarterly meetings.

5.332. To the best of my recollection meetings between the Department and the Macfarlane Trust were minuted. I can be confident that the minutes of meetings I have seen from December 2001 onwards were minuted by my team, as they are written in my preferred style. However, without sight of them, I am less sure who may have minuted earlier meetings.

5.333. The Macfarlane Trust documents that the Inquiry has referred me to (see §5.330 above) record that, by October 1999, the Department had not provided the Trust with formal confirmation of the S64 core grant for the financial years 1999/2000, 2000/2001 and 2001/2002. It appears from [DHSC0003209_011] that the Department had made an interim S64 payment of £90,000 (the records I have seen suggest it was £90,500 [DHSC0006162_099]. Ordinarily, the first instalment of the S64 payment, covering the first quarter, would have been made in around May of the financial year.

5.334. I have no clear memory of this issue but the papers I have seen in compiling this statement show a series of administrative confusions and delays that are

now embarrassing to revisit. I and my team were under immense pressure at the time but it is clear to me that the delay could have been avoided with a minimum of effort. Unfortunately, I cannot now account for why we did not deal with the relatively straightforward paperwork in a timely way, especially as I received regular and increasingly stern reminders from Simon Jones in the Department's S64 grants unit. This issue was not fully resolved until January 2000.

5.335. As explained above, officials prepared a briefing for Lady Hayman in advance of her meeting with the Macfarlane Trust on 17 June 1999. That briefing for Lady Hayman records that [WITN4505373]:

> *"The 1999/2000 S64 grant of £187,000 has been approved by Ministers and the formalities are now going through. The Trust is also to receive £23,000 project monies, to cover the late costs of the strategic review."*

5.336. On 14 June 1999, I sent a formal award letter for the project grant to the Macfarlane Trust [WITN4505371]. For the core grant, there was an additional administrative process to complete which involved the S64 team signing off the award. This was required for all grants in excess of £100,000. Getting this sign-off for the Macfarlane Trust's S64 core grant should have been a formality that was completed quickly. However, the documents show that this became a rather long and torturous process because of administrative failures on the part of me and my team.

5.337. On 19 August 1999, Ann Hithersay wrote to me saying that: [WITN4505364]

> *"…The Macfarlane Trust has received quarterly core grant instalments each year since 1988….This year, despite many letters and telephone conversations, we have received no Core Grant funding since February 1999. This has meant that all management expenditure in the current financial year has been drawn from the Trust Fund. I know that you and predecessors are aware that it was not the intention of Government, when the Trust was set up in 1988, to fund administration of the Trust from this fund. The Chairman and Trustees are now concerned at the*

lack of Section 64 funds flowing to the Macfarlane Trust. They have asked me to write to you on their behalf to say that we will soon be reluctantly forced to write to Lord Hunt to express our dissatisfaction and seek his personal intervention in this matter.

I very much hope you can make the necessary arrangements to pay the two outstanding quarterly Core Grant instalments to The Trust before the end of the month."

5.338. On 20 August 1999, I wrote to Simon Jones in the Department's S64 grants unit as follows: [DHSC0003235_003]

"1. Ministers have approved a core grant for the Macfarlane Trust of:

1999/2000 - £187,000

2000/2001 - £192,600

2001/2002 - £198,300

No payments have been made to the Trust so far this year because the grant is over £100K and we have not sent you the necessary papers for approval. Unfortunately we have mislaid the original grant application, and will need to obtain a copy from the Macfarlane Trust before we can complete the checklists, and this will hold up the process even further.

2. The Trust have now written the attached letter of complaint [I attached Ann Hithersay's letter dated 19 August 1999] *asking for payment of the first two quarters of the core grant by the end of this month. Given the circumstances outlined in the letter and the fact that the delay is entirely our fault, I would be grateful if you would consider authorising an interim payment of two quarters (£93,500) to be made to the Trust next week. We will then ensure that the Checklists are completed and sent to you for approval in the next few days…"*

5.339. Simon responded the same day, clearly frustrated with us, writing: [DHSC0038637_034]

> *"I am not really surprised by MT's request and, in the circumstances, will agree exceptionally* [he stressed exceptionally] *to payment of two quarters, rather than one, on the usual interim basis…"*

5.340. However, he made clear, firstly, that payment of these two quarters would be at the 1998/1999 rate (so £90,500 rather than £93,500) and secondly, that payment could only be made after we had gone through the required procedures, which he described. He also added:

> *"I cannot fail to comment that I have been reminding you orally of the need to process MT's over £100K award for 1999-2000 et seq over several months. If HSD1 has not already done so, I must suggest that you book up for the S64 training sessions this autumn…"*

5.341. On 20 August 1999, I wrote to the Macfarlane Trust confirming the interim payment of £90,500 [DHSC0006162_099] By letter dated 24 August 1999 Marian Awuley, from the S64 grants unit, wrote to the Trust confirming that the money would be paid into the Trust's account over the next few days. [WITN4505374]

5.342. On 17 September 1999, Simon Jones emailed me to say that he was still awaiting the full papers requested on 20 August to approve the Trust's core grant for the current year (i.e. 1999/2000). [WITN4505375]

5.343. As is clear from the agenda for the meeting on 12 October 1999 between the Department and the Macfarlane Trust [DHSC0003209_011], by 4 October 1999 the Macfarlane Trust still had not received a formal letter confirming the S64 core grant.

5.344. On 25 October 1999 Simon Jones wrote to me again in very stern terms [WITN4505376]:

> *"...It is now nearly a year since HSD1 should have processed MT's renewal core grant application for 1999-2000 et seq, including seeking SC2-GAU's* [the S64 grants unit's] *financial approval for the renewal*

before submission to Ministers. I do realise that you were not in HSD1 at that time but the work does need to be completed. The situation ***must*** *be put in order as we all have a responsibility to protect public funds.*
I did agree in August, as an exceptional measure, to payment of two quarters, not least in the expectation that the work to regularise the award approved by Ministers for 1999-2000 et seq was in hand. I understood that HSD1 has mislaid the original application from and a copy was being sought from MT.
Payment of the next quarter would normally fall due on 6 November. But ***NO*** *further payment will be made until all papers have been sent to me…and I have been able to approve them. The additional grant of £52k, proposed for this year, will require separate processing."*

5.345. Following the meeting between the Department and Macfarlane Trust on 12 October 1999, Ann Hithersay also wrote to me on 28 October 1999. Her letter included the following on Section 64 core funding [DHSC0003209_009]:

"The issue was discussed at the meeting. We pointed out that, as yet, we had not yet received formal confirmation of the Section 64 Grant applied for in September 1998, and intended to cover the period 1999-2002 inclusive: or three years of Core Funding for the Trust.
It was agreed that you would write to confirm the grant within a week of our meeting. It was also agreed that our third Quarter's funding would be due shortly. We normally receive this payment during the first week of November."

5.346. For reasons I now cannot explain, this issue was still not resolved by 6 December 1999 when Simon Jones wrote to me yet again: [WITN4505377]

"…I also look forward to receiving the Macfarlane Trust (MT) papers which are still outstanding tor this current year. It is now over a month since my last reminder. We cannot carry on like this – SC2-GAU monitors the use of grants over £100K as well as approving such grants on behalf of Treasury – and all of us are subject to audit by the NAO [National Audit Office]. *If I do not receive from you the MT application*

and completed Checklists etc for 1999-2000 et seq ….by this Friday 10 December, then I shall have to take the matter further..."

5.347. I replied the same day, saying: [WITN4505378]

"*Thanks for your E-mail and for your very justified reprimand on the Macfarlane Trust papers. I will get these to you this week as requested.*"

5.348. Shortly after this I must have provided the necessary paperwork as Simon Jones informed me on 22 December 1999 that the Macfarlane Trust's S64 core grant was approved, "*up to a maximum of £187,000 for 1999-2000 and, subject to the availability of funds approved by Parliament, up to a maximum of £192,600 for 2000-2001 and £198,300 for 2001-2002*". [DHSC0038637_010].

5.349. Simon's email to me also said:

"*As I have remarked at previous renewals, MT is almost unique in the S64 General Scheme in being wholly dependent on DH for its administration costs, as it was created solely to administer capital funds. The additional £3m to those funds at the end of 1997-98 has clearly distorted the figures in the accounts. Given that this is a straightforward renewal, it is a pity that it has taken so long for these papers to reach SC2-GAU.*"

5.350. The Macfarlane Trust therefore had no S64 payment from the start of that financial year 1999/2000 to September 1999, when an interim payment was made (at a slightly lower level than would otherwise have been the case). Then there was another delay in the S64 payment for the third quarter. The Macfarlane Trust was also left without formal confirmation of its S64 funding in the financial years from 1999/2000 – 2001/2002. During this time I was or should have been aware that, at times, we were leaving the Macfarlane Trust with no option but to use its general fund for administrative expenditure. That was not what the general fund was intended for – a point made to me by Ann Hithersay in her letter of 19 August 1999 [WITN4505364]. That is likely to have led to a small loss of interest/ investment return which I cannot quantify. As far

as I can recall the Macfarlane Trust did not ask the Department to reimburse it, and the Department did not offer.

5.351. I am asked about the minutes of the Macfarlane Trust meeting held on 1 February 2000 which record the "*Trustees expressed continuing outrage at the inefficiency of the Department in meeting its commitments to the Trust*" [MACF0000013_030]. I am asked if I or the Department was provided with AHO minutes of meetings and what were the reasons for delays by the Department.

5.352. As far as I can say neither I nor anyone else in the Department was provided with the minutes of the meeting on 1 February 2000. More generally, to the best of my recollection, in my early years in the blood team neither I nor anyone in the Department, was provided with minutes of the AHO's board meetings. However, as I have described in this statement, I was in regular contact with Ann Hithersay and would have been made aware of these sentiments. After Robert Finch joined my team, giving us more resources, it became the practice for Robert and his successor to attend Macfarlane Trust board meetings I have not seen a complete run of Macfarlane Trust board minutes for my period, but I note that Robert attended the meetings on 28 May 2002 [MACF0000011_003] and 30 July 2002 [MACF0000011_004] for example and that Zubeda Seedat attended on 20 January 2003 [MACF0000009_012]. I assume from that point, that my team would have been sent the minutes of the meetings but I do not recall seeing them personally.

5.353. I was also not present at this meeting and so can only try to interpret the minutes. Based on the documents I have seen I do not think there was further delay, over and above that described in the preceding paragraphs of this statement.

5.354. Picking back up on the chronology of the Macfarlane Trust's S64 payments, by letter dated 23 December 1999 Mike McGovern wrote to Ann Hithersay confirming the awards for 1999/2000 – 2001/2002 [DHSC0038637_009]. The S64 awards, and the terms attached, were accepted by Ann Hithersay in her

letter dated 6 January 2000. This was a Thursday, although I cannot say exactly when this arrived with the Department [DHSC0038637_008].

5.355. On 10 January 2000 (a Monday), Ann Willins from my team sent an 'authority to pay' form to the S64 grants' unit, in respect of the Macfarlane Trust's outstanding S64 payments, asking that it pay the Trust £48,250 to cover the third quarter of 1999/2000 [DHSC0038637_006]. I have seen an email from Simon Jones to me, dated 14 January 2000, saying, "*I have received the papers from Ann* [Willins] *to activate payments for this year. I hope to be doing a payment batch around 25 January and this will pick up the first half of the balance. The remainder should be paid in early February*" [DHSC0038637_005].

5.356. The minutes of the Macfarlane Trust meeting on 1 February 2000 [MACF0000013_030] record that the Trust had received the third quarter's payment (i.e. the one due in around November 1999 and which Simon Jones hoped to make around 25 January 2000). The minutes state that the final quarterly payment was now due. As stated above, the final quarterly payments for S64 grants in any financial year were due to be paid in around February 2000. This meeting was held on 1 February 2000.

5.357. It would appear therefore that a little time passed over the Christmas period before the Department received the Macfarlane Trust's acceptance of the S64 grant (around 6 January 2000) and then the November 1999 outstanding payment was paid in the next batch of S64 payments made by the S64 grants' unit.

Eileen Trust S64 Funding in 2001

5.358. I am asked about a letter from Ann Hithersay to me dated 9 October 2001 [EILN0000010_107]. The letter says that the Eileen Trust had received no S64 core funding since January 2001 and it was now owed two instalments. The letter says that Ann had called the S64 grants' unit and had been advised that

the S64 grant had been suspended because the Eileen Trust had not sent a copy of last year's audited accounts or a budget for 2001/2002.

5.359. Ann Hithersay also points out in her letter that she sent copies of the relevant audited accounts to me in October 2000 and sent the budget in April 2001.

5.360. I am asked to explain why the Eileen Trust's S64 core funding was suspended in this way, whether the Department informed the Eileen Trust before suspending the S64 funding, and whether efforts were made to obtain the required information from the Trust before the funding was suspended.

5.361. I have no recollection of this and the documents I have seen do not assist. I can only now say that this appears to have been another administrative oversight by my team and that the problem was that my team had not sent the grants' unit the correct documentation, although this had been provided to my team by the Eileen Trust. Suspending the grant would have been an automatic process by the grants' unit in these circumstances. I can no longer recall whether we were warned in advance that this was going to happen, and the documents I have seen so far do not assist.

5.362. I have seen a note of a meeting between the Department and the Macfarlane Trust on 5 December 2001 which I read as indicating the Eileen Trust's S64 payments had been reinstated. That note records [WITN4505379]

> "*Sec 64 payment delays*
> *This problem had now been solved with recent payments made to both the Macfarlane Trust and Eileen Trust. DH apologised for the delays in these payments being made.*"

5.363. It is not an excuse, but this happened at a time when I was leading negotiations for the UK on the EU Blood Directive and setting up the process for securing supplies of US plasma (Project Red).

Department's Role in Identifying New AHO Registrants

5.364. I am asked to explain the Department's role in identifying new registrants of an AHO, including how infected intimates were identified, and the responsibilities of the Department and the AHO in ensuring all those eligible for assistance were aware of support available. I have been referred to a letter from Ann Hithersay to me, dated 6 August 1999 [EILN0000020_037].

5.365. The question is a broad one, potentially covering many years. I can only comment on my knowledge or involvement of this during the time that I was in the blood policy team.

5.366. The letter from Ann Hithersay relates to the son of an Eileen Trust registrant who had sadly died. The boy was also infected with HIV. I was being asked if he had been identified for a lump sum payment from the Department and whether he was aware he was therefore eligible for support from the Eileen Trust. I recall receiving letters like this from the Eileen Trust from time to time, but they were fairly infrequent and I do recall individual cases.

5.367. It appears from the papers I have seen, and from my own recollection, that this kind of issue was most relevant for potential registrants of the Eileen Trust. My understanding now is that haemophiliacs (and their families, where relevant) who were infected with HIV were part of the HIV litigation settlement and, as a result, would in the main have been aware of support available from the Macfarlane Trust. However, I was not in role at that time and cannot comment in detail on this.

5.368. My recollection is that the situation was somewhat different for non-haemophiliacs who were infected with HIV in the course of receiving treatment with blood, blood products or tissue transfer and, adopting the terminology used at the time, "*infected intimates*" of those individuals. It was less straightforward to identify these individuals or for them to necessarily know about the financial support that was available. The documents I have seen support my current understanding that the main concern was potential gaps in the Eileen Trust's cohort of registrants.

5.369. Ann Hithersay's letter of 6 August 1999 [EILN0000020_037] reflects the pathway for eligibility for the Eileen Trust in that a person was first assessed as eligible for a lump sum payment under the "*Scheme of Payments for those Infected with HIV Through Blood of Tissue Transfer*" (the "Scheme") [EILN0000016_001]. That Scheme was established by the Government in 1992, so well before my time. It was the Secretary of State who determined whether a person was eligible for a lump sum payment under the Scheme, and individual cases could be referred to a panel to make that decision. Once a person was considered eligible for the Scheme then he or she could register with the Eileen Trust. I recall that we kept files on all individuals who has received payments under the scheme. These are the record that Ann Hithersay is referring to. The records made available to me do not include a reply to this letter. We also, from time to time, sought advice from the Department's legal advisers on behalf of the Eileen Trust. One example was included in a minute I wrote to Anita James on 6 January 2003 [DHSC0003284_007].

5.370. In preparing this statement I have seen a copy of the Scheme and note that clause 10 set out ways in which the Secretary of State would "*seek potential qualifying persons*", as follows:

- Seeking Communicable Diseases Surveillance Centre and National Blood Transfusion Service records;
- Circularising National Health Service Consultants and general practitioners;
- Contacting solicitors acting in HIV litigation in respect of blood transfusion and tissue transfer;
- Making a press release explaining how an application may be made.

Save to the extent set out below, I cannot say what steps were taken. The Chief Medical Officer's Update was another vehicle we had available at the time to publicise information to clinicians. I recall using it from time to time and it is clear from the documents I have reviewed that we did use it to publicise the Eileen Trust.

5.371. I have seen a minute of a meeting between the Department and the Macfarlane and Eileen Trusts on 5 December 2001, which I attended [WITN4505379]. The minute records that Ann Hithersay "*asked the Department to consider publicising the Eileen Trust. She said it had been some years since there had been any direct publicity and there was a good chance that there were many eligible people who had not heard of the Trust but who might be entitled to payments.*" The action was for the Department to consider this request and report back.

5.372. This issue was revisited at the next meeting between the Department and the Macfarlane and Eileen Trusts on 13 March 2002, which I attended [WITN4505354]. The minutes record that I agreed the Department would put an item in one of the publications that sent to clinicians in the NHS, such as the CMO update. I also asked the Eileen Trust to provide details of those people who had requested help but, after being passed onto the Department, were then not heard from again. The Department agreed to look at these names "*to ensure that anybody who was entitled had not been 'lost' in the system.*"

5.373. The next meeting between the Department and the Macfarlane and Eileen Trusts took place on 19 June 2002. I attended this. The minutes [*EILN0000013_262]* record the following:

> "*Ann Hithersay (AH) had been asked to provide a list of names of people who had contacted the Eileen Trust about being possible registrants, were given DH contact details and then never heard from again. AH reported that having looked through her records she felt the numbers were too small to be of any significance."*

5.374. I take it from this note that no names were provided by the Eileen Trust, but do not have a recollection of this.

5.375. The minutes of the meeting on 19 June 2002 also record:

> "*DH had arranged for a note to publicise the existence of the Eileen Trust to go forward for consideration for the Chief Medical Officer's*

Bulletin, which is sent 3 to 4 times a year to all Doctors in England. The next edition would be published sometime in August."

5.376. There was a further meeting between the Department and the Macfarlane and Eileen Trusts on 25 September 2002, which I attended [DHSC0003242_008]. The minutes of that meeting record that the Department had placed information about the Eileen Trust in the September 2002 edition of the Chief Medical Officer's update, which was disseminated to all doctors in England.

5.377. I have also seen minutes from an Eileen Trust board meeting on 11 October 2002 which refer to this issue of publicity for the Eileen Trust. The minutes record [EILN0000013_369]:

"*…The Department had recently put an announcement about the Eileen Trust in the Chief Medical Officer's Update. This was because it was possible that The Trust no longer came to mind when patients were diagnosed as HIV positive and the likely cause could be contaminated blood or tissue. Whilst it was not felt likely that the announcement would create much response, it had been some years since CMOs had been advised about the Eileen Trust and the reminder was thought to be worthwhile.*"

5.378. In preparing this statement I have seen a copy of the Eileen Trust's annual report and accounts for year end 31 March 2003 [EILN0000016_051]. It reports that:

"*During the year the Department of Health ("the Department") once again brought the existence and purpose of the Trust to the attention of the medical practitioners throughout the country in order to minimise the possibility of anybody who might properly be a registrant of the Trust being ignorant of the Trust's existence and potential support.*"

5.379. This indicates that the Department had, prior to September 2002, taken similar steps to raise awareness of the Eileen Trust amongst medical practitioners.

5.380. Aside from steps to raise the profile of the Eileen Trust amongst medical practitioners, it was the Department's responsibility to pass on to the Eileen Trust the details of potential new Trust registrants. As stated above, when a person was considered eligible for a lump sum payment under the Scheme, he or she was also eligible for support from the Eileen Trust. As far as I recall the Eileen Trust would then seek to make contact with that person. That could include "*infected intimates*".

5.381. I cannot, so many years later, recall exactly what the respective responsibilities of the Department and the Eileen Trust were in making those eligible for assistance aware of support. I am not sure if there was ever a formal division of responsibilities agreed, although as I have explained eligibility for the Eileen Trust was triggered by eligibility under the Scheme, so the Department passed that information to the Eileen Trust. For example, I can see from the Eileen Trust annual report and accounts for the year end 31 March 2001 that the Department notified the Trust of a possible new registrant who had a HIV positive child but at that time the Eileen Trust had been unable to establish contact with these potential new beneficiaries [EILN0000016_053]. During the time I was in post I can see that there was a small number of new registrations with the Eileen Trust and so the number of referrals from the Department to the Eileen Trust must have limited.

5.382. I can see from papers that the Eileen Trust made efforts to reach new beneficiaries. For example, I have seen the Eileen Trust annual report and accounts from year end March 1999. It records that:

> "*In recent months, efforts have been made to trace children whose mothers have died as a result of HIV infection and are now living with widowed or remarried fathers…"[EILN0000016_055]*

5.383. I can also see from papers provided to me that on occasion healthcare practitioners made contact with the Department seeking information about financial support. For example I have seen a letter, dated 14 December 1998, from Debbie Barnes in the NHS Executive to Professor Dr van Aken in the

Netherlands enclosing information about the Scheme and the Eileen Trust (Professor Van Aken was also a NBA board member) [DHSC0002797_005]. I cannot now say how frequently that happened.

5.384. The Skipton Fund was established after I had left the blood policy team and so I make no comment about steps taken to identify registrants of it.

Support for Child of Deceased Registrant

5.385. I am asked about a letter from Ann Hithersay to me, dated 13 January 2000, which asks me to confirm if the Eileen Trust may regard the eldest child of a deceased registrant as a dependent [EILN0000010_017]. I am asked to explain my role in advising the AHO (I assume this means the Eileen Trust) on the eligibility of potential beneficiaries, the Department's position on providing counselling and support for affected people like this, and the outcome of this request.

5.386. I do not have any specific recollection of this letter It appears to describe a young man who was over 18 when his mother died in 1989. Ann Hithersay asked for me to confirm if the Eileen Trust may regard this young man as a dependent of the Trust for the purpose of providing him with such help as was necessary to enable him to address his past trauma.

5.387. Looking at the issue now, it appears Ann Hithersay had doubts about whether the young man could receive financial support under the terms of the Eileen Trust deed. I have seen a copy of the original trust deed (I understand there were variations which are not relevant to this issue) [EILN0000016_017]. Clause 3 sets out the objects for which the Trust was established, namely:

> "*…to relieve those qualifying persons who are in need of assistance or the needy dependants of qualifying persons and the needy dependants of qualifying persons who have died.*"

5.388. Clause 4 set out the powers that the Trustees had "*in furtherance of the above object but not further or otherwise…*". I assume that Ann Hithersay was asking

me if the young man could be regarded as a dependant under the Eileen Trust deed. I can see now that the Trust deed does not define "*needy dependant*".

5.389. Having said that, the Eileen Trust's annual report and accounts for year end 2001 [EILN0000016_055] report that:

> "*The Trust also supports nine families with deceased registrants involving 13 children under 18, together with a further three young people under 25 who are or could be dependent on the Trust for financial support.*"

I do not know now whether that means the Eileen Trust determined that these young people who were over 18 but under 25 were dependents under the Trust deed. I have seen minutes from an Eileen Trust board meeting on 19 October 2001 which suggest this is the case [WITN4505380, see §0.120].

5.390. I cannot explain now why Ann Hithersay chose to ask me this question. I do not believe I did or would have asked her to.

5.391. I do not now know what I did with this query or how I responded to it. It has not been possible to locate my/ the Department's response to this letter but, of course, I am happy to consider any further documents provided to me.

5.392. I have seen minutes of the Eileen Trust board meeting on 26 January 2000 [EILN0000006_033] which record that Ann Hithersay was waiting for a response from the Department in relation to this young man. The subsequent Eileen Trust board meeting papers appear not to be available either to see what happened with this issue. If the Inquiry locates these or other papers then I will, of course, consider them and do my best to assist.

5.393. If the young man had been considered a "*needy dependant*" for the purpose of the Eileen Trust deed, so that support could be provided by the Eileen Trust then, to the best of my recollection, it would have been for the Eileen Trust to decide what support should be provided. That could have included financial support for counselling. I do not think the Department would have been involved

in that kind of detail. I am therefore not sure that the Department had a position at this time on providing counselling and support for affected people such as this young man. However, again, this relates to matters around 20 years ago and I may be mistaken. If the Inquiry provides further relevant documents then I will revisit this.

5.394. I have seen another example of Ann Hithersay asking me about eligibility for charitable support that seems to turn on the interpretation of Trust documents. By letter dated 11 February 2000 [DHSC0003234_002], Ann asked me to confirm if two "*infected intimates*" who received lump sum payments under the Macfarlane (Special Payments) (No. 2) Trust were eligible for ongoing financial support from the Macfarlane Trust, where they were no longer living with their partners with haemophilia and HIV. She wrote:

> "*My reading of the position is that an 'Infected Intimate' is in a different category to a 'dependant' of a person registered with the Trust. As such they have as much right to support from the Macfarlane Trust as other registrants, by virtue of having become infected through relations...I would be grateful if you could advise me.*"

5.395. By letter dated 24 February 2000 I replied saying:

> "*I agree with your reading of the position, namely that infected intimates are eligible for continued financial support from the Trust regardless of whether they live with the Trust registrant. It would therefor appear from the evidence that the two above cases are entitled to continuing support from the Trust." [MACF0000082_002]*

5.396. As explained above, I cannot now say what the outcome of Ann Hithersay's request in her letter dated 13 January 2000 was.

5.397. All of this raises the question of whether the Trusts should have come to the Department with questions about the interpretation of the Trust Deed as opposed to taking their own legal advice. This was not something I encouraged or requested. But nor was it something that I questioned. It felt reasonable that

the Trust should ask us about the interpretation of a deed which the Department had drafted. I also saw it as my role to be as helpful as possible to the Trust in resolving questions about their scope. However, although I might express an opinion, as above, I was always clear that final decisions on matters such as this were for the trustee board to determine. There are also examples where the Trustees did seek their own legal advice, such as on the question of loans and advances referred to below.

Funds Until Maturity

5.398. I am asked if funds were held by the AHO for children until they reached maturity and whether the AHO or Department of Health received any advice on this. I am not sure if this question intends to relate to lump sum payments, paid via either the Macfarlane (Special Payments) Trusts or the Scheme, or charitable payments made by the Macfarlane and/ or Eileen Trusts.

5.399. My understanding, supported by documents I have seen [WITN4505349], is that lump sums paid to minors under the Macfarlane (Special Payments) Trusts and the Scheme were held by the Court until majority. Master Turner oversaw this at the Royal Courts of Justice.

5.400. I think a note of a meeting between the Department and the Macfarlane and Eileen Trusts on 13 March 2002 also supports this [DHSC0003255_004]:
"***Payment to new registrant (and daughter)***
AH clarified how payment should be made for this new registrant…Money for her daughter, £21,500, should be placed with Master Turner until she is 18."

5.401. I have also seen advice legal advice provided by Anita James to me on 6 January 2003 which states that the Department did not take part in these Court proceedings which were brought by or on behalf of the minor under Part 8 of the Civil Procedure Rules [DHSC0003284_006 and WITN4505381]. I have seen reference in the papers to money being put into trust for minors but my understanding of this is that it refers to money being paid into Court until the

age of 18 (or any earlier application made by or on behalf of the minor) [WITN4505382].

5.402. If the question also intends to ask about the AHOs holding funds paid on a charitable basis by the Macfarlane or Eileen Trust, then I suggest this is directed to the AHOs. I do not recall this and have not seen any documents to suggest it occurred or that the Department was involved, when I was in post. Again, of course, if the Inquiry wishes me to consider any specific documents on this issue then I am happy to do so.

Loans and Advances: Macfarlane Trust Policy

5.403. I am asked to comment on the Macfarlane Trust policy of issuing loans and advances rather than grants. I am asked if the Trust sought advice from the Department on providing loans (I am referred to DHSC0003209_011) and whether this policy was approved by the Department. I am also asked about my knowledge of these loans and about any role I had in the process.

5.404. I have seen minutes from the Macfarlane Trust board meeting on 28 April 1999 [MACF0000017_067]. These record a board discussion about a possible deed of variation to the trust deed to provide the Trust with powers to make long term loans to registrants and that the Trust had received legal advice that a deed variation would be needed. The minutes record, in relation to the Department:

> "*The Chairman invited comment, and amongst other things, it was observed*
>
> *That whereas legally the proposed modification did not require the prior consent of the Secretary of State, none the less, the granting of long-term loans of the type proposed would be a departure from previous practice, and there was a case for obtaining from The Department an understanding that the practice (if adopted) would have the support of Government….*
>
> *…The Chairman agreed to raise the principal of making loans to registrants when he met Baroness Hayman, Minister of State for Health,*

in June. He would also arrange a further meeting with Paisner & Co and report back to Trustees at the July meeting."

5.405. As explained elsewhere in this statement, I have not seen minutes from the meeting between Baroness Hayman and the Macfarlane Trust on 17 June 1999. The letter Baroness Hayman wrote to the Trust after the meeting, dated 1 July 1999 does not refer to the loans having been discussed [DHSC0006162_006]. I have also seen a minute I wrote about the meeting on 7 July 1999 which does not refer to loans [DHSC0006162_003].

5.406. Minutes from the Macfarlane Trust board meeting on 12 July 1999 [MACF0000017_068] contain a report of the meeting with Baroness Hayman but do not refer to the issue of loans being discussed in that meeting. However, the minutes do state:

"***Loan Agreements***

The issue of the Trust making loans to registrants was raised with Civil Servants at the meeting prior to the Trust's presentation to Lady Hayman. No objection had been raised. The Chairman would therefore meet with Paisner & Co, as agreed at the April Meeting, to discuss the matter of a Variation to the Trust Deed."

5.407. I was at a meeting between officials and the Macfarlane Trust on 14 June 1999. I have seen a note of that meeting (as stated above, there are two very similar versions – DHSC0003212_004 and WITN4505319]. Neither note refers to loans. Given the passage of time I cannot recall the content of any discussions.

5.408. The agenda for a meeting between the Department and the Macfarlane Trust on 12 October 1999 (prepared by the Macfarlane Trust) [DHSC0003209_011] included "*debts and loans*" as an agenda item. It records that the Macfarlane Trust was considering the possibility of making loans as an advance of a proportion of regular payments, repayable over a period, to alleviate cases of severe financial problems. The agenda states that this was "*mentioned*" at the June meeting.

5.409. The agenda also records that the Macfarlane Trust had, in the past, made larger loans based on taking an equity share of registrants' property but that practice had been discontinued a year before. However, the Trust was reconsidering this practice.

5.410. I have not seen minutes from the meeting on 12 October 1999. Ann Hithersay wrote a follow-up letter to me on 28 October 1999 which states I was present at the meeting. That letter included: [DHSC0003209_009]

> "*Debts and Loans*
>
> *The Chairman noted that the Trust had sought advice from Solicitors to vary the Trust Deed to enable loans to [be] made to those registered, where poverty and debt seriously threatened their health or their home. Trustees approved this variation at their meeting on 19th October 1999."*

5.411. Based on the documents I am confident the reference to the Trust seeking advice from solicitors is advice from its own solicitors and not the Department's solicitors. Minutes from a Macfarlane Trust board meeting on 19 October 1999 [MACF0000013_029] record at page 6:

> "*The Chairman said that the proposed Variation to the Trust Deed to enable the Trust to make loans to registrants had initially been raised at the April meeting of the Board. At that time it had been agreed that he would raise the matter with representatives of Government, and if there were no objections, he would discuss the proposed wording of the Deed again with Paisner & Co.*
>
> *The Chairman had referred to the proposed Variation to the Deed at a meeting with civil servants in June, and again in October 1999. No objections had been raised. The Chairman had met with Paisner & Co, and was now confident the Deed would provide powers to enable the Trust to make loans to registrants of the Trust if it were so minded….The Variation was approved by a majority of Trustees present.*"

5.412. I have no particular recollection of this issue but these documents from October 1999 suggest I was or must have been aware that the Macfarlane Trust wished to make loans to registrants. The Macfarlane Trust meeting minutes, dated 19 October 1999 record that the Department had raised no objections to the proposal, although I cannot now say exactly what information I or the Department had. I do not think the Macfarlane Trust required the Department's approval to vary the Trust deed to allow it to make loans. I do not think that the Macfarlane Trust sought the Department's advice at this point on providing loans. The documents show the Macfarlane Trust obtained legal advice from its own solicitors.

5.413. I can see from further papers provided to me that the Macfarlane Trust sought further legal advice in around October 2001 on the powers of trustees under the Trust deed to make grants or loans to beneficiaries. The Trust was advised by Berwin Leighton Paisner (i.e. its own lawyers) that there was no requirement in the Trust deed for the Trust to make loans rather than grants. [MACF0000006_123]

5.414. Again, I do not recall that the Macfarlane Trust sought advice from the Department at this time.

5.415. I do not recall having any knowledge, or certainly any in-depth knowledge, of loans issued by the Macfarlane Trust. I do not recall having any particular role in the process. I would not have expected to be involved in this. Again, if papers indicate that I was then I am happy to consider them.

5.416. Finally, I have been made aware that Ann Hithersay's oral evidence (on 25 February 2021, p111 WITN4505383) was that the Macfarlane Trust sought approval of the Department when it was making loans and the Department's legal department said "*yes, this is ok*". I understand Ann Hithersay did not give a time frame for this. I have set out above the documents I have seen that are relevant to my time in post. I have not seen any documents that suggest the Department's legal department advised on the policy or practice of the

Macfarlane Trust making loans. As far as I can see the documents indicate that the Trust obtained its own legal advice on this.

Trustees' Update Day

5.417. I am asked about minutes of the Macfarlane Trust board meeting on 23 January 2001 which record that a summary note of the Trustees' Update Day would be sent to me at the NHS Executive [MACF0000006_013]. I am asked to explain how the NHS Executive received and acted on reports.

5.418. I cannot now say if I received a summary note of the Trustees' Update Day from the Macfarlane Trust or, if I did, what it contained.

5.419. More generally, I do not understand the reference in the question to how the NHS Executive received reports. At times reports would have been shared with me for information. Any action taken by me would depend on the content of a report and any issues specifically for the Department. I cannot speak more widely for the NHS Executive.

5.420. I am also asked to explain if and how the NHS Executive supported the Macfarlane Trust on the issues identified in this summary note, and reference is made to:

- "*how to bring purpose into the lives of Trust registrants*"
- "*the needs and treatment of widows and dependent families*"
- "*the sensitive nature of HIV infection and continuing discrimination and fear of discrimination*".

5.421. As explained above, I cannot say now if I saw the summary note at the time. It has not been provided to me in the preparation of this statement and so I cannot comment generally on the issues identified in the document.

5.422. However, I can see from the documents that I had a meeting with the Macfarlane Trust on 5 April 2001 [MACF0000006_019]. The Macfarlane Trust's

report of this meeting records that a brief for a consultancy study the Trust was planning would be revised. The revised brief would include issues that had been identified at the Trustee update day. Examples of such issues are included in the Trust's report. At this point in time I cannot recall what level of detail Macfarlane Trust representatives went into at this meeting.

5.423. Decisions about Macfarlane Trust policies to support the needs of registrants and their families were for the Trustees. I would not normally have expressed a view on those to the Macfarlane Trust.

Meeting on 5 April 2001

5.424. I am asked about a meeting between the Department and the Macfarlane Trust on 5 April 2001 (the question refers to 6 April 2001) and the Macfarlane Trust's report to the board on this meeting [MACF0000006_019]. I am asked whether any of the recommendations were implemented and whether changes were made to the support available for the following and if not, why not:

- *"fertility treatment to enable registrants to have families without prejudicing the health of the partner and child"*
- *"use of combination therapies, particularly for registrants for whom combinations therapy regimes had failed."*

5.425. I am not sure I understand the question about whether any of the recommendations were implemented. The document identifies a number of issues the Macfarlane Trust wished to be included be included in a future consultancy study as part of a review of Trust strategy. It does, as far as I can see, not contain recommendations.

5.426. The consultancy study was a review carried out by the Department in 2001 into the Macfarlane Trust's financial controls, the operation of the Trust's treasury management function, the performance management arrangements and the claims management process [MACF0000006_010]. Recommendations on

those matters were made. I do not believe the review made recommendations on substantive issues, e.g. additional support in specific areas like fertility.

5.427. However, decisions on the types of support provided to registrants were matters for the Trustees, within the boundaries of the Trust deed and within funding constraints. They were not matters for the Department.

5.428. I explained this in my briefing for the Parliamentary Under-Secretary, Hazel Blears before her meeting with the Macfarlane and Eileen Trusts in February 2003 [DHSC0003279_012]

"4. This long-term survival and change in expectations places demands on the Trust's resources, and there is a resulting tension between the expectation of registrants, the Trustees assessment of what it is reasonable to support and the Department's wish to keep Trust spending within agreed budget limits. We are managing this tension at present because of the close and amicable working relationship between the Trust and officials (we have a particularly good relationship with Peter Stevens who appreciates the Department's wish not to let costs spiral) but this may get harder as the expectations of registrants increase. To take one example, the Trust has been pressed by some registrants to support the cost of assisted conception techniques to avoid transmission of HIV. The Trustees have decided not to help with the cost of treatment but to assist with expenses such as travel and hotel accommodation close to the hospital providing the service."

5.429. In preparing this statement I have also seen legal advice provided to the Macfarlane Trust by Berwin Leighton Paisner, dated 11 October 2001 [MACF0000006_123]. The Trust obtained advice about whether it could fund fertility treatment. The advice was that the objects of the Trust deed were sufficiently wide to cover this and it was open to the Trust to meet the costs of such treatment notwithstanding that it may be available on the NHS in some areas. The advice stated, "*...However whether or not the trustees choose to give funding for such treatment is entirely a matter for their discretion.*"

5.430. After the completion of the consultancy study (renamed as the Corporate Management Review), the Macfarlane Trust asked the Department if we could find a management trainee to second to the Trust to help with projecting future needs. [WITN4505384]. On 19 October 2001, I wrote to Peter Stevens to confirm that we had found a NHS finance trainee, Kathleen Macfarlane, a 3rd year CIMA finalist who was very interested in 6 month secondment to the Trust. [WITN4505385].

5.431. The secondment went ahead and, at the liaison meeting with the Department on 13 March 2002, Ann Hithersay reported that:

"*Kat is working well and is a popular addition to the Trust staff. She will be going on study leave in the middle of April before returning in June to complete the project. Kat is working on a project that will enable the Trust to forecast future expenditure more accurately.*" [WITN4505386]

Supporting After Death of a Registrant

5.432. I am asked about the Macfarlane Trust's Chief Executive's report dated 9 July 2001 [MACF0000006_004]. That report states, "*…It is interesting to note from recent correspondence with Charles Lister…that when the Trust was set up, no account was taken of the continuing need to support families after the death of a registrant*". I am asked what the Department did to assist the Macfarlane Trust to address this.

5.433. I have not seen the correspondence from me that is referred to in this Chief Executive report. Assuming the reference is correct, then it is important to remember that I was not involved in the establishment of the Macfarlane Trust. I therefore do not know the basis on I may have made this comment.

5.434. In preparing this statement I have seen a copy of the Macfarlane Trust deed, dated 10 March 1988 [MACF0000003_064]. Clause 4 states that:

> "*The objects for which the Trust is established are to relieve those persons suffering from haemophilia who as a result of receiving infected blood products in the United Kingdom are suffering from* [AIDS] *or are infected with* [HIV] *and who are in need of assistance or the needy spouses parents children and other dependants of such persons and the needy spouses, parents, children or other dependants of such persons who have died.*"

5.435. My reading of that clause now is that the Trust deed enabled the Macfarlane Trust trustees to support families after the death of a registrant. Of course, in practical terms, the Macfarlane Trust did operate within funding limits and so would have had to make choices about the support it in fact provided.

5.436. Certainly my focus was on moving the Macfarlane Trust from reliance on ad hoc top-up funding to an annual budget agreed for three years. As I have explained in section 5(C) above, this was achieved in the 2002 spending review. The aim was to give the Trust more certainty in planning the support it wanted to give to families but within a cash limited budget based on the Trust's spending at the time but consciously not giving them room to increase provision beyond that. During my time on the blood policy team, the annual payment to the Macfarlane Trust rose from £2m in 1999/2000 to just over £3m in 2003/04.

5.437. Within the budget set by the Macfarlane Trust and the funding available to it, the Trust was free to support registrants and their families in the ways it considered most appropriate. There was a clear understanding that requests from the Trust for additional funding could be made through a business case which the Department would consider at the next spending review

5.438. In many ways this harked back to the conclusion of the Macfarlane Trust Strategic Review which concluded that:

> *"In order to continue to meet its role as stated in the Trust Deed, the Trust must reconsider the way it utilises its financial resources, prior to identifying any additional funding requirements. To support any case for*

increased funds, the Trust should employ business planning processes to identify the anticipated future need as well as deciding on the level and type of funding that it should offer to registrants and their dependants in future. In addition, financial policies and key financial controls should be present to provide the Department of Health with the assurance that, should further funds be made available, they will be applied for the purpose of benefiting registrants."

Macfarlane Trust and Homosexual Partners

5.439. I am asked about the minutes of the Macfarlane Trust meeting on 20 January 2003 which recorded that Peter Stevens had had a meeting with civil servants in December 2002 and "[t]*he issue of homosexual partners needed further work before a recommendation could be made to the Trust. In particular advice on 'recognition of legal partners' must be sought by The Department*" [MACF0000009_012]. I am asked whether the Department was making a recommendation to the Trust as to whether it should accept homosexual partners as beneficiaries and what recommendations were made by the Department

5.440. I have reviewed the minutes of the Department's meeting with Peter Stevens on 10 December 2002, which I attended [MACF0000009_060]. On this issue the minutes record: [MACF0000009_060]

"***Trust recognition of same sex partners:*** *DH had not yet progressed this query. DH will seek to ensure progress early in the new year.*
Action: *DH to seek legal clarification and inform the Trust of the advice when received.*"

5.441. By email dated 20 September 2002 Peter Stevens raised with me "*the question of possible changes to the Trust Deed to let us treat homosexual partners as we do heterosexual ones – our current differential treatment appears to reflect a bygone age.*" It appears from this email that this was the first time the issue

had been raised with me, and it was raised in the context of preparations for our regular meeting to be held a few days later. [DHSC0003247_007]

5.442. The minutes of the meeting on 25 September 2002 between the Department and the Macfarlane and Eileen Trusts record: [WITN4505386A]

> "***Trust recognition of same sex partners***
>
> *The Trust had been asked to give homosexual partners of registrants the same rights as those of spouses or, as mentioned in the deeds, 'common law wife'. CL agreed with the conclusion reached by Trustees, that this would be appropriate given current practice in other areas, eg recognition of same sex partners in pension schemes.*
>
> ***Action: DH to seek legal clarification and inform the Trust in time for the next trustees meeting on 29 October."***

5.443. It is clear from the documents that the Department had not made progress on this issue by 29 October or by 10 December 2002. The Macfarlane Trust board meeting minutes from 20 January 2003 refer to "*problems within the Legal Department of the Department of Health which had prevented a number of issues being resolved*" [MACF0000009_012]. I cannot now say what those problems were, but nor does this sound like something I would have said.

5.444. On 6 January 2003 I sought advice from Anita James, a lawyer in the Department's legal department, writing [DHSC0003284_007]:

> *"The Trust have received a request that would give homosexual partners of registrants the same rights as those of spouses or as mentioned in the deed 'common law wife'. We consider that this would be appropriate and that a common law wife could reasonably expect to be of either sex. I should be grateful for legal clarification so that we can inform the Trust.*"

5.445. Anita James responded on 6 January 2003 [DHSC0003284_006]:

"*If same sex partners are recognised there will have to be a deed of variation but before anyone is asked to do this can you let me know if it is a real issue*".

5.446. I can see from the documents that this issue was discussed at the next meeting between the Department and the Macfarlane and Eileen Trusts on 5 March 2003. I attended that meeting. The minutes record: [DHSC0003270_014]

"***Trust definition of partners***

DH had been advised that if same sex partners are to be recognised, there would need to be a deed of variation. PS [Peter Stevens] *reported that he was currently considering a definition for the term "partners". PS suggested that he would consult with the Partnership Group prior to further discussion with the DH. CL confirmed that payments would not be made retrospectively*."

5.447. As far as I can tell from the documents, this was not further progressed while I was on the blood policy team, so I am unable to assist with the outcome

5.448. I do not think I was making a recommendation as to whether the Macfarlane Trust should "*accept homosexual partners as beneficiaries*". From my reading of the documents the Macfarlane Trust thought homosexual partners should be treated in the same way as spouses. I happened to agree. The legal advice I received was that, if this was to be done, the Trust deed should be varied.

Long Term Review

5.449. I am asked about minutes of a Macfarlane Trust meeting on 20 January 2003 which record [MACF0000009_012]:

"*The Chairman reported that the Long Term Review had arisen from a meeting with The Department of Health at which Charles Lister had said it was time for the Government to make a new 'political commitment to the Trust'.*"

I am asked to explain:

- The context of the meeting in which I suggested this;
- How it was intended that the Long Term Review would achieve political commitment;
- Any role I had in the Long Term Review process; and
- If, in my view, the Long Term Review was successful (and if not, why not).

5.450. The minutes of the Macfarlane Trust meeting on 20 January 2003 continued:

"It had been agreed that in order for this happen the Trust should carry out a further Review to mark the 15th anniversary of the establishment of the Macfarlane Trust in 1988….The Chairman saw the Review as being a means to establish new priorities for the Trust and to look at different ways to use limited funds rather than seek to increase funds made available by the Department."

5.451. I do not recall the exact context of the meeting (if it was a meeting) in which I made the statement attributed to me by the Chairman.

5.452. However, my review of the documents suggests the background goes back to a position paper Peter Stevens sent to me on 20 September 2002 [DHSC0003247_008]. This was aimed at setting out key issues the Trust was "*grappling*" with. My reply to Peter was that the paper raised a number of interesting issues and I suggested we discuss them in detail at our meeting on 25 September 2002 [DHSC0003247_007]. I also suggested that the position paper was too detailed to use as a basis for a meeting with the Minister and said "*my inclination would be to see if we can make your paper for Hazel Blears more of a strategic overview. Underlying all of this seems to be a question about how the Trustees and the Department see the role of the Trust going forward and I think the first stage is to get some clarity on that broader issue.*"

5.453. There was a meeting between the Department and the Macfarlane and Eileen Trusts on 25 September 2002 [DHSC0003242_008]. The minutes record that

the expected lifespan of the Macfarlane Trust had changed in the intervening 15 years and,

> *"… this was thought to be a good time to step back and consider the future direction. The Trust were not convinced that they were fully supporting the registrants to the extent they would like. However it was acknowledged that there might be a gap between the Trust's perception and that of DH. There was also a legal and political interpretation of their commitment.*
>
> …
>
> ***Action: DH to seek legal views on the commitment to the Trust in relation to the deeds. PS to redraft the paper in consultation with the other trustees to fully understand the Trust's view. AH/ PS to write to Hazel Blears using the redrafted paper as a basis for a meeting…"***

5.454. In November 2002, Robert Finch from my team, recommended that Hazel Blears should meet with the Macfarlane Trust, saying [DHSC0003281_004]:

> "*We recommend accepting the request* [for a meeting with the Macfarlane Trust]…
>
> *A meeting would be timely considering that the Trust is coming up to its 15th anniversary next year and are keen to get a feel for the governments long term funding commitments to the Trust.*
>
> *The continuing medical advances in the treatment of HIV have resulted in the Trust becoming something quite different to what was anticipated when it was set up in 1988. At that time HIV was inevitably fatal and the likelihood of the Trust lasting this long was extremely unlikely.*"

5.455. These discussions led to the Macfarlane Trust undertaking its Long Term Review.

5.456. On 15 January 2003, Jill Taylor (from my team) and I wrote to Ron Powell, who was working in DWP at the time. Jill Taylor's email said [DHSC0003284_011]:

> "*We would be very grateful for your advice on the following issue concerning the Macfarlane Trust Deed…*
>
> *We understand that you drafted the original Trust Deed in 1988. The issue now arising is about the long term responsibility of the Department of Health to the Macfarlane Trust.*
>
> *When the Trust was first established the full life expectancy of registrants with HIV was sadly not expected to be long. In the years that followed the advance of new treatments for HIV has meant that the health and quality of life for many registrants has improved and the Trust is making payments for longer periods.*
>
> *The total number of original registrants was 1240 (haemophiliacs with HIV and 39 infected dependents – partners) and around 800 have since died and in recent years the number of deaths per year has declined. The Trust is now about to undertake an assessment of the need for support for the remaining registrants.*
>
> *Could you advise in accordance with the Trust Deed, what is the obligation on DH to provide continued longterm funding to the Trust?*"

5.457. I followed up this email with [DHSC0003284_011]:

> *"I'd like to add a second part to the question posed by Jill… about the obligation on DH to provide continued long term funding to the Trust. The remit of the Trust is drawn fairly widely. To what extent is the Department obligated by the Trust Deed to fund the cost of whatever the Trustees deem to be justified within their remit? Examples of things currently under consideration are employment re-training and assisted conception – things not necessarily envisaged when the Trust was established but arguably within the remit. We have been working hard to keep the Trust spending within agreed budget limits (£3m pa from 2003/04). But if the Trustees agree that an item of spend is justified, even it exceeds agreed budget limits, could we be challenged legally if we refuse to meet those extra costs?..."*

5.458. It may help the Inquiry if I attempt to explain what we were trying to achieve here. We had established a commitment to annual funding of the Trust through the Spending Review, an important commitment which provided the Trust with a clear basis for their financial planning. Requiring the Trust to operate within budget was in line with standard financial discipline and nothing unusual. However, I wanted to establish that there was nothing in the Trust Deed that could lead to this position being challenged. In particular I wanted confirmation that there was no legal obligation to meet requests for novel or extended funding requests not envisaged when the Trust was established, rather that the level of funding was discretionary and a matter for policy consideration (ultimately by Ministers).

5.459. By email dated 20 January 2003 Ron Powell advised [DHSC0003284_010]

> "There is no obligation on the DoH to give the Macfarlane Trust any more money, though I recollect that the department has done so in the past. It follows that the answer to Charles' question about the extent of our obligations on continue long-term funding is, not at all.
>
> The deed supplied simply sets out what the trustees must do as regards the money that comes into their possession.
>
> Whether you want to supplement their fund is therefore a matter of policy."

5.460. We had of course already taken a decision as a matter of policy to make annual payments to the Trust, so this advice provided assurance but did not alter the policy position, which was a continued commitment to support the Trust.

5.461. My briefing for Hazel Blears meeting with Trust in February 2003 set out this advice and linked it to what we wanted to achieve through the Long Term Review process. Having touched on the changing needs of registrants earlier in the briefing, I went on to say

> *"We need to work with the Trust to establish how best to meet the needs of registrants within funding constraints. We have agreed to support*

the cost of 3 yearly assessments of registrants' needs and the strategy to meet them" [WITN4505387].

5.462. Through the combination of putting Macfarlane Trust top-up funding into the spending review and establishing long term reviews we had established a process that was designed to be both fiscally sound and receptive to the changing needs of registrants, within funding constraints. Political commitment to the Trust had already been achieved through recognition of the need for annual funding. I hoped that the Long Term Review would add to this commitment by giving officials and Ministers a clear understanding of the needs of registrants that would underpin future business cases considered as part of future spending reviews.

5.463. On 24 January 2003, I emailed Vicki King, forwarding the advice from Ron Powell and saying: [WITN4505388]

"You should be aware of this useful advice from SOL. This confirms me in my resolve to keep the Trust firmly within whatever budget is agreed through SR2002 and to suggest that PS(PH) emphasises this when she meets the Trust next month. The Trust want an ongoing commitment to funding from PS(PH) which we can give but it has to be strictly cash limited.

There has been a tendency in the past to give the Trust whatever funding Trustees think is needed, which means that the Trust has got into the habit of giving into registrants demands. This has begun to change over the past couple of years since we put the Trust on to a fixed budget but Ann Hithersay in particular is still not on message.

My message to the Trust now is that any request for further funding must be done through a proper business case which we can consider in line with future spending reviews."

5.464. The point being made here, although expressed in slightly critical terms, was again about the importance of the Trust maintaining financial discipline. I was not making a point about whether particular support for registrants was justified or not. We were trying to achieve a position in which

- the Government provided planned cyclical funding so that the Trust's financial position was more predictable and secure.
- The Trust, for its part, would be expected to make the 'business' case for the size of that funding in the spending review process, and then manage its payments within the budget granted by the spending review process.

Funding for the Macfarlane Trust was not designed to ameliorate all need in the sense of providing financial compensation of the type that would be awarded by the Courts and so, on any view, some budgetary limits needed to be imposed within which the Trust would be expected to work.

5.465. At the next regular meeting between the Department and the Macfarlane and Eileen Trusts on 5 March 2003 [WITN4505388] it was recorded that:
"*PS reported that he welcomed the assurance from Hazel Blears to support the Trust in the future and confirmation on funding for the next three years….*

PS provided an update on the Long-term review…"

5.466. I understand from the Long Term Review was completed in October 2003. That was after I had left the Blood Policy team. I therefore do not feel able to comment on the success of the Long Term Review.

Statement of Truth

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

Signed GRO-C

Dated 19.05.2022