Witness Name: Richard Gutowski
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INFECTED BLOOD INQUIRY

SECOND WITNESS STATEMENT OF RICHARD GUTOWSKI

I, Richard Gutowski will say as follows: -

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SECTION 1: INTRODUCTION

1.1. I am a retired Civil Servant. My date of birth and home address are known to the Inquiry.

1.2. This is my second witness statement to the Inquiry. My first statement dated 10 May 2022 addressed the destruction of Department of Health ('DH') papers. I am providing this statement in response to two Rule 9 Requests received from the Inquiry on 1 November 2021 and 14 February 2022.

1.3. In this second statement I respond to :

(1) A Rule 9 Request dated 1 November 2021 which was accompanied by 55 documents and posed questions in relation to Alliance House Organisations ('AHOs'); roll-out of recombinant Factor VIII; vCJD; and Record Keeping. There were also some introductory questions about my career history and my role at DH, as well as two final questions which were more general in nature. The Inquiry also provided an additional 705 documents for me to review.

(2) A second Rule 9 Request dated 14 February 2022. This made some changes to the questions asked in the first Rule 9 Request and raised some new questions. The further questions were additional questions on the AHOs (specifically the Skipton Fund) and vCJD, and a new area of questions on Inquiries and reviews. Some 296 additional documents were provided for me to review.

1.4. I have done my best to answer the questions raised in the Rule 9 Requests from both my memory and the documents that have been made available to me. Before I address the detail of the Inquiry's requests, I wish to highlight two limitations on this statement. The first relates to the documents that I have been asked to review. The second relates to my recollection of the relevant events.

1.5. As regards the issue of disclosure of documents, I have been provided by the Inquiry and the Department of Health and Social Care ("DHSC") with a large number of documents to review in a relatively short period of time. These are from both hard copy records and electronic records. However, the volume of documents overall means that there may be relevant documents to which I've not been referred and if I'm referred to further documents, I may need to add to or amend my answers to the issues raised. I have, of course, done my best with the documents made available to me.

1.6. It has helped me to review the documents. While I do remember some details, the Inquiry is asking about events some 15 years ago. As a result, my memory of some of the specific matters contained in the Inquiry's request is limited and I have relied on documentation from the time to jog my memory and fill in some of the gaps.

1.7. In my first statement, I set out details of my role as Head of Blood Policy between 9 June 2003 and December 2004. I refer the Inquiry to this as I have explained the nature of my role, including setting up the Skipton Fund in collaboration with the devolved administrations. With regard to the Skipton

Fund, subject to the usual oversight and supervision of senior civil servants above me, I had a lead responsibility and was involved in briefing ministers during the negotiations with devolved administrations. I also briefed ministers on matters such as lobbying by voluntary organisations and the All-Party Parliamentary Group ('APPG'). Additionally, I provided briefings on media interest in the scheme and I was involved in securing the agreement of the MacFarlane Trust to administer the Skipton Fund. In my first witness statement I also set out details of the team I managed and those I reported to at DH who were Grade 5 and were themselves managed by more senior Grade 4 civil servants.

1.8. As I explained in my first statement, my predecessor as Team Leader was Charles Lister and I was succeeded by William Connon. Charles Lister arranged handover briefings with me when I took up the position. I have seen some written handover notes drafted by Charles Lister which I referred to in my first statement. Charles would also have taken me through all the issues I would have to deal with in my new role.

SECTION 2: MY ROLE IN THE DEPARTMENT OF HEALTH WITH RESPECT TO THE AHOS

Introductory AHO matters raised by the Inquiry

2.1 As Head of Blood Policy at DH there were many different and demanding areas of work; included within these, I had significant involvement with the AHOs.

2.2 Both the Macfarlane Trust and Eileen Trust had been set up and operating for many years by the time I started my role as Head of Blood Policy in June 2003. My dealings with the Macfarlane Trust were mainly concerned with setting up the Skipton Fund and the important role that the Macfarlane Trust would play in this. I do not recall having very much to do with the Eileen Trust except on the periphery of section 64 deliberations. I have set out further information in relation to my understanding of how AHOs operated in the relevant sections of my statement below. The Inquiry has asked me about the Caxton Foundation but that entirely post-dated my involvement and I do not recall having any knowledge of this organisation.

2.3 A large part of my time as Head of Blood Policy was taken up helping to develop the Skipton Fund. I was one of the officials from the four administrations responsible for this. This comprised representatives from DH, the Scottish Executive, the Welsh Assembly and the Northern Ireland Assembly (the latter three, I shall refer to as the 'devolved administrations'). The Skipton Fund was a joint venture - it was not devised by DH with the devolved administrations invited to be part of it. All decisions on structure, eligibility criteria, level of

payments, guidance and application forms had to be agreed by all of the four administrations and signed off by their respective Ministers. The Skipton Fund had a very narrow remit and was unlike the Macfarlane Trust and Eileen Trust which had wide discretion as to what payments they made.

2.4 As the Macfarlane and Eileen Trusts had been up and running for many years, the Trustees were likely to have a regular schedule of meetings throughout the year to discuss trust business. To the best of my recollection, I did not attend those meetings and so far as I am aware, there was no DH attendance at such meetings.

2.5 Meetings did take place between DH and the Macfarlane Trust (with Peter Stevens and Martin Harvey) to discuss the development of the Skipton Fund. I was involved in many meetings in relation to setting up the Skipton Fund, both in person and by telephone. There were discussions on all different aspects of the scheme between the four administrations and also with politicians, patient groups, medical experts and lawyers. I recall that it was mainly myself and Robert Stock ('Bob Stock') of Scotland who played the most pro-active role among the four administrations in relation to setting up the Skipton Fund. The Northern Ireland officials did not get involved very much and the officials from Wales were involved but only sporadically. It was mainly myself and Bob Stock pushing things forward. That said, it is important to reiterate that it was a joint scheme and had to be agreed by all four administrations. This was particularly important given that each individual administration had to identify and find the money for their own beneficiaries.

2.6 Minutes of meetings with outside organisations, including other government departments, were always taken. Minutes were usually taken by a member of staff who hosted the meeting. The minutes would have been circulated to all those that attended. Minutes of meetings should be in the relevant DH policy file.

2.7 I do not recall attending board meetings at any of the AHOs. I am not even sure whether the Skipton Fund had moved to a regular pattern of board meetings by the time I left my role as Head of Blood Policy in or around December 2004.

2.8 I considered the working relationship between the AHOs and DH during my time to be professional and constructive. As I have already explained, my main interaction with AHOs was with the Macfarlane Trust and the Chairman at the time, (Mr Peter Stevens) and Chief Executive (Mr Martin Harvey). As I recall, our interaction was almost exclusively concerned with setting up the Skipton Fund.

2.9 By this stage (2003), the Macfarlane Trust had well over a decade's experience in helping Haemophiliacs who had contracted HIV through infected blood or blood products. This meant that those involved with it (including Mr Stevens) had a wealth of knowledge which was invaluable when setting up the Skipton Fund and ensuring it operated well. I was very glad when the Macfarlane Trust agreed to administer the Skipton Fund as this meant the scheme could be set

up more quickly and the Macfarlane Trust could provide valuable input on many aspects of the scheme and how it should operate.

2.10 I considered I had a good working relationship with Mr Stevens and Mr Harvey; I felt we shared the common goal of getting the Skipton Fund up and running so that people infected with Hepatitis C due to infected blood and blood products could receive ex-gratia payments under the scheme.

2.11 After this length of time, I don't recall in detail the funding arrangements between the DH and the Macfarlane and Eileen Trusts. Having reviewed a number of documents, I am reminded that the funding was divided into two categories – operational funding and capital funding.

2.12 The operational costs were funded annually by a section 64 grant, while capital funding was agreed on a 3 year cycle. At the time I started my role as Head of Blood Policy, the government had committed itself to a three year capital funding package for the Macfarlane Trust up to 31 March 2006. This had been agreed with Hazel Blears MP, the responsible Minister, at a meeting with the Trust on 27 February 2003. [MACF0000172_001]. This meant that my involvement in funding would have been mainly in relation to section 64 costs.

2.13 The Macfarlane Trust's Annual Report and Accounts for the year ending 31 March 2005 show the trust received a Government Capital Grant of £3 million (this was to be used to assist beneficiaries) and £287,000 by way of a section

64 grant which was to be used to cover administrative costs. [MACF0000045 012]

2.14 As the level of capital funding was now based on the three year spending review cycle and had been set for three years relatively shortly before I joined the team, the level of capital funding for the existing AHOs (the Macfarlane and Eileen Trusts) did not feature that prominently during my tenure as the Head of the Blood Policy team. However, as I explain in paragraph 2.16 onwards, the Macfarlane and Eileen Trusts wished to move to a different funding model which did not involve section 64 grants.

2.15 I cannot recall what the formal reporting obligations were for AHOs such as the Macfarlane Trust and Eileen Trust. The AHOs relied solely on DH funding and given the substantial amounts of money involved, DH would have expected a certain level of oversight. I recall AHOs providing copies of their annual accounts to DH. I have also seen documents showing that the Macfarlane Trust notified DH when it made loans to beneficiaries [DHSC0006164_017].

2.16 The Macfarlane and Eileen Trusts wanted to move away from section 64 funding for operational costs to a different financing model which covered both operational and capital funding. This would remove the need to apply for section 64 funding each year. Discussions had taken place to facilitate this. In an email to me dated 2 November 2004, Peter Stevens said, "*...I gathered from comments you made some time ago that a change of policy is imminent and it*

would be really helpful if we could combine the s.64 requirement and the block grant into a single year-on-year payment." [DHSC0003288_007].

2.17 An email from Eileen Lawrence to Gerard Hetherington on 4 November 2004 (to which I was copied in) shows that the Trust's wish to move away from the section 64 funding was shared by Ministers [DHSC0038526_024]. The same email chain also shows that the total section 64 budget was insufficient to meet the Macfarlane Trust's bid for a section 64 grant, let alone the bids from other organisations. It appears that everyone involved considered this unsatisfactory – the Macfarlane Trust, myself and Ministers. [DHSC0038526_024].

2.18 In my email to Eileen Lawrence on 8 November 2004, I set out my views:

> *"I have no problem with the administration costs being met from the revenue budget provided that the budget is increased accordingly. At the moment their budgets are fully committed and it would be unacceptable if registrants or their families didn't receive payment because of money being diverted into an administrative pot. Gerard has suggested using Programme money but I am not sure how permanent or secure that is.*
>
> *Happy to discuss some cunning plan." [DHSC0038526_024].*

2.19 Although I have no recollection of having these discussions, what I can see from the emails is that I did not want registrants or their families to lose out due to a shortfall in funding – this was unacceptable to me. My email also suggests that I was concerned to ensure permanent and secure funding for the Macfarlane Trust. I think it is likely the changes to funding were brought in after I left my role as Head of Blood Policy.

2.20 I am not sure that the AHOs I dealt with at the time, such as the MacFarlane Trust, the Eileen Trust or the Skipton Fund, could be regarded as wholly independent of government because they relied on the government for funding. However, in my dealings with the AHOs (mostly the Macfarlane Trust), I found the Trust to be independent of the government. Its role was to represent the best interests of its beneficiary population i.e. Haemophiliacs who had contracted HIV through infected blood or blood products. In my experience, this is what the Macfarlane Trust sought to do.

2.21 During my time as Head of Blood Policy, the vast amount of lobbying I encountered was in relation to the government's plan to set up the ex gratia payment scheme which would become the Skipton Fund. AHOs, patient organisations and those infected and affected, as well as their families, lobbied for changes in government policy in relation to the Skipton Fund.

2.22 The decision to set up an ex gratia payment scheme was taken during my first weeks in the Blood Policy Team. I was therefore not involved in responding to any lobbying to persuade the government to provide ex gratia payments to Hepatitis C patients infected through contaminated blood as this pre-dated my time in post. I would have had no problem with an organisation lobbying on behalf of its membership and would have been surprised if this had not taken place.

2.23 The scheme was announced by John Reid on 23 August 2003 but details of how the scheme would operate, eligibility criteria etc were not announced until 23 January 2004. During this time, we consulted AHOs, patient organisations and medical experts. We were subjected to lobbying on a number of issues, including from members of the public. The main issues included whether payments should be made to those co-infected with HIV or those who had naturally cleared the virus within 6 months; and whether payments should extend to the surviving dependents of those who had already died from Hepatitis C infection.

2.24 I was grateful for expert input from AHOs such as the Macfarlane Trust and other groups representing potential beneficiaries such as the Haemophilia Society. They knew their beneficiaries better than we did. All representations were given due consideration and often the Minister was briefed on campaigning/lobbying that took place. Various options would have been set out for the Minister to decide how s/he wanted to proceed in relation to what was being suggested. The scheme was very high profile so attracted a lot of attention from both the press and politicians. It was also the subject of very many PQs.

2.25 By way of an example, during the early stages of development of the scheme, discussions were taking place between DH and the Macfarlane Trust about how the scheme should operate and whether the Macfarlane Trust would be prepared to administer it.

2.26 In an email dated 25 September 2003, Peter Stevens made it clear that before the Macfarlane Trust could commit to managing the scheme, he wished to consult his co-trustees and that there were a number of issues that they were considering as potential caveats to their involvement. These included:

> *"…- the entitlement of the co-infected haemophiliacs (MFT registrants) to payment in respect of HCV, and any limitation in their entitlement compared with other beneficiaries (full, or nearly full, entitlement is likely to be a sine qua non of our participation).*
> *- the availability of post-mortem payments to bereaved families. This is a very difficult issue on which there is not yet a settled MFT view, and we would also wish to try to reach agreement with the Society. I cannot predict whether the consensus view would make this essential for our participation.*
> *- exemption of payments from determination of eligibility for social security and from tax (in our view essential for the scheme, but probably not a constraint on our involvement)*
> *- support for the scheme from our registrants (with two Trustees who are themselves MFT beneficiaries we cannot totally ignore this - it depends on the scheme finally chosen)*
> *- whether the payments would be conditional on an MSPT2-type waiver (we might find that difficult, again thinking of our registrants' reaction)*
> *- whether the scheme is a once-for-all payment or has some form of top-up payments or hardship fund to deal with long-term development of disease.*
>
> *I would hope to eliminate some of those points with a bit more consideration and, if permitted, consultation." [SKIP0000032_248].*

2.27 The reference to 'the Society' in the quotation above is in relation to The Haemophilia Society. I had a meeting with the Macfarlane Trust and the Haemophilia Society on 18 September 2003 to discuss the proposals for the ex gratia payment scheme. In a letter to me on 29 September 2003, Karin

Pappenheim, Chief Executive of the Haemophilia Society, explained that following this, the Haemophilia Society had held an extraordinary meeting on 25 September 2003 and agreed that the following principles were essential as regards the scheme:

- "*The scheme cannot exclude HIV/HCV co-infected people who may already be registrants of Macfarlane Trust.*
- *It must include provision for dependents of those who have died.*
- *Registrants to the new scheme should not be required to sign a waiver or similar document excluding future action.*
- *Our board would not accept the proposals put forward by Malcolm Chisholm in Scotland for an alternative scheme to that proposed by his own expert working group chaired by Lord Ross, and would regard Lord Ross's proposals as the minimum level that might be agreed.*
- *The Society favours the establishment of one scheme for the whole UK rather than different ones for each 'jurisdiction'.*
- *The design of any scheme must allow for future need as proposed by our expert group and the Ross group i.e. not just a one-shot payment. If a one-shot payment is the only way forward it must be sufficiently generous to take account of future declines in health etc as shown in the Society's future projections of the health of the affected group.*
- *The scheme must include a benefits/tax disregard as applies with the Macfarlane Trust payments (and extending to income from investments).*
- *The scheme should include some provision for those who have cleared the virus as proposed by our expert group.*" [HSOC0003257]

2.28 I recall that the Macfarlane Trust's own Trustees were concerned about the impact on the Macfarlane Trust's reputation if co-infected haemophiliacs were not included within the ex gratia payment scheme. It was felt that this would

impact negatively on how the Macfarlane Trust was viewed by the Haemophilia community and the Macfarlane Trust made it clear this was a red line for their involvement.

2.29 Some HIV sufferers had received ex gratia payments at an earlier date and signed a waiver. There was a discussion around whether the co-infected and those subject to the waiver could apply for ex gratia payments from the Skipton Fund. The Macfarlane Trust's views on this issue were clear and it lobbied to include payments for the co-infected. Amendments were made to the scheme to reflect this as discussed later in paragraph 2.141.

2.30 There were, of course, areas of disagreement between what AHOs wanted and what the government could in practice achieve, against the financial constraints on government spending in place at the time. The government compromised in some areas but could not meet what the interest groups wanted in other areas. A prominent example of this was the exclusion from the scheme of payments to dependents of those who had already died from Hepatitis C from infected blood and blood products. The reasons for this are explained in paragraph 2.136 onwards.

2.31 There was also an issue around the impact of ex gratia payments on social security entitlement. It would have been undesirable for those receiving ex gratia payments to have their entitlement to social security negatively impacted. Advice was sought from the Department of Work and Pensions ('DWP') and a

statutory instrument drafted and laid before Parliament to ensure this didn't happen.

2.32 Another example of a change to the scheme was to remove the condition that stated that ex gratia payments would be deducted if compensation from another source had previously been received. I wrote a submission to Melanie Johnson on 5 March 2004 seeking her agreement to make this amendment to the eligibility criteria of the Hepatitis C ex gratia payment scheme [DHSC0004425_029]. I think it important to stress that any proposed changes to the scheme would have had to be agreed by all four administrations.

2.33 The Haemophilia Society wanted the scheme to have a wider remit than that being proposed, while the Macfarlane Trust made it clear to DH that it would not administer the scheme if those co-infected with HIV were to be excluded from the ex gratia payment scheme.

2.34 In a letter to me dated 30 October 2003, Martin Harvey, the Chief Executive of the Macfarlane Trust explained that:

> *"The Macfarlane Trust does, of course, have some sympathy with the sentiments expressed and we can, to some extent, understand why campaigning bodies such as the Society might have a number of reservations about the proposed scheme. Our only non-negotiable condition is that MFT registrants should be included in any proposed scheme on an equal basis to those mono-infected. You have indicated that this would, in all probability, not represent a problem. Other matters, such as the treatment of taxation and benefits, have been met with a positive response and for that we are grateful."* [DHSC5328280].

2.35 On 1 April 2004, following a meeting with me the previous week, Ms Pappenheim wrote to Gerard Hetherington to once again set out her concerns about the scheme as follows:

> *"You may be aware that the Society has already raised a number of concerns, such as the exclusion of bereaved families from the payments scheme. My reason for writing now is to raise two further aspects of the proposed scheme, which only became clear at last week's meeting.*
> *From this we understand that it is possible that:*
> □ *Claimants will be "asked to sign an undertaking not to institute proceedings against the NHS or Ministers in relation to their having been infected with hepatitis C from blood, blood products or tissue received from the NHS before September 1991"*
> *And that:*
> □ *Any form of monetary award that has been made in respect of the person being infected with hepatitis C will be deducted from the ex gratia award. This applies "as a result of receiving blood, blood products or tissue from the NHS prior to September 1991 - including awards in the civil courts or out of court settlements in the UK or abroad and also awards from the UK government and from other governments".*
> *Both these conditions are unacceptable to the Society. At the meeting of the Society's board this week, trustees re-affirmed their view that the imposition of such conditions would be morally wrong, and entirely inappropriate in an ex gratia scheme where payments are apparently being made on compassionate grounds rather as part of any legal settlement." [HSOC0016820]*

2.36 The APPG published a report in January 2015: "*Inquiry into the current support for those affected by the contaminated blood scandal in the UK*" [RLIT0000031]. This report contained a section on "*The Relationship between the Trusts and the Department of Health*" [RLIT0000031]. I have been asked by the Inquiry to

review this document, together with the letter referred to in the following paragraph and to comment on these.

2.37 In a letter from Jan Barlow, Chief Executive of the Caxton Foundation, to Diana Johnson MP and Jason McCartney MP, comments were provided on the report (the Caxton Foundation having been provided with an advance copy). The letter, dated 28 January 2015 (the Inquiry has advised that document has the incorrect year of 2014), discussed the contents of the report. Ms Barlow makes the point that the Caxton Foundation "*…were interested to see that the report revealed a perception amongst many that the organisations have what amounts to a "cosy" relationship with the Department of Health (DH). Whilst we would describe our relationship as cordial and professional, it is certainly not cosy*." [CAXT0000111_029]

2.38 I do not recognise this as a true description of the relationship between DH and the AHOs. From my experience, I found my relationship with the Macfarlane Trust and Skipton Fund to always be professional and respectful of our different roles. They were clearly committed to get the very best for their beneficiaries. DH wanted to set up an ex gratia payment scheme that operated well and in line with the eligibility criteria set by DH. As I explained earlier, we had a shared goal and I do not think the Macfarlane Trust would have agreed to help administer the Skipton Fund if there wasn't a good working relationship in place.

Contact with and knowledge of the beneficiary community

2.39 My knowledge and understanding of the needs of beneficiaries of AHOs during my time as a Head of the Blood Policy Team came from discussions with the relevant representative organisations and medical organisations, correspondence from the beneficiary community and discussions with affected individuals. I also had correspondence with interested Parliamentary individuals, such as Michael Connarty who was Chair of the APPG on Haemophilia and Contaminated Blood. The APPG's concerns in relation to contaminated blood were well documented and I was aware of them. Details were also available on relevant policy files. Additionally, during the process of setting up the Skipton Fund, there were regular meetings and correspondence with various organisations representing beneficiaries, such as the Haemophilia Society and Hepatitis C Trust and medical experts, such as the Haemophilia Doctors Association ('UKHCDO').

2.40 Contact between the Blood Policy Team and beneficiaries of the AHOs took a number of different forms. There was indirect contact via the Macfarlane Trust which notified DH when it made certain payments to beneficiaries. The Blood Policy Team also received a large volume of correspondence directly from beneficiaries in relation to the ex gratia payment scheme once it was announced. The departmental phones were ringing constantly with enquiries from those wishing to register for the scheme and those wanting further information. I also recall a couple of meetings with individual beneficiaries of the Skipton Fund during the development of the scheme. I personally had phone conversations with potential beneficiaries. However, as is the norm in these cases, there was also a lot of communication with the Haemophilia

community on a range of issues via their representative organisations such as the Haemophilia Society.

2.41 During the setting up of the scheme we received a number of complaints from individuals concerning the amount of time taken to set up the scheme, which they saw as delay. Additionally we received complaints from widows, families and dependents of those who had died from Hepatitis C as they were not eligible to receive payments under the terms of the scheme.

2.42 The announcement of the ex gratia payment scheme was made by the Secretary of State John Reid on 29 August 2003. The Skipton Fund was not ready to begin processing applications until July 2004 as there were a number of hurdles to get over before the scheme could become operational. These included the legal status of the scheme, who would administer it, the number of beneficiaries and sources of funding. Policy had to be agreed in relation to eligibility criteria and advice sought from patient groups and medical experts. Furthermore, issues pertaining to the social security disregard needed to be resolved, as did those relating to the co-infected, and whether payments received at an earlier date would be deducted.

2.43 There is a short note from me to Melanie Johnson written on 17 May 2004, in which I explained that the setting up of the scheme had taken longer than hoped for a number of reasons:

> *"• Officials had to set up the Skipton Fund as a limited company because the ex-gratia one off payment could not be regarded as a charity.*

> • *Officials had to set up a working group-of hepatologists and haematologists to advise us on the criteria for the second payment.*
> • *Officials also had to devise an application process which was as user friendly as possible."* [DHSC0004555 _091].

2.44 A limited company had to be registered and an agency agreement negotiated between government lawyers and those instructed by the Macfarlane Trust. The relationship between DH and the Skipton Fund was formally set out in an agency agreement [SKIP0000030_ 139]. This provided that the Skipton Fund would act as DH's agent in relation to the scheme. The agency agreement had not been signed by the time I left my role as Head of Blood Policy. I understand from the Inquiry that the agency agreement was not signed/executed until 2007. I am not sure why this took so long but the important thing is that the Skipton Fund began processing applications and making payments in July 2004.

2.45 Every aspect of the ex gratia payment scheme required approval from all four administrations in England, Scotland, Northern Ireland and Wales. It was a challenging task and given everything that had to be agreed, organised and put in place (especially given the number of parties involved), I consider we did well to have the scheme operational within a year from the time of the announcement. Nevertheless, I do understand (and did at the time understand) that it was difficult for the potential beneficiaries to have to wait when many of them had been campaigning for years and there were many cases of genuine financial need.

2.46 Once the scheme was up and running, DH received correspondence about the eligibility criteria, level of payments and appeals process. This correspondence came directly from individuals or through MPs. On 14 July 2004, I provided a submission to Melanie Johnson in response to some questions she had asked about the number of applications the Skipton Fund had received; how long it was taking on average to process applications; how long it was likely to take to process the applications received to date; whether there was a backlog; and how many people were working for the Skipton Fund. I provided the answers to these questions in my submission. [DHSC0041162_140]. I was asked for and provided a further update to Melanie Johnson one week later on 21 July 2004 [WITN5292017]. Melanie Johnson continued to request updates on the scheme, which my team and I provided. Another example is the update provided to the Minister by Zubeda Seedat on 10 September 2004. [WITN5292018].

2.47 On 19 October 2004, I received an email from Anna Norris notifying me that Melanie Johnson had noticed that there had been delays in processing of applications and she sought reassurance that the Skipton Fund was operating as it should:

> *"PS(PH) has noticed that there have been lots of correspondence on delays processing payments through the Skipton Fund. Is this a matter of the Skipton Fund initially raising expectations of processing times it could not meet?*
>
> *PS(PH) has asked for reassurance that the Skipton Fund is running okay. She has asked that she should be informed early if it appears that anything is going wrong. This is the sort of issue that the media and other*

MPs take an interest in - PS(PH) does not want to find out through other routes that there are problems." [DHSC5014739]

2.48 I think there was an expectation from beneficiaries that they would receive a payment within a day or two of submitting an application form but applications were taking 4 to 5 weeks to process and this resulted in a number of complaints. In an email to Anna Norris on 25 October 2004, I explained the reasons for the delay:

"I think the perceived problem is one of initial teething problems with the Scheme and public expectation. Having waited so long for a scheme to be announced then to become operational both potential recipients and the Scheme's administrators were keen that payments would be made as quickly as possible. In fact the Skipton Fund publicly stated on their website that they would process applications in three weeks. This proved over optimistic and applications are in fact taking between four and five weeks to be dealt with mainly because of the need for a Director of the Fund to sign off each payment and there are in fact only two Directors based in London. The three week promise has now been removed. There was also a problem in the early stages of Skipton Fund personnel failing to deal with aggressive claimants demanding to know the latest state of play but I believe this has now been addressed." [HSC5014739]

2.49 DH had a centrally set target that all correspondence should receive a formal reply within a laid down timescale which I believed was 20 days. Unfortunately, the volume of correspondence against the background of finite resource in our team meant that there were probably quite frequent occasions when we did not meet the target. Replies at one point had to be outsourced to other parts of DH. All letters received formal replies which would have been placed on the relevant correspondence file. I cannot recall each individual concern raised or the detail of the response given.

2.50 The Skipton Fund provided DH with the number of applications received, the number of those applications which met the criteria to receive payments and the amount spent. I have seen various emails from Peter Stevens to me setting out this information in the early months of operation of the Skipton Fund. For example, in an email to Bob Stock and myself on 28 October 2004, Peter Stevens updated us on the number of application forms sent out and number of payments made in the past 9 days. [DHSC5351246]. These statistics were the basis of requests for additional funds which were paid in instalments rather than in one lump sum.

2.51 I note from the bundle of papers supplied by the Inquiry there is a document from the organisation Tainted Blood [DHSC6696633]. In that document they speculate about whether there is a "small chance" that I may have accidently marked papers for destruction. I categorically deny that I inappropriately marked any papers for destruction, accidently or otherwise, during my time in the Blood Policy Team. In fact, in this role in the Blood Policy Team, I was not involved in the archiving process and, to the best of my recollection, I would not have marked any papers for destruction. The archiving decisions were taken by responsible but more junior members of staff.

2.52 Whilst I understand and had sympathy with various individuals' anger and frustration, I have to say that the Blood Policy Team, during my tenure, had on occasion been on the receiving end of some very unnecessarily aggressive and

threatening phone calls and correspondence. I hasten to add that it was only a minority who acted in this way.

2.53 I was aware that some (not many) potential recipients expressed concern about the involvement of the Macfarlane Trust in helping set up and administer the Skipton Fund. This would have been in correspondence or over the phone. I cannot recall any specifics and have not found any further details in the documents available to me, but I would have tried to explain the process involved in putting the payment scheme together and the need for the involvement of all interested parties.

2.54 The Inquiry asks if I was aware of tensions between the beneficiary community and the AHOs. Looking back after all these years, I do not recall beneficiary concern about the AHOs as being a very prominent issue. I am not suggesting that this did not come up from time to time but so far as I recall, it was not something that was raised frequently with me or as a fundamental problem.

Appointment of Trustees/Directors

2.55 I have been asked about the selection and appointment process for Trustees or Directors of AHOs. I cannot recall any details about the selection or appointment process for AHOs; I was in the post for a relatively short time and it may be that there were few if any appointments during my time other than appointments to the Skipton Fund. This may be why the issues of appointments doesn't stick in my mind. I have been reminded by reviewing the documents that four of the directors of the Macfarlane Trust were appointed by the

Secretary of State for Health. I set this out in an email to Gerard Hetherington on 30 April 2004:

> *"As far as the relationship with the Department is concerned this should not change - four of the Macfarlane Trustees (two of which are Directors of the new Company) are appointed by the Secretary of State and this will continue. I don't see the Department being on the Board of Directors or there being set up a formal accountability processes."* [DHSC5336152]

2.56 In terms of my involvement in the appointment of Directors for the Skipton Fund, I do recall writing to the Registrar of Companies to request that their details remain confidential for safety reasons. [DHSC5796071]. This is because there were concerns that directors could be subjected to threats from a very small minority of activists. Other than this, I do not recall either myself or the Blood Policy Team having any involvement in the appointment process for the AHOs.

2.57 Having reviewed the documents I can see that on 2 November 2004, Melanie Johnson provided a written answer to a PQ from Pete Wishart MP explaining why some of the Trustees, the Chairman and Chief Executive of the Macfarlane Trust were asked to take on the role of Directors and Company Secretary for the Skipton Fund on an interim basis:

> *"Peter Wishart: To ask the Secretary of State for Health (1) what criteria have been developed for the appointment process of the directors of the Skipton Fund; and if he will make a statement; (2) what the term of office is for the directors of the Skipton Fund once they have been appointed; and if he will make a statement; (3) whether, when the Skipton Fund was established, its directors were drawn from the Macmillan [Macfarlane]*

> *Fund; and if he will make a statement; (4) from what backgrounds the directors of the Skipton Funds have been recruited."*
>
> *"Miss Melanie Johnson: Three trustees and the chairman and chief executive of the Macfarlane Trust were asked to take on the role of directors and company secretary for the Skipton Fund on an interim basis. This decision was made so that we could make progress with establishing the Skipton Fund. The trustees have a background in management, administration and working with haemophilia patients.*
>
> *We have been seeking advice about the recruitment of directors to the Skipton Fund on a more permanent basis."* [WITN5292019].

2.58 I do not have any direct knowledge of why the Department was originally given a hand in selecting Trustees/Directors of the Macfarlane and Eileen Trusts. I would assume it was a method of providing some accountability to DH which was the only funder of these two AHOs. I do not recall being aware of any difficulties in the appointment process or there being issues around finding sufficient applicants of sufficient quality. I also do not recall DH having a view about user trustees during my time as Head of Blood Policy.

Funding of the AHOs

2.59 Both the Macfarlane and Eileen Trusts were set up many years before I became Head of Blood Policy so I was obviously not involved in the original evaluation of their likely costs. The Inquiry has referred me to minutes of a meeting which took place on 12 July 2006 at which Peter Stevens put to the government attendees in the context of the Eileen Trust that " *…the real cost of support was never properly evaluated from day one even if support, at current levels, had*

broadly maintained cash values in line with inflation". [GLEW0000357]. This was well after I had left post, and Mr Stevens was referring to the initial evaluation of the cost of support when the Trust was first formed. Someone who took part in the setting up of the Eileen Trust or Macfarlane Trust would be better placed to assist the Inquiry as to how the capital funding was initially evaluated. As I have explained above, the capital funding for the Macfarlane and Eileen Trusts for my time in the post, had already been set on a three year cycle before I took over and my predecessor Charles Lister would have been involved in that, though the ultimate decisions would obviously have been taken at a higher level. In general terms, my understanding was that the funding had always been based on the ex gratia support basis: it did not purport to meet the needs of beneficiaries in the same way as compensatory damages would have done. However, DH had to look at areas where needs had increased and at the scope for better support but this was always against the background of other competing financial demands.

2.60 I was more involved in the debate around allocation of funding in relation to the Skipton Fund. There were many discussions about how much money was likely to be needed to make the ex gratia payments and to cover the operating costs of the Skipton Fund itself. Following discussions with Macfarlane Trust and UKHCDO, calculations were done on the likely number of beneficiaries – and assessment of how many would qualify for Stage 1 payments, how many for Stage 2.

2.61 A minute to John Reid from Melanie Johnson on 3 December 2003 set out how estimated costs for the scheme had been derived:

> *"The original cost estimates for this scheme were made on the basis that up to 8,500 potential claimants would be eligible for payments under the initial draft eligibility criteria (attached as Annex A). This suggested that a budget of between £162.Sm and £212.5m would be required depending on the number of eligible claimants making applications (£162.5 = 50% take-up, £212.5m = 100% take-up). DH Finance has a £150m provision scored in the 2002/3 accounts to fund the scheme."* [WITN5292020].

2.62 Melanie Johnson went on to explain that these figures appeared to be an over-estimate:

> *"Updated estimates and a more comprehensive analysis of these figures appears to show them to be an over-estimation due to double-counting and inclusion of some non-eligible groups. Further analysis shows that the original calculations included those patients that have cleared the virus with treatment and those who are co-infected with HIV. However, the analysis also found that two patient groups were overlooked in the original submission. Despite this, the balance of the revised estimates indicates that there are significantly less potential claimants (6,707 as opposed to 8,500). The revised costs are therefore estimated to be approximately £179m at 100% take-up. Given that there is unlikely to be such a take-up, the revised costs fall within the scored funds currently available."* [WITN5292020].

2.63 The Skipton Fund was also allocated money for start-up costs and ongoing running costs. In an email to Bob Stock and others on 25 March 2004, I confirmed that DH had provided the Skipton Fund with £60,000 towards start-up costs [SCGV0000257_ 022].

2.64 The Inquiry has provided me with a copy of an invoice from the Skipton Fund addressed to me and dated 18 January 2005 [DHSC0006798_065]. This is a request for £20 million capital funding to cover ex gratia payments to be made

to claimants. I recall that money was released to the Skipton Fund in phases – not the full amount up front. As I remember it, the Skipton Fund would request money from DH to cover payments to claimants whose applications had been approved. I think this was done by the Skipton Fund providing an invoice that I would review and approve for payment.

2.65 At one point in time, I recall the Skipton Fund saying it had received 2,000 applications so the money to cover those payments would have been released. I ensured that sufficient funding was allocated to cover both these aspects.

2.66 I have been asked about how section 64 grants operated, how section 64 budgets were set and whether there were DH guidelines to the AHOs on the use of s. 64 funds. I only recall having minimal involvement in allocation of section 64 grants. This wasn't the main focus of my role. I do not recall having involvement in making section 64 grants. I think this was the responsibility of another part of the Health Protection Division within DH run by Helen Christmas who had overall responsibility for section 64 grants. [DHSC0032299_116]

2.67 As I explained in 2.16 above, section 64 was no longer considered a suitable way to fund Macfarlane Trust's administrative costs and a new model was being considered. Whereas capital funding and administrative funding had been applied for and allocated separately, the move was towards combining the two into a single annual payment.

2.68 I do recall that there was a finite amount of money that could be allocated by way of section 64 grants and various charities and AHOs had put in bids for an allocation. I think Gerard Hetherington (Grade 4) and David Harper the Director General and Head of Health protection were responsible for deciding whether to accept or reject section 64 applications. I recall that they would consult the relevant policy leads so I would have been copied in on emails but I do not recall being the decision-maker. I would have been consulted on section 64 grant applications for the Macfarlane and Eileen Trusts as a matter of course as these fell within my portfolio as they were both blood-related. It is likely that my HEO Zubeda Seedat will have dealt with the day to day queries which arose.

2.69 In an email to Gerard Hetherington on 30 April 2004, I set out the Macfarlane Trust's wish to move to a different funding model:

> *"The Macfarlane Trust have written to us requesting that they move away from Section 64 funding and that we supplement their annual block grant with an element to cover their management and administration costs. This is also in line with Melanie Johnson's wishes for the Trust to move away from S64 Funding as they eat up a large amount - about £250k.*
> *They believe that such a move will give them more flexibility to deal with the needs of their HIV registrants. Hep C administrative costs are being met from the block amount allocated for the Scheme. I have no problems with the suggestion as it is clear funding The Trust from S64 is not what the money should be used for. I have made initial contacts with the relevant Finance section who also agree with the request and we are pursuing other funding streams. In the present financial climate this is proving difficult and we suggested to the Trust that in the interim they submit an initial bid to extend their S64 funding for next year as otherwise they could end up with no money.*
> *You could tell Peter that we are positive about their request and that they should pursue it but in the interim to continue with a S64 request just to be safe."* [DHSC5336152].

2.70 On 2 November 2004, Peter Stevens emailed me to provide the details of the money the Macfarlane Trust would be seeking over the next funding period [DHSC0003288_007]. He took the base the figure of £3.05 million that he said he believed has been established as the funding rate for the current year and went on to say:

> "*…I would hope that we can plan on something like £3.2 million in 2005/6, rising to £3.35 million in the following year and 3.5 million in 2007/8. But this would be without prejudice to the additional sums for which we will be making a business case in the not-too-distant future*."

2.71 In terms of the Eileen Trust, it seems that only an inflationary rise to capital allocation was being sought.

2.72 The Inquiry states in its request to me that the AHOs had very little success in increasing their funding allocation and asks what more the AHOs could have done to persuade DH to increase their funding allocation. The next Spending Round cycle of funding was only starting to be negotiated right at the end of my time in post. Since there was not a major allocation of capital funding for the Macfarlane and Eileen Trusts during my time as Head of Blood Policy, I do not feel that I am best placed to answer how the Trusts may have had more success, save to note that it was always the case that the levels of support had to be decided upon by DH against many other competing and deserving causes for funding.

2.73 I have been referred to a letter dated 3 December 2003 sent to me by Martin Harvey, Chief Executive of the Macfarlane Trust [DHSC0003289_006], dated 03 December 2003 and the Macfarlane Trust's Long Term Review dated 1 October 2003 [MACF0000172_001].

2.74 I have seen from the email I sent to Gerard Hetherington on 30 April 2004 that my view at the time was that the Long Term Review had been sent to DH for information not approval:

> *"They submitted this to the Department at the end of last year for information. No formal accountability system exists for the MacFarlane Trust so it was not submitted for approval. It is a useful document and shows that the Trust are thinking very carefully about their future role and functions. This is important given that when they were set up 1987 it was not envisaged that they would still be in existence as it was then perceived that all HIV infectants would die quickly. However advances in medicines etc have prolonged lives.*
> *Not sure what Peter wants to address but it could just be a question of listening."* [DHSC5336152]

2.75 I do not think that it was a case of the Long Review being "rejected" while I was the Head of the Blood Policy Team. I understand that the Macfarlane Trust used the Long Term Review of October 2003 to produce a business case for future funding but this was not completed until much later on, I believe, November 2005. That business case was then the basis of a request for further funding from DH but I was no longer involved at that time.

Blood Policy Team input into AHO Policy and decision making

2.76 The Macfarlane and Eileen Trusts were governed by their Trustees who had wide discretion as long as they stayed within the remit of their trust deeds. I don't recall giving instructions to them about how they should operate. DH would have provided advice to the Macfarlane Trust about the basis on which the Skipton Fund should function in line with its agreement to administer the government's new ex gratia payment scheme. This means that DH would have set the scheme's criteria, but it was for the Skipton Fund to decide applications in line with the laid down criteria and run its affairs operationally.

2.77 In an update on the Skipton Fund which I sent to Melanie Johnson on 23 June 2004, I explained my view of the decision-making by the Skipton Fund in relation to Stage 1 payments:

> *"The Skipton Fund will in the first instance adjudicate applications on the basis of criteria set-down by DH. The criteria are not complex to administrate, and in most cases will lead to a clear-cut decision. More complex decisions will be made on the balance of probabilities and at the Skipton Fund's discretion."* [DHSC5182409]

2.78 I cannot recall any discussions on the Macfarlane Trust policy of issuing loans and I do not recall having any involvement in the decision-making process regarding loans. I do not recall being consulted on this and would not have expected to be. This was an internal matter for Macfarlane Trust's Trustees.

The Skipton Fund

The moves towards the introduction of the HCV payment scheme

2.79 When I arrived at the DH in my role as Head of Blood Policy, there had been considerable political pressure to set up a scheme to provide ex gratia payments to HCV sufferers. The Scottish Government was planning to set up such a scheme and I was advised very early on by the Private Secretary to John Reid that the Secretary of State was minded to set up a scheme in England for people infected with Hepatitis C as a result of being given blood products by the NHS.

2.80 Before turning to some of the individual questions which the Inquiry has raised on the Skipton Fund, I will try to give an overview to give context for the more detailed points about which I am asked.

2.81 Prior to my joining the team, the Law Officers had been asked to advise whether an HCV payment scheme was within the areas devolved to the Scottish Executive.

2.82 On 17 June 2003, the Private Secretary to John Reid sought early briefing from my then head of Branch Vicki King (I was not on the copy list probably because I was so new to the team but I was forwarded a copy of the email by Gerry Robb):

> *"As you can imagine, both SofS DWP and Malcolm Chisholm/Jack McConnell are wanting to speak to the new SofS about Hep C. At the moment SofS is totally unsighted on this. I've told his special advisers the broad outline - ie, the Scottish Health Minister - Malcolm Chisholm -*

announced unilaterally last year that Scotland was considering financial compensation for people infected with Hep C via contaminated blood products, breaching the principle we'd all UK-wide adhered to that there would be no such scheme. DH, DWP and HMT have all been very firm that Scotland should not go ahead unilaterally with a financial assistance scheme, and that we share a strong concern about the financial knock-on to England and the other devolved administrations if Scotland breach the principle on Hep C and compensation. We have been working with DWP on this (as we think any kind of financial assistance scheme would count as a benefits scheme and would therefore be a social security issue) to look at whether the Scots in any case have the right to do this unilaterally as social security matters are reserved, not devolved. We have asked the Attorney General for a definitive legal view. This was delayed so it wouldn't arrive before the Scottish elections, but is now due any day. Obviously this will be quite a difficult one for SofS given that he is a Scottish MP now in charge of the NHS in England!
However, this will not really be adequate for SofS. So, ahead of those calls, please could you let me have a one or two page note for SofS that sets out the background and issues, plus latest state of play and the suggested line to take with each Minister." [DHSC5541406]

2.83 I provided the requested two page note the same day, 17 June 2003 [WITN5292021]. This gave the background to the (until then) reasons for opposing an HCV payment scheme (paragraph 6) and the existing line to take pending Law Officer's advice (paragraph 10).

2.84 The Law Officers' advice was received shortly after this and was to the effect that a payments scheme was within the devolved powers of the Scottish Executive. This was referred to in a minute to me from Mary Trefgarne (Solicitor's Division) dated 20 June 2003. [WITN5292022].

2.85 In a brief email to the Secretary of State's Private Office that day, I forwarded the legal note from Mary Trefgarne, noting that costings were being prepared separately. I noted that "*We need to sit down with all interested parties and consider what our position would be if Scotland decide to go ahead*" [WITN5292022]. Dr Reid's Private Secretary replied on 23 June noting that Dr Reid was shortly to speak to the Secretary of State for Work and Pensions and may want a meeting with officials, "… *although he [Dr Reid] has said that given both the precedent on HIV and the likely Scottish decision to now go ahead, it looks as though we will on the basis of fairness have to go down the compensation (ex-gratia route)*". [DHSC5320726].

2.86 On 25 June 2003, there was a meeting between Dr Reid, Andrew Smith (Secretary of State for Work and Pensions), Alistair Darling (Secretary of State for Scotland) and Paul Boateng (Chief Secretary to the Treasury). Dr Reid's Private Secretary emailed me after this meeting in these terms:

> *"SofS has just met with Andrew Smith, Paul Boateng and Alistair Darling to discuss Hep C compensation.*
> *It was agreed that:*
> (i) *SofS plans to meet with Malcolm Chisholm before summer Recess to discuss a range of issues. He will use this to raise Hep C. Malcolm Chisholm has already said he is planning to come down to London in the next couple of weeks and would like a meeting. Jessie - please can you get on with fixing this up (NB: you must not mention. Hep C. You must just say it's an introductory chat to discuss a range of issues);*
>
> (ii) *In terms of how SofS raises it with Malcolm Chisholm, the plan will be to let him know the legal advice has been received, that they have ruled it is a devolved matter, and to agree a process*

for how we handle this - ideally getting agreement that officials in the various Departments work together over the summer to develop a realistic (in cost-terms and possible phasing terms to help manage the costs further) with a view to a UK-wide announcement being made in September;

(iii) *SofS will also need to speak to Paul Murphy and Peter Hain over the next week or so to brief them on the issues, given that Wales and Northern Ireland will also need to be brought on board. Jessie - please can you fix up, checking timing with SofS - eg he may wish to do these before Chisholm meeting. Richard G - on Wales, please can you confirm for SofS that any Welsh scheme would be a matter for Wales, and that he would not have to rule on what Wales do.*

(iv) *on financing an English scheme, the Chief Secretary was very non-committal. Andrew Smith, an ex-CST, suggested there may be some indirect ways of helping - ie giving us some more money bagged for something separate. as I understand it, there are issues about if HMT give us money for a Hep C scheme, there are then consequentials for money also [having] to be found for Scotland which lets them off the hook and removes the disincentive for them devising yet more schemes. Richard/Martin - please can you continue to push on this.*

(v) it was agreed that we would work up a line to take between SofS, CST, Alistair Darling and Andrew Smith in case we get asked over the next week or two what's happening on Hep C, and a line for after the Malcolm Chisholm meeting (along the lines of we are discussing the legal advice with the Scottish Executive and that we want to approach this in a common way). Andrew Smith's office will circulate something tomorrow on this." [WITN5292023]

It is of note from the above that the early guidance was that we should aim for a realistic (in cost terms, possibly phased) scheme on a UK basis.

2.87 The further DWP submission referred to above, was copied to me amongst quite a few others, on the same day, 25 June 2003 [DHSC0042275_005]. It was noted that the Ministers who had met that day had agreed that the UK Government would introduce a scheme for Hepatitis C sufferers in England. These records are consistent with my own recollection that it was very early on in my role in the Blood Policy Team that the move came from the Secretary of State to agree to a form of ex gratia scheme, reversing the Westminster Government's previous position. On 1 July 2003, I provided the joint submission to this group of Ministers [WITN5292023A]. While I was the signatory to the submission, a submission of this kind would have been cleared with my Head of Division and – as the submission made clear – it followed discussions between DH, DWP, The Scotland Office and the Treasury. Based on the legal advice received at this stage, I noted that it was thought that the kind of HCV scheme in contemplation would not be a devolved matter for Wales but would be for Northern Ireland as it was for Scotland. My submission addressed the options of (a) extending the remit of the Macfarlane Trust; (b) extending the remit of the Eileen Trust; or (c) setting up a brand new Trust from scratch. The preferred option was to consider using the existing Macfarlane Trust structure and work with the other administrations to see how this could best be taken forward. I noted the pressure this would bring on the s.64 budget.

2.88 On financial implications, we noted that:

> *"16. The scheme that the Scottish Executive is considering would cost up to £210m if a similar scheme were implemented in* ***England*** ***which is the basis upon which we are workin****g. This is a worst case and assumes that all those infected are identified and make a claim. If only 50% of the 5,000 unidentified people who are estimated to be infected make a claim the costs are likely to be in the order of £140m. If the payments detailed in the Scottish Expert Group proposals were accepted then the costs would be up to £600m.*
>
> *17. The proposed Scottish Executive scheme would pay a lump sum of £20,000 to all people living who still have the virus and a further £25,000 to those who develop cirrhosis.*

18. There are around 3,500 people in England that we know have long-term hepatitis C infection from contaminated blood transfusions and blood products. The initial £20,000 payment would cost £70m for this group. On top of this there are around 5,000 people who may have been infected …[through]…blood transfusions who we have not identified. If all these claimed, the cost would be an addition £100m. There proportion of these people that actually claim compensation will be dependent on how pro-active we are in seeking to identify those infected. If only 50% of those infected actually claim compensation the additional cost would be £50m.

19. We estimate that, normally, around 20% of those with long-term hepatitis C infection will progress over time to develop cirrhosis. This would cost an additional £42.5m, making a total of £212.5m for the whole scheme. Current drug treatment reduces the likelihood of patients going on to develop cirrhosis, with overall success rates of around 40%. A more effective form of interferon (pegylated interferon) with overall success rates of around 55% is currently being appraised by NICE.

20. However, it is difficult to estimate what proportion of the group in question might be successfully treated with antiviral drugs. Some individuals may have already progressed to cirrhosis, others may already have been treated and cleared the virus, and it is not possible to say how many will have reached the disease stage at which treatment is indicated. It is likely, though, that successful drug treatment will have some impact in reducing compensation costs." (emphasis added)

2.89 At paragraphs 21 -23, we noted under "Possible Financial Pressures" and "Funding the Scheme" as follows:

*"**Possible Financial Pressures***
21. The proposed scheme makes no provision for making payments to the dependants of people with Hepatitis C who have since died. The scheme proposed by the Scottish Expert Group did propose payments for dependants and it is possible that we will come under pressure to extend the scheme in such a way. This would increase the cost substantially. It is also possible that we will come under pressure to increase the value of the scheme towards that proposed by the Scottish

Experts Group. Again, this could increase costs significantly. If the Scheme is administered by the Macfarlane Trust which pays dependants of HIV sufferers it would be difficult not argue against similar provisions for Hepatitis C sufferers.

Funding the scheme
22. As the Law Officers have ruled that this is a health issue, the costs of the scheme in England would need to be borne by the Department of Health

23. The Treasury have said that no additional funding would be available for a hepatitis C compensation scheme. Any such scheme would need to be funded from SR2002 settlements. We will need to work with the Devolved Administrations to attempt to reduce and/or re-profile the cost."

2.90 The conclusion of the submission stated,

"28. At your meeting on 25 June it was decided that once further issues had been worked up then John Reid would communicate the decision that the Government would introduce a compensation scheme in England to the Devolved Administrations.
29. You are therefore asked to agree that once the devolved administrations have been informed that Officials from all interested Departments work over the Summer to devise an appropriate Scheme with a view to making an announcement in September."

2.91 As I have highlighted in the emphasised text from paragraph 16 of the submission, from the outset the working approach was that the UK scheme would be based on the scheme which the Scottish Executive had already been working on and intended to implement.

2.92 The Scottish Executive had already communicated the approach of staged payments at £20,000 and £25,000. The available papers remind me that in

January 2003, Malcolm Chisolm had written to Lord Ross explaining the outcome of the discussion on Hepatitis C at the meeting of the Health and Community Care Committee on 29 January. He stated:

> *"As you are aware, I announced my intention to establish a scheme to make ex-gratia payments to those who are suffering harm, at the meeting of the Committee on 11 December 2002. Following further consideration of the complex issues involved, I am now in a position to inform you in more detail of the type of scheme which the Executive would like to implement.*
>
> *I believe that an initial lump sum of £20,000 should be paid to those who have Hepatitis C as a result of receiving blood, blood products or tissue from the NHS in Scotland. In addition, a further £25,000 should be paid to those who suffer serious deterioration in their physical condition because of their Hepatitis C infection, eg cirrhosis, liver cancer or other similar serious condition(s).*
>
> *I appreciate that these proposals do not fully implement the recommendations of the Expert Group but I hope you will agree that given the current constraints on the NHS, they are a significant step forward and to a large extent reflect the principles of the Group's recommendations.*
>
> *We are still awaiting a view from the UK Government on the 'devolved and reserved powers' issue which I hope will be resolved shortly."* [HSOC0020367]

2.93 Scotland was therefore far more advanced than England in developing a scheme and had by this time already settled on a different formula for payments to that recommended in Lord Ross' report. That is why the staged payments of £20,000 and £25,000 were from the outset the proposed basis of the UK scheme. And it is also why, again from the early stages, the proposal was that payments would not be made to the dependants of people with Hepatitis C who

had since died. This was set out in paragraph 21 of the submission as quoted above, and it was recognised that this was an area where we were likely to (and did) come under pressure to extend the scheme. As was set out in the submission, the estimated costs of the Lord Ross' earlier proposals were up to £600m if applied to the UK, for a scheme for which the Treasury was not prepared to provide additional funding. My understanding was that the Scottish Executive had ruled out that approach on affordability grounds (see Malcolm Chisholm's reference to the "*...the current constraints on the NHS*"). Likewise Dr Reid as Secretary of State for Health had made clear that we needed to find a scheme that was realistic in cost terms (note of the meeting of 25 June 2003).

2.94 On 15 July 2003, I provided a draft letter for the Secretary of State to send to Malcolm Chisholm [DHSC5110388]. The initial steer I had been given was to work on the proposals with the Scottish administration before inviting Wales and Northern Ireland to join in. My note briefly addressed the pros and cons of this approach. This was complicated about the doubts as to whether it fell within devolved issues for Wales. We had to go for Counsel's advice on that issue (see my email response to Mary Trefgarne of 17 July 2003 [DHSC5110388].

2.95 In the event, the very early meetings on the scheme in the summer of 2003 were limited to the Scottish Executive and DH with Wales and Northern Ireland being brought in slightly later.

2.96 On 30 July 2003, David Reay and I met Andrew MacLeod and Bob Stock to discuss the necessary collaboration [DHSC0004421_141]. This set out in some

detail the proposed parameters of the scheme. This level of detail reflects that the fact that the proposed Scottish scheme was being taken as the starting point for what was hoped to the UK-wide scheme. Of note within these proposed parameters was that:

(1) It was expected that the scheme would be administered independently and that Government should be distanced from the disbursement process. A scheme under the umbrella of the Macfarlane Trust was the preferred option (paragraphs 1 and 2);

(2) It was not expected that dependents of patients who had died would receive payments. It was recognised that "*This approach would mark a change in precedent, as similar Trusts do compensate the 'personal representative' of eligible deceased patients*" (paragraph 3);

(3) The level of awards would be based on the Scottish model already speculated to the Scottish Parliament. Those qualifying would receive a £20,000 payment, followed by a further £25,000 should their disease progress to a medically defined trigger point (paragraph 4);

(4) The initial £20,000 payments would not be made to patients who are co-infected with HIV and who have received awards from other Government sponsored schemes such as the Macfarlane Trust (as detailed below, we reversed this position later). However, it was intended that this group would be eligible to claim the £25,000 award should their condition progress to the trigger point (paragraph 5);

(5) Eligible patients who cleared the disease spontaneously (approx. 20%) would receive no payments (paragraph 6);

(6) Those patients eligible for awards who had successfully sued the NHS or private supplier or reached an out of court settlement, would have the settlement deducted from the amount awarded by the proposed scheme (paragraph 6). Again, as detailed below, we reversed the position on this aspect later.

The fact that some of the proposals did change shows that the proposals were open to further discussion and review. The fact remains however that the Scottish model was the starting position.

2.97 I attended a meeting of officials on 31 July 2003 [DHSC0016743]. This was a meeting with DH lawyers to discuss whether an ex gratia payments scheme would be a devolved issue in Wales and Northern Ireland and also because we had some concerns that we may need to share information with the devolved administrations in Wales and Northern Ireland if it was determined not to be a devolved issue. Advice was also sought on the legal aspects of constituting a new Trust and how Trust payments might be made accountable by Government/Parliament.

2.98 I put a further submission to the Secretary of State on 26 August 2003. This focussed on the difficulty that Mr Chisholm had a Scottish Parliament Committee hearing on 9 September which was, at this stage, before we had intended to announce the proposed UK-wide scheme [DHSC0004421_121]. I can see that the Secretary of State was going to speak to Mr Chisholm later that day.

2.99 On 27 August 2003, we received Counsel's advice to the effect that the kind of scheme proposed would be a devolved matter so far as Wales was concerned. [WITN5292024].

2.100 On the same day, the Chief Secretary to the Treasury wrote to Dr Reid noting the Treasury's reservations about the scheme (though understanding the pressures upon the government) and setting out requirements including that the cost of the scheme be met entirely from the DH settlement with no claim on the Treasury reserve [DHSC0014997 _116].

2.101 John Reid's decision was officially announced on 29 August 2003. The press release stated:

> *"Health Secretary John Reid has decided to establish a financial assistance scheme for people infected with Hepatitis C as a result of being given blood products by the NHS,*
> *Mr Reid said:*
> *'After becoming Secretary of State, I looked at the history of this issue and decided on compassionate grounds that this is the right thing to do in this situation.'*
> *'I have therefore decided in principle that English Hepatitis C sufferers should receive ex-gratia payments from the Department of Health,'*
>
> *The details of the payments have yet to be worked out."* [NHBT0015207_002]

The devolved assemblies in Wales and Northern Ireland issued simultaneous press releases and the Scottish Executive (having confirmed that a devolution issue had been resolved), also announced that a scheme would now be worked up.

2.102 One of the supplementary questions the Inquiry has asked me to address is what I understood to be that rationale for the government agreeing to make payments to those infected with HCV as a result of their treatment with blood and blood products. In part, this can be seen from the Secretary of State's announcement: it was decided on compassionate grounds that this was the right thing to do in this situation. I have addressed at paragraph 2.144, below a submission I provided to Melanie Johnson on 10 November 2003. At paragraph 14 of that submission, I referred to the rationale of the scheme and the fact that:

> *"...the original philosophy of the scheme was to provide ex gratia payments to all of those who developed chronic hepatitis C as a result of inadvertent infection from blood or blood products. This would emphasise the fact that payments are not being made on the grounds of past or current suffering, but on compassionate grounds because this is the right thing to do. ...."* [DHSC5328495]

2.103 Following the announcement, there was immense pressure to get the scheme up and running from scratch as quickly as possible. Accordingly, we continued to work on the detail of the schemes and this was done with representatives of the administrations of Wales and Northern Ireland as well as with wider consultation as I shall return to below. I was the representative for DH. Bob Stock was the representative for Scotland and Cathy White was the representative for Wales. The representative for Northern Ireland was Gerry Dorrian. We had little time to prepare and sought assistance from the Macfarlane Trust which obviously had considerable experience in this area, having run the financial support scheme for haemophiliacs with HIV since 1988.

2.104 As I have set out above, no new Treasury funding was to be provided for the scheme so funds had to be found from existing health budgets for the four administrations. There was criticism at the time, but I still consider we did well to set up a scheme from scratch - have all four administrations agree the terms; set up a company to administer the payments; consult with patient groups and medical experts; finalise application forms and guidance; and have the scheme up and running and making payments within a year.

2.105 A number of issues had to be agreed by the four administrations and finalised before the scheme could become operational. These included: eligibility criteria; determining the numbers eligible for the scheme; the level of payments; content of application forms and guidance; and methods of publicising the scheme. It was also necessary to negotiate with the Finance Division in DH to ensure funding was available and that they could act as agent for the other Health Departments in terms of providing the Skipton Fund with its money.

2.106 There were discussions with solicitors about the legal structure of the Skipton Fund. We also needed to consult with the DWP to ensure payments were granted a social security disregard as we did not want recipients to lose out on benefits as a result of receiving an ex gratia payment under the scheme.

2.107 We spent a lot of time consulting with medical and patient organisations. I, along with my counterparts in the four administrations also had to ensure that

our respective Health Ministers were kept informed on progress. I was involved in updating Ministers on the developments. To take just two examples,

(1) My submission to the Secretary of State of 3 October 2003 in which I sought agreement on the criteria for the scheme, and the exceptions and variations set out in the submission [DHSC0016672].

(2) My note to Melanie Johnson of 2 April 2004 advising that the Skipton Fund had been registered as a limited company [SCGV0000258_099]

2.108 On 6 January 2004, I invited the Secretary of State to re-confirm the details of the scheme, noting the issues that still remained outstanding and to agree the proposed name for the scheme [DHSC0016663]

2.109 On 23 January 2004, the Secretary of State made an announcement, providing details of the scheme which were set out in a Written Ministerial Statement and Press Release [WITN5292025].

2.110 Against his background, I turn to address a number of particular issues on the Skipton Fund which the Inquiry has raised with me.

Link to the Scottish Scheme

2.111 The Inquiry asks whether the establishment of the Skipton Fund was linked to the Scottish Executive's decision to provide ex gratia payments to victims infected with HCV. It is clear that this issue had been discussed over a number of years and for a long time, the Government's view had been that there should

be no payments made as the NHS was not at fault. This was, as I understand it, a long-standing principle.

2.112 A memo dated 5 August 2003 from Martin Campbell (FID RPA) to Paul Gilbert (FID Accounting), to which I was copied in, referred to Malcolm Chisholm's announcement in January 2003 and said:

> *"We believe this statement of intent placed the English DH under an obligation to implement a similar scheme. We also believe the statement has raised an expectation in England that such a scheme will be made available for English residents which we suspect may have be further fuelled by charities and pressure groups".* [DHSC0004421_147].

2.113 I agree with this statement as I think the announcement in Scotland undoubtedly put pressure on the UK Government to introduce a similar scheme. However, the key decision was taken by Ministers on or around 25 June 2003 and other than the obvious point that that Scottish decision clearly did put pressure on UK Ministers, I cannot comment on the balance of factors that they ultimately took into account.

The choice of award level and expert advice

2.114 I am asked why the DH set the payments at the level it did, rather than adopting the recommendations made by Lord Ross in his report to the Scottish Executive. As I have set out in the introductory section on the Skipton Fund above, Scotland was far more advanced than England in developing a scheme and had by this time already settled on a different formula for payments to that recommended in Lord Ross' report. It appears that the Scottish Ministers had

already decided that Lord Ross' proposals were unaffordable and developed an alternative by the time John Reid made his announcement. In an email from Sandra Falconer (a colleague of Bob Stock) to David Reay, copied to myself and Bob Stock 12 November 2003, Ms Falconer explained this by reference to lines given in October 2003 to their own Minister:

> *"The underlying principle behind the ex gratia payments announced is that they should go to people who are still alive and suffering. Have to weigh the issue of making a fair and reasonable payment to these people against all the other demands on the health budget. Lord Ross and the Expert Group were asked to ensure that any recommendations be consistent with efficient health service operation and represent a fair deal for all patients – but clearly they did not have access to information on other demands on the health budget to enable them to make that sort of judgement"* [DHSC5328644] .

2.115 The Scottish proposals (by the time we adopted them as the basis of the new scheme) had already envisaged providing for two payments – (i) a payment of £20,000 to those who were alive and living with the virus (this would become the Stage 1 payment); and (ii) a further payment of £25,000 to those who went on to develop cirrhosis of the liver (this would become the Stage 2 payment).

2.116 The Inquiry asks about the extent to which DH received expert advice on the appropriate level at which to set the payments. To the best of my knowledge, we did not commission or receive expert advice in that sense. The same exchange of emails between David Reay and Sandra Falconer in November 2003 touched on this issue. David Reay wrote:

> *"…because of the Haemophilia Society's renewed campaign, we are now suffering from a deluge of PQs on the hep C scheme. For most we can*

> *stonewall with the "details still being worked out" line but one of the questions asks this –*
>
> *Mr Mike Hancock (Portsmouth South): ... what research his Department (a) has commissioned and (b) is evaluating in order to determine the level of compensation for people infected with hepatitis C due to inflected blood products; and if he will make a statement.*
>
> *We can say that we, if not evaluated, then certainly considered the Lord Ross and Haem Soc Working Group recommendations, but we certainly haven't commissioned anything. Seeing as we basically transposed your proposals, and bearing in mind you've gone public and we need to try and avoid being seen to be led by Scotland, is there anything that we can say was commissioned when you determined your proposals!! I don't remember you saying that any studies were undertaken, more that you based the proposals on the Lord Ross awards, but just in case...!* [DHSC5328644].

2.117 The figures for the costs of implementing Lord Ross's recommendations in full in England were very high (up to £600 million) and – given the firm view of the Treasury – would need to have been found from existing DH budgets. That approach had already been rejected by the Scottish Executive and the costs implications for DH would have been very severe.

2.118 While we did not commission expert advice of the kind the Inquiry is asking about, we did hold meetings and discussions with the Macfarlane Trust, UK Haemophilia Doctors Association, the Haemophilia Society and other interested parties (I have referred at paragraph 2.124 to a longer list of organisations who were involved in later meetings). I don't in fact recall very much lobbying or dissent about the level of payments or amounts involved. I seem to recall that the amounts were settled quickly and discussion centred around other issues

such as the trigger point for stage 2 and, in particular, whether dependents or family members of the deceased would be entitled to payments.

Robert Stock's email of 24 March 2004

2.119 An email dated 24 March 2004 sent to me by Bob Stock set out some of the evidence that would be acceptable to prove eligibility for the Skipton Fund [SCGV0000257_022]. In the email Bob Stock provided a list of contaminated blood products we had discussed and agreed were known to be associated with Hepatitis C infection. As far as I recall, this list was to be used as the basis for discussions with medical experts or patient organisations. At this point in time, no policy decision had been finalised and there were still many questions unanswered and issues outstanding.

2.120 The agreed policy was reached following many discussions and consultation between the four health departments. I do not remember any major areas of disagreement between the four administrations; I think we managed to find consensus on most aspects of setting up the Skipton Fund. There were however obvious areas of disagreement with the patient and interest groups.

The change of approach: not off-setting prior compensation

2.121 The Inquiry has asked why DH altered its approach and decided that prior compensation awarded to individuals should no longer be deducted from any award from the Skipton Fund.

2.122 DH did alter its approach so that prior compensation awarded to individuals would not be deducted (off-set) from any award from the Skipton Fund. I should make it clear that it was not DH alone that altered the approach – this was agreed by all four administrations, following lobbying by patient organisations. The rationale for this was set out in a submission I wrote to Melanie Johnson dated 5 March 2004. I recommended the removal of a condition of the scheme which provided for ex gratia payments to be deducted if compensation from another source had previously been received. The rationale I gave for at the time was as follows:

> *"DH officials and counterparts in Scotland, Wales and Northern Ireland now feel that it is unjustified, inefficient and potentially controversial to deduct ex gratia payments to take account of any compensation. Officials propose that recipients of compensation as a result of the 'Burton Judgement' be fully eligible for the £20,000 and £25,000 Skipton Fund ex gratia payments. Agreement from health ministers is now being sought in Wales and Northern Ireland to amend the eligibility criteria accordingly. Malcolm Chisholm, Minister for Health in Scotland, has already given tacit approval".* [DHSC0004425_029].

2.123 I also noted that changing the approach on this issue would not involve any increased costs because of the way the initial calculations had been done. My submission also sought agreement to make British citizenship at the time of a person's infection with Hepatitis C a pre-requisite to a successful application.

Skipton Fund Guidance

2.124 The Inquiry asks about any involvement I had in drafting the Skipton Fund guidance. Along with representatives of the other three health departments, I did help to draft the Skipton Fund guidance. Meetings were also held with

patient organisations to discuss the application process for Skipton Fund. This included getting their input into the Skipton Fund application forms and guidance. One such meeting was held on 26 March 2004 with representatives of the Scottish Haemophilia Forum, Hepatitis C Trust, Capital C, Macfarlane Trust, Primary Immunodeficiency Association, Haemophilia Wales, Haemophilia Society. Notes from the meeting show that a number of topics were discussed including application forms and guidance and one of the action points was for "*Suggestions for guidance notes to accompany application forms requested by DH*" to be sent as soon as possible [DHSC5982561]. We were keen to ensure the Guidance Notes that would accompany the application forms were helpful, accessible, and contained all the information applicants needed to complete their application. Input from patient organisations was invaluable for this and many other aspects of the scheme.

2.125 In a submission to Melanie Johnson on 23 June 2004, I provided an update that the Skipton Fund would become operational on 5 July 2004 [WITN5292026]. On that date, the Skipton Fund was to begin to distribute application forms to those who had registered with it. Following consultation, final drafts of the application form for the initial £20,000 payment and the guidance to accompany these had been prepared.

2.126 I explained that the Skipton Fund application process would consist of six steps:

> *"1. Complete a Registration Form, either using a paper copy or the online version available at www.skiptonftind.org*
> *2. Wait for an application pack — this will be sent to applicants on or before 5 July*
> *3. Complete application form and return to Skipton Fund*

4. Once the application has been considered, the Skipton Fund will inform applicants of the decision regarding their eligibility and either authorise payment or detail why they did not qualify
5. The amount of time it will take to receive payment will depend on individual circumstances, but the Fund expects to make payments to most successful claimants within a few weeks. If applicants do not qualify for payment, details of the appeals process will be sent to them.
6. At any point in the future, request from the Skipton Fund the application form for the second payment

The Skipton Fund Registration Form
A copy of this form has been attached for information. Its purpose is to efficiently introduce applicants to the Skipton Fund and allow for the managed distribution of application packs. A copy of this form was sent on 18 June with a detailed covering letter to all 2,100 registrants of the Department of Health's confidential mailing list. In addition, it will be circulated to voluntary organisations and targeted hospital centres". [WITN5292026]

Publicising the Skipton Fund

2.127 DH wanted to publicise the Skipton Fund to potential eligible beneficiaries. From memory, I recall various steps being taken to publicise the Skipton Fund to potential beneficiaries. This was done through relevant beneficiary organisations and statements to Parliament. I expect there would have been press releases and mentions in the CMO's Bulletin and on the Macfarlane Trust and Skipton Fund websites. Consideration was also given to a poster in GP's surgeries but I am not sure if this suggestion was pursued. The number of applications received in the early days and number of people who registered suggests that the Skipton Fund was well-publicised - 1,800 registration forms and over 100 completed application forms had been received by 14 July 2004 [DHSC0041162_140] I cannot remember specifically how DH advertised the

Skipton Fund to non-haemophilia infectees but I expect in a similar manner as for haemophiliacs.

2.128 I remember there was some delay due to doctors having to confirm the medical history of applicants. The vast majority of cases this could be done by GPs but some of them were refusing to provide the information required unless they were paid. Usually consultants' evidence was only needed for stage 2 applications. Guidance notes with the application form explained that:

> *"All the rest of the form after page 2 must be completed by a medical professional, to whom you should give the form after you have completed and signed the first two pages. You should also give these guidance notes to that medical professional. Generally this medical professional should be the principal clinician treating you; this will probably be a clinician treating Hepatitis C, but in the case of applicants with bleeding disorders it might be a haematologist. If you cannot give this form to such a clinician to complete, you should take it to your General Practitioner, again with these guidance notes."* [DHSC0004213_014]

2.129 Once the Skipton Fund was up and running, it had to provide the DH with the number of applications received; the number of those applications which met the criteria to receive payments; and the amount spent. In the early months of operation of the Skipton Fund, Peter Stevens provided this information which was often passed on as updates to Melanie Johnson.

Day to day management of the Skipton Fund and the extent of DH's Role

2.130 The Blood Policy Team, whilst I was there, had no day to day involvement in the management of the Skipton Fund. The four administrations maintained

policy responsibility because the Skipton Fund was running the scheme on their behalf. They retained the right to determine whether any policy changes were required to the scheme such as eligibility criteria or payment amounts.

The registration and application process

2.131 I was involved in the process to set up the application and registration process along with officials from the other health departments of the devolved administrations in Scotland, Northern Ireland and Wales. There were many meetings and discussions between us – especially between myself and Bob Stock as we took the lead in progressing the scheme from the time of John Reid's announcement on 29 August 2003 to the time when the Skipton Fund began processing applications in July 2004. I have already explained the different areas of work involved in this process and the challenges faced. The way that the application and registration process was structured was agreed between the four administrations, after many discussions and after consultation and feedback from patient organisations.

2.132 We wanted to ensure that the process was user-friendly, not onerous and was easy to access and understand for potential applicants who were likely to be elderly and/or in ill health. There were regular meetings with patient organisations so we could receive input and feedback on the proposals for the scheme. On 23 June 2004, I provided a submission to Melanie Johnson on the application forms and accompanying guidance in relation to stage 1 applications [WITN5292026]Attached to the submission was an example of the application form and guidance. In the submission, I set out the various steps in

the application process for stage 1 and noted that the stage 2 application form was now in the final stages of drafting, I explained that the Skipton Fund would, in the first instance, adjudicate applications on the basis of criteria set-down by DH. The criteria were not complex to administrate, and in most cases were expected to lead to a clear-cut decision. More complex decisions would be made on the balance of probabilities and at the Skipton Fund's discretion,

2.133 The inquiry refers me to a document which is an example of minutes of one such meeting which took place on 26 March 2004 [DHSC0004425_017]. As to this meeting,

(1) A number of patient organisations attended the meeting, including Haemophilia organisations for Scotland and Wales. Other attendees were the Macfarlane Trust, Hepatitis C Trust and Primary Immunodeficiency Association.

(2) Feedback was provided by the patient organisations on additions that should be made to the application forms. There was a discussion about what evidence should accompany an application and should be done in relation to applications that weren't clear cut. The meeting also discussed the guidance notes for applicants with useful information and FAQs, as well as separate guidance for clinicians on both 1st and 2nd stage applications.

(3) Policy considerations were also discussed such as eligibility of those who spontaneously clear the virus. It was also noted that since the last meeting, Ministers had taken the decision that no waiver or undertaking would be applied to the scheme.

(4) The meeting was also told that the Skipton Fund would provide frontline support to applicants through a telephone helpline. A communication

strategy was discussed as steps needed to be taken to publicise the scheme. Several suggestions are listed in relation to this, such as using the CMO Bulletins, providing multi-lingual posters in GP surgeries and enlisting the help of patient organisations.

Difficulties for the Skipton Fund in administering the scheme

2.134 I have set out at paragraphs 2.46 - 2.48 above, examples of the difficulties of which we were aware in relation to the administration of the scheme and in my submission to Melanie of Johnson of 14 July 2004.I have also set out there that the original indication that claims would be processed in three weeks proved to be too optimistic.

Criticisms of the Skipton Fund: further consideration given to co-infected, those clearing the virus with treatment and to the exclusion of dependents

2.135 The Inquiry asks whether I was aware of criticisms of the Skipton Fund. I recall that there was some criticism of the Skipton Fund when it was first established. This was mainly around the level of payments, eligibility criteria and dependents. There was also some criticism about the length of time it had taken to get the scheme up and running. There were a number of negative press articles. On 26 April 2004, I provided a Briefing Note to the Secretary of State addressing the issues outlined in one such article in the Sunday Herald published on 24 April 2004. In my Briefing Note, I explained the reasons for delays in finalising application forms which meant payments would be delayed.

I also explained why the Skipton Fund website was not up and running and I addressed some unattributed quotes in the article [DHSC0014997_070]. It has to be acknowledged that some of the potential recipients were angry and we had a great deal of sympathy for them. No matter what scheme was put in place, it never would have satisfied all potential recipients. I recall that we did receive some correspondence thanking DH for its efforts in setting up the Fund.

2.136 A particular focus of criticism was that the scheme did not include payments to relatives, dependants and estates of individuals who had died of Hepatitis C. The same policy position was adopted for the UK-wide scheme. Reviewing the available papers and drawing on my recollection, the reasons for this overlapped with the reasons for the payment amounts being set at the levels they were:

(1) The Scottish scheme had been designed with this exclusion. As I have indicated above at paragraph 2.98, it was recognised early on that this approach would mark a change in precedent. We alerted Ministers to the likelihood of this being a point upon which we would come under pressure (see the submission to Ministers of 1 July 2003 and paragraph 2.91, above).

(2) However:

a. The scheme was designed to help those who were living and suffering as a result of being infected with Hepatitis C.

b. Affordability was a very major issue. Again, it should be emphasised that the Treasury had made it clear that money for the scheme would need to be found from existing health

budgets and including payments to dependents and families of the deceased would have significantly have increased the cost of the scheme. This increased cost would have resulted in cuts to the health budget as there was a finite amount of money available for health spending.

2.137 One of the action points from the meeting of 30 July 2003 was for David Reay to consider the implications of "potentially contentious proposals" – one of these was "…not making awards to 'personal representatives' of deceased patients" [DHSC0004421_141]. Further consideration would have been given to this issue. We received representations from patient groups such as the Haemophilia Society and some medical professions but ultimately the decision was taken to exclude deceased patients from the scheme. As I have indicated, following the initial Scottish proposed scheme, my understanding was that the scheme was designed to assist survivors who were suffering as a result of contracting HCV from contaminated blood or blood products and it was a choice on affordability grounds to focus the support in this way.

2.138 From the announcement of the scheme on 29 August 2003 until the scheme was operational, I received input from other organisations about how the scheme should operate and who should be eligible. On the dependents issue, for example, on 29 April 2004 I received an email from Frank Hill, Chairman of UKCHDO:

"I am writing in the hope that you will be able to feed comments through to the Department of Health about the above scheme. A number of my

> *colleagues in UKHCDO throughout the country have been contacting me, highlighting the disappointment of families whose relatives have died as a result of hepatitis C infection. Is there any plan within the scheme that where these families are experiencing hardship etc. that there will be any ex gratia payment to them?"* [HCDO0000254_341].

2.139 In my response on 7 May 2004 I tried to be clear but remain sympathetic when setting out the position the Minister had decided to take on this issue:

> *"Thanks for your note. As you and your Colleagues are aware the Scheme does not cover dependents. It is an ex-gratia payment scheme introduced by the Government on compassionate grounds and is aimed at those alive to help with their suffering. I have to say that the decision not to include dependents was an extremely difficult one to make. As to providing help to those families experiencing hardship again that is not the purpose of the Scheme which is simply to provide one off payments. It is not like the Macfarlane or Eileen Trusts. I am sorry that is not the reply that perhaps you were hoping for."* [HCDO0000254_341].

I genuinely sympathised with those who had lost loved ones but it was clear from the outset that the scheme was not designed to cover payments to those who had died. It was part of my job to relay difficult messages on behalf of the government.

2.140 The Inquiry refers me to another occasion on which the exclusion of dependents was raised. On 29 October 2003, Melanie Johnson met with Michael Connarty MP, Chairman of the All-Party Parliamentary Group on Haemophilia and Karin Pappenheim. I provided a briefing beforehand dated 27 October 2003 in which I explained that: "*The meeting is therefore likely to be fairly robust in terms of them pushing for the level of payments to be increased*

and payments to be made to dependants and co-infectants." [DHSC0014997_092]

2.141 Following the meeting, Melanie Johnson asked me to prepare a submission setting out estimates for the cost of extending the scheme: to those who were co-infected with HIV; to those who cleared the Hepatitis C virus following treatment and to the dependants of those who had died prior to the announcement of the scheme. These groups had not been included under the initial eligibility criteria agreed by the Secretary of State in October 2003 (but not made public) and Mr Connarty and Ms Pappenheim had raised concerns that without their inclusion, they would not be able to endorse the scheme.

2.142 I provided this submission on 10 November 2003 [DHSC5328495]. I noted in paragraph 11 of the submission that the Haemophilia Society and the All Party Group had four outstanding concerns regarding the proposals and draft eligibility criteria for the scheme:

> "• *The proposed payments are lower than those recommended by the Scottish Executive Expert Group and their own expert working group recommendations*
>
> • *No payments are being made to dependants*
>
> • *People who have cleared HCV following drug therapy are not eligible*
>
> • *People who are co-infected with HIV will not be eligible for the initial £20,000 payment"* [DHSC5328495].

2.143 We had taken the opportunity to revise the original cost estimates for the scheme. These had originally been made on the basis that up to 8,500 potential claimants would be eligible for payments under the initial draft eligibility criteria. This suggested that a budget of between £162.5m and £212.5m would be required depending on the number of eligible claimants making applications (£162.5 = 50% take-up, £212.5m = 100% take-up). Updated estimates and a more comprehensive analysis of these figures now appeared to show them to have been an over-estimation due to double counting and inclusion of some non-eligible groups. Further analysis appeared to show that the original calculations included those patients that had cleared the virus with treatment and those who were co-infected with HIV. These were two of the key concerns of both the Haemophilia Society and the All-Party Parliamentary Group.

2.144 I advised that subject to more detailed calculations being carried out, it would appear that we could offer to include these two groups (co-infected and those who had cleared the virus with treatment) within the proposed scheme without incurring any additional costs.

2.145 The estimated cost of extending the scheme to people with HIV co-infection was £12m. I explained that this should fall within the difference of the original and revised total cost estimates caused by the above double counting, therefore representing no actual increase in cost. This group was already eligible for the second payment under the draft eligibility criteria.

2.146 The costs for making payments to people who cleared HCV following treatment was unknown, but the figures used to calculate the total number of potential claimants made no allowance for those people who cleared HCV following treatment. It was therefore assumed that these people had already been included in the calculations and as such it would involve no additional cost to include this group.

2.147 The third estimate was the cost of including dependants. At paragraph 10 of the submission I set out that:

> *"The cost of extending the scheme to dependants (>£154m) would at least double the cost of the scheme and remains unaffordable within the existing budgets of all the four Health Departments"*

2.148 I concluded that there was little scope for satisfying the Haemophilia Society's demands in full as their request that DH consider increasing the size of awards and that dependants be eligible for financial assistance were unsustainable on the grounds of affordability. However, extending the eligibility criteria to include co-infectants and successfully treated patients would not require additional funding.

2.149 I also pointed out that by agreeing to extend the scheme to include co-infectants, the Macfarlane Trust would sign up to the scheme.

2.150 I therefore recommended that Melanie Johnson ask the Secretary of State to agree to amend the draft eligibility criteria for the proposed scheme to -

> *"• make eligible for the initial £20,000 payment those people with HIV co-infection*
>
> *• make eligible for the initial £20,000 payment those people who have cleared HCV following successful drug therapy."*
> [DHSC5328495]

2.151 I have set the above out in some detail because it illustrates that

(1) We were prepared to consider – and did make – changes to the scheme originally envisaged by the Scottish Executive. As a result of the submission above, Ministers agreed to change the position on the co-infected and those clearing the virus only after treatment;

(2) There were some aspects – and the exclusion of dependents was perhaps the most obvious – where the criticisms and wishes of the potential beneficiaries and interest groups could not be met at the time. Against other priorities they were seen as unaffordable. But the concern was considered; the cost was assessed and put to Ministers.

The decision that all four administrations would contribute to the cost.

2.152 The Inquiry asks why it was decided that funding for the new scheme would be drawn separately from the four administrations and refers me in this regard to the meeting note of 31 July 2003, to which I have referred at paragraph 2.99, above [DHSC0016743]. A UK-wide scheme was the favoured option of both

the Scottish Executive and the DH as this would be easier to administer and ensure equity and precedents were already in place. However, the funding would come from each of the administrations because there was no central funding from the Treasury for the scheme and it was equitable that all four administrations should contribute, forced as we were to find the funds from our existing budgets. Once it was established that the scheme was also within devolved competence it was even clearer that each administration would have to be tasked with identifying and providing the finance for recipients within their territories.

Proof that the virus had not been cleared

2.153 I have addressed this issue alongside other issues on natural clearers, at paragraph 2.158, below.

The meeting of 30 July 1993 and exclusion of dependents of HCV patients who had died.

2.154 I have addressed this issue under earlier headings.

Whether those with Hepatitis B were considered for inclusion in the scheme

I've been referred to an email dated 3 November 2003 sent to me by Peter Stevens [SCGV0000256_051]. In the email, Peter Stevens raised the possibility of including Hepatitis B patients in the scheme through an administrative process without it being announced. When I forwarded the email

to my opposite numbers in the devolved administrations, I didn't specifically refer to that point. I have to say I don't have any recollection of this issue and seeing this email has not brought back any recollection about it. Looking at it now, it certainly wouldn't have been possible to include Hepatitis B patients in the scheme administratively without changes to the scheme. Such a change would need to have been dealt with formally, not as an administrative matter and would have required further consultation with interested groups but it would also have required government clearance as a change to the eligibility requirements.

Peter Stevens' email of 10 November 2003

2.155 I have already referred to the change of position on the co-infected which was agreed by DH and the devolved administrations. The Inquiry refers to an email from Peter Stevens to Moira Protani on 10 November 2003 [SKIP0000032_214]. Although I don't recall these discussions in detail, I think I am the DH 'official' referred to. Mr Stevens stated:

> *"The position now is that most of the key elements of the scheme have been agreed between the various health department officials, the main outstanding point being whether or not the Macfarlane registrants (the "co-infected") are eligible for payments on the same basis as those mono-infected .*
>
> *We have said all along, and repeated today, that the use of our resources and expertise is conditional on this eligibility. The official involved has to convince the Sec of State (John Reid) that this must be included in the scheme. The Under-Secretary to whom he reports, Melanie Johnson, has agreed to it, but it is Reid's call."*

2.156 The date of this email corresponds with the prepared submission I put to Melanie Johnson recommending that she ask the Secretary of State to amend the scheme criteria so those who were co-infected would be eligible to claim ex gratia payments, see paragraph 2.144 above.

Natural Clearers

2.157 The decision to exclude natural (or spontaneous) clearers was made early on in the process of developing the scheme. On 3 October 2003, I updated the Secretary of State with progress on setting up the Scheme and sought his agreement on the various component parts [DHSC0016672]. In this document, I explained that there had been a meeting between the four administrations and it had been agreed that the Scheme should be identical to that proposed by Scotland i.e. initial payment of £20k plus an additional £25k on reaching a medically defined trigger point. Payments were to be made only to those alive when the scheme was announced on 29 August 2003 and who had not cleared the virus spontaneously.

2.158 About 20% of patients who were infected by HCV cleared the disease spontaneously in the acute phase usually within the first 6 months of infection. It was decided to exclude natural clearers from the outset. The policy adopted by all four Health Administrations from the outset has been that no account would be taken of any pain, discomfort, loss of earnings etc incurred in the past, or of psychological damage or social disadvantage continuing after they cleared the virus. [DHSC0006798_ 072].

2.159 When it later transpired that a very small number of people clear the virus after the infection continuing beyond the 6-month period i.e. in the 'chronic' phase, it was decided to include these people within the scope of the scheme. People who cleared the virus in the chronic phase as the result of treatment were already included (following advice from DWP). [DHSC0006798_072].

2.160 I have reviewed an email from Bob Stock of the Scottish Executive, to Zubeda Seedat and myself dated 13 October 2003 concerning Skipton Fund eligibility. In the email, Bob Stock adjusted the Stage 1 criteria to say that *"It should be assumed that the virus has been cleared in the acute phase unless robust medical evidence is cited*." [DHS00004520_057].

2.161 In the preceding paragraph, Bob Stock had set out the rationale for this:

> "*The intention of the amendments is to make it more explicit what should happen in situations where spontaneous clearance in the chronic phase is claimed but the date of the PCR test does not allow a judgement to be made as to whether clearance occurred before or after the 6 month time limit for the acute phase*."

This amendment was providing for the situation where a claim was being made that spontaneous clearance occurred after 6 months (this was a requirement of the scheme). Where the evidence from a PCR test was inconclusive about whether clearance occurred before or after the 6 month time limit, the applicant would be required to provide evidence that clearance happened after the 6 month acute phase. I have no idea what was meant by 'robust medical evidence' in this context. I think it probably means reliable evidence such as a letter from a relevant clinician.

2.162 I do not recall the rationale for placing the burden of proof on the applicant for showing the virus had not cleared within 6 months. We may have thought it would be quicker and more straight-forward for the applicant to obtain this evidence from their GP or consultant rather than for the Skipton Fund to obtain the applicant's consent to access their medical records and speak with their doctor to obtain the evidence required. Consideration would have been given to how easy it was for applicants to obtain this information from the relevant clinician. We would not have requested information that would be difficult for recipients to get. The aim of setting up the Skipton Fund was to distribute the ex gratia payments, not to put barriers in the way of people getting what they were entitled to under the scheme.

2.163 The application forms were drafted to be as straight-forward as possible. We were aware that many recipients were elderly or in poor health and we tried to keep the language simple and the requirements as least onerous as possible. We did, of course, require some evidence to substantiate a claim as this was taxpayers' money so we wanted to ensure it went to the right people.

2.164 As the four representatives of the administrations were not medical experts, in instances such as this, we sought expert input from Dr Hugh Nicholas, the DH's Senior Medical Officer in the Health Protection Division. As can be seen from the 15 October 2003 email from Zubeda Seedat to Mike Simmons (the Medical Advisor to the Welsh Assembly) and Hugh Nicholas: "Richard has asked me to

check whether you are content with the revised wording from Bob. Can you please let me know by next Tuesday." [DHSC00004520_057]

2.165 We also sought extensive input from medical experts and organisations representing patients such as the Haemophilia Society and the UKHCDO.

2.166 There was no exact science in relation to defining the 'natural clearers' exclusion. There were no precedents and experts had differing opinions. Many of the issues we were grappling with were new to the experts too. As regards medical knowledge and testing, there were new things being discovered all the time. Having said that, I note the concerns raised by Professor Lee at the meeting which took place on 21 September 2004 to which I have been referred by the Inquiry [DHSC0004510_080]. As well as Professor Lee and myself, the meeting was attended by Christine Lee of the Royal Free Hospital; Bob Stock and Aileen Keel of the Scottish Executive; Caroline Lewis and Mike Simmons of the Welsh Assembly; and Hugh Nicholas and Mike Brannan from DH.

2.167 It is clear that these concerns were taken seriously during the meeting. The thinking behind excluding natural clearers who cleared the virus at the acute phase was based on the belief that the scheme was designed for those who "*...have endured physiological suffering / damage by contracting Hepatitis C and not for the 'worried well' or asymptomatic.*" [DHSC0004510_080].

2.168 It was noted that most natural clearers clear the virus very soon after infection (i.e. during acute phase) and never become symptomatic. Hence, according to

the terms of the Fund, they should not receive payment. There was also a discussion about the difficulties for medical professionals of accurately determining at which stage a patient cleared the virus (i.e acute or chronic). The conclusions reached were: *"Original criteria defined by Ministers must be adhered to (i.e.physiological damage). Acute stage clearers are not eligible. Chronic stage clearers are eligible."* [DHSC0004510_080]

2.169 With regard to determining whether there was any residual suffering for individuals after clearing HCV after treatment, in the absence of any recollection about this, I can only assume medical advice would have been sought on this issue. There was a lot of input from medical experts, patient organisations and Macfarlane Trust on devising the scheme as is evidenced by the number of meetings held to discuss these matters as mentioned in Bob Stock's email to me of 10 October 2003 [SCGV0000256_071].

2.170 As the applications for Stage 1 payments were processed, it had become apparent to those at the Skipton Fund, medical professionals specialising in this area and representatives of the four administrations, that this was a very complex area. Even the experts didn't agree. This is evident from email from Peter Stevens to Mark Winter dated 8 September 2004 which was also copied to Frank Hill:

> *"The subject of "spontaneous clearance" was clearly less understood by the politicians and their advisers than it might have been. We now have over cases (sic) of people (not all with h[ae]mophilia) who are PCR negative without receiving interferon, some of them with no records of chronic stage infection. But some of those have indications of cirrhosis.*

Christine Lee is not passing any spontaneous clearance applications to us, believing the whole attempt to exclude them to be logically or scientifically flawed. Other Centres are taking different approaches, but certainly there is inconsistency, which is quite understandable.

There is also inconsistency within Skipton … In the early days I certainly passed, and we have paid, a number of spontaneous clearers who had evidence of chronic-stage infection. Now, with Liz obviously following Christine's line, I am having to fall into line, so cases I would earlier have passed are being held.

I have urged Richard Gutowski (DoH) and Bob Stock (Edinburgh) to review the whole subject and amend the scheme rules so that we do not try to discriminate against those who cleared naturally.

The purpose of this Email is to ask whether UKHCDO as a whole could add their weight to my request.

I fully accept that it might have been better for your views to have been sought on this before the questionnaire was finalised , but hope that it is not too late now to put things right." [HCDO0000242_ 102].

2.171 Mr Stevens had sent an email to Bob Stock and me the previous day (7 September 2004) pointing out that the questions in section 2A of the application form were leading to inconsistencies and "…*not leading us* [ie Skipton Fund] *(or the clinicians) to clear conclusions*." [DHSC5346629]

2.172 He went on to explain the difficulties:

"Furthermore, one of the London-based directors is Elizabeth Boyd, who is a DOH-appointed MFT Trustee who works at the Royal Free. Her understanding, based on Christine Lee's knowledge of Hep C, is that "nobody who is PCR negative without receiving Interferon based treatment would have experienced any of the symptoms mentioned in 2A(iv)." She is, therefore, not passing any "natural clearers", which forces

the rest of us to follow suit - but until she made this plain I had already passed quite a lot of such cases.
So we have inconsistency of treatment on this point within Skipton, matching that from the clinicians, about which I have already told Bob. ."
[DHSC5346629]

2.173 All parties involved in the scheme wanted the application determination process to be fair and consistent. Mr Stevens suggested in the same email that the best way to achieve this was to "... *abandon the distinction of viral clearance between those whose clearance followed treatment (the majority of clearers) and those who did so "naturally"*." Mr Stevens did not think the cost to the scheme of doing this would be a significant one [DHSC5346629].

2.174 He stressed the need for "...*greater clarification on this point at the very least, and [we] should not be distinguishing between those whose clinicians only tick the boxes and those who add sufficient arguments as to indicate that being PCR negative without taking interferon and without clear evidence from the acute stage is not, in fact, a sound or fair reason for withholding payment".* [DHSC5346629]

2.175 In an email to Bob Stock on 9 September 2004, I confirmed that there was no scope for re-opening the spontaneous clearers issue: *"I agree that the whole spontaneous issue is closed and not open for re negotiation. We agonised long and hard over this before going to Ministers*." [DHSC5346956]

2.176 Bob Stock sent me an email on 9 September 2004 about the PCR issue relating to spontaneous clearers:

> *"1 Re the two messages from Peter Stevens. I think we need either to hold a meeting or a video conference involving MOs as well as officials to resolve this matter — since we currently have different views on how best to proceed coming out of Scotland and Wales, and none as yet from England or NI. And we probably need to do this fairly urgently before this becomes the next Sunday Herald issue. We also need to decide whether it would be helpful to involve this Christine Lee from the Royal Free for the technical part of that discussion.*
>
> *I worry that we have boxed ourselves into a corner with this by accepting the inclusion of the group that supposedly clear spontaneously after chronic infection — but that is all water under the bridge. It is all very well for Peter to carry on about the principles behind the scheme but that is not his role. And if we believe the statistics, then inclusion of the whole spontaneous group will increase the number of eligible applicants by 20%."* [DHSC5346956]

2.177 Quite clearly steps needed to be taken to resolve these inconsistencies.

2.178 On 19 November 2004, I minuted Alison Langley explaining the background and issues with spontaneous clearers. I set out 'Suggested lines to take' [DHSC0006798_072]. These were that:

> *"Ministers have made it clear from the outset that the scheme would only make payments to patients who had experienced lasting physical damage as a result of their infection.*
>
> *That means that patients who cleared the virus spontaneously within the first six months of infection are not eligible. It is thought that very few people clear the virus spontaneously in the chronic phase of the disease that follows. However, such people would be eligible if their clinician's*

can provide evidence that shows, on the balance of probabilities that this had occurred.

This is a lower standard of evidence than is normally applied and reflects Ministers' commitment to keep bureaucracy to a minimum for claimants. However, it would be quite wrong to use public money to make payments where this evidence is not available." [DHSC0006798_ 072].

2.179 On 22 November 2004, Peter Stevens sent an email to Mark Winter asking for help concerning "*those who are deemed to have cleared HCV "spontaneously" - i.e. without interferon*." Mr Stevens suggested that the Skipton Fund had "*...been sitting on applications [from] this lot for ages while I have argued with the DoH to relax the scheme rules and let them all be paid. I have got nowhere and we are now under instruction to settle the matter.* "[HCDO0000242_051].

2.180 Mr Stevens further suggested that the applications on hold could be divided into two groups - those for whom there has been no evidence of chronic infection and those for whom such evidence is claimed. He explained that the first group had been written to and their applications turned down. Those rejections he said arose "*...from the design of the scheme itself, not from our interpretation of their application*."

2.181 Mr Stevens explained that there were around 100 applications in the second group (those who have claimed and provided evidence) which he felt he could not (as an agent of DH) refuse to pay. He went on to describe inconsistencies between doctors from Haemophilia centres. Mr Stevens suggested this could be resolved if "*...those Centre directors who do* understand *and have not put any "evidence exists" applications through could either a) persuade their less*

informed colleagues to withdraw their applications, or b) adopt the same less robust criteria that they did and let their applications go through."

2.182 Mr Stevens went on to say: "*There was a meeting a few weeks ago at which Christine Lee and a Scottish doctor (name unknown to me) were at one on this, but Gutowski (only 2 weeks to go in that post) failed to understand, whether or not deliberately*." [HCDO0000242_051]

2.183 Mr Stevens then told Mr Winter that he would like him to "… *lead to a common approach by UKHCDO on this point*" [HCDO0000242_051]

> *"Keith Foster is writing this week to all the applicants who are still on hold telling them that we are still trying to clarify things and that they will hear from us soon. In theory we could wait 2 weeks until Gutowski goes, but I doubt that his successor will have been appointed by then so we will still not be able to get an intelligent change of mind from the DoH.*
> *Of course, if we were to pay the bunch we currently have, those from whom we have not heard would be no worse off than they are at present; so we could then take up their cause with Gutowski's successor at a later date and hope to get them admitted to the scheme.*"[HCDO0000242_051]

2.184 On 26 November 2004, an email from Peter Stevens records that I called the Skipton Fund about this issue:

> *"…I had a phone call from the office saying that Gutowski was leaping up and down and telling us to pay the natural clearers with chronic stage infection [infection] evidence at once. I am about to call Gutowski to say that we will do what we're told; in practice that means the payments will go out mid-week. So your discussions might need to focus on what to do about those left out*." [HCDO0000242_054].

2.185 I neither recognise nor recall this description of me 'leaping up and down', but in this context it appears to suggest that I was simply encouraging payments to be made to those whom it had now been decided would be eligible for stage 1 payments, namely those who naturally cleared the virus in the chronic phase.

2.186 As I explained to Alison Langley in my minute of 19 November 2004, a number of claimants (about 90) had made claims (knowingly or mistakenly) outside the stated eligibility criteria of the Scheme. Unknown to us at the Skipton Fund who administer the scheme on our behalf had held on to these claim forms rather than reject them on receipt. They asked for further clarification of the situation from DH and were instructed to send out the rejection letters. DH asked Skipton Fund to include the following explanatory paragraph in the letter:

> *"patients would only be eligible for the first payment if (i) there was evidence that they had developed chronic hepatitis C infection but this had resolved spontaneously (thought to be a reasonably rare situation) or (ii) had developed chronic hepatitis C infection but subsequently cleared the virus as a result of treatment. Patients who had, or were thought to have, eliminated the virus in the acute stage, when they would most likely have been. asymptomatic or where any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. Lt should be assumed that the virus has been cleared in the acute phase unless robust medical evidence is cited that proves, on the balance of probabilities, that the patient experienced chronic infection i.e. infection that extended after the first six months of illness*"[DHSC0006798_ 072]

2.187 As I explained at the time, this approach was considered reasonable and entirely consistent with the principles underpinning the scheme that had been stated from the outset. It was also considered an unreasonable use of public money to pay out where this was not substantiated by evidence. The DH felt

that in holding onto the application forms, and saying advice is being sought from the Departments, the Skipton Fund had given people a hope that their applications may well be successful even though they did not fulfil the criteria of the Scheme. [DHSC0006798_072]

2.188 DH also received representations from Dr Paul Giangrande, a Consultant Haematologist at Oxford Haemophilia Centre. Dr Giangrande was in favour of changing the scheme in relation to natural clearers and wrote to Dr Hugh Nicholas in a letter dated 24 October 2003 to which I was copied in. [DHSC0004421_005]. This was during the early days of development of the scheme. I have been asked whether DH considered the proposal by the Haemophilia Society that payment should be provided to individuals who tested positive for the Hepatitis C antibody whilst clearing the infection in the acute phase.

2.189 The letter referred to above was addressed to Dr Hugh Nicholas, the DH's Senior Medical Officer in the Health Protection Division. Dr Nicholas would have given this matter his consideration. As he was the expert, this was not really a matter for me to decide without his input and guidance. What I would say is that a lot of consultation was carried out with experts, patient groups and AHOs when making decisions on the ex gratia payment scheme, especially in relation to eligibility criteria.

2.190 In the letter, Dr Giangrande also set out three points on which he says:

"…there are some clear differences of opinion between our own group and that which met on October 14th". The view of Dr Giangrande's group of experts is:

"1.Our group strongly felt that some form of payment should be made to patients who have simply tested positive for the HCV antibody, even if they subsequently cleared this and did not have abnormal liver function tests. It may be difficult for you to appreciate the tremendous anxiety that was generated in the early 1990s when patients were tested ·and informed of their results for hepatitis C. People with haemophilia were among the first cohorts to be investigated and tested systematically, and this group of patients was particularly mindful of problems related to AIDS only a few years beforehand.

2. We think it grossly unfair that patients co-infected with HCV and HIV should not receive additional compensation. It is certainly true that ex gratia compensation was offered to people with haemophilia in 1991, and that the agreement included a commitment not to seek compensation for any further infections that might be acquired through blood products. In fact, it is quite clear that many patients had already been tested for hepatitis C but not informed of their results when they signed away these rights.

3. Equally, we feel it grossly unfair that compensation should not be offered to the relatives of those who died from hepatitis." [DHSC0004421_005].

2.191 Dr Giangrande was advocating that some form of payment should be made to patients who had simply tested positive for the HCV antibody even if they subsequently cleared this and did not have abnormal liver function tests. Although I have no recollection of Dr Giangrande's letter or what action Dr Nicholas took in relation to the matters raised, co-infected patients were included in the Skipton Fund scheme after further consultation with interested parties.

2.192 There were ongoing representations to change the scheme to include natural clearers at the time I left my role as Head of Blood policy but as of 6 December 2004, the Skipton Fund had made 2,560 stage one payments and 112 stage two payments which I considered to be a positive outcome. [WITN5292027]

2.193 Pressure to change the scheme to include natural clearers continued after I left my role. In an email on 11 January 2005 from Peter Stevens to Frank Hill, Mr Stevens set out details of a meeting with my successor William Connon:

> *"Martin Harvey, CE of Macfarlane Trust, and I had a long meeting yesterday with William Connon, the new official at the DoH who has succeeded Richard Gutowski. In the course of some 2 1/2 hours on a range of Macfarlane and Skipton issues we spend quite a while on the issue of the exclusion of natural clearers from the Hep C scheme. Connon had clearly not been briefed on this, so while he knew nothing about it, at the end of a long discussion he did at least venture the opinion that there might be something there to consider. One of my lines of argument is that the scheme looks like being much smaller than the officials had estimated: in place of the 8,000 applicants they had allowed for, we are still a long way of sending out 5,000 applications, and even of those we have sent we are beginning to suspect that several hundred might never result in actual claims. Therefore, I went on to argue, the extension of the scheme to embrace a few hundred natural clearers is not going to cost the 4 health administrations any more than they had originally budgeted anyway."* [HCDO0000242_ 051]

2.194 As will be more than evident from the quotations set out above, the issue of the non-eligibility of natural clearers in the acute phase was an area of contention where we did not reach agreement. I am somewhat surprised and disappointed (in equal measure) to see some of Mr Stevens' more pejorative comments about me in some of these materials. As I have explained, at the time, I felt we

had a good working relationship. It was certainly one that was good enough to allow him to raise concerns with me and he did not do so in the terms to which he was writing to others. I can only say that I worked hard and in good faith to try to resolve the issues where compromise could be found. To the extent that Mr Stevens was suggesting that I may have been deliberately failing to understand points in a meeting because I was due to move posts soon, that suggestion is entirely unfounded. At the same time, I recognise that tensions and difficulties are – to a certain extent – to be expected in dealing with complex criteria for a scheme where there are fiscal limitations on what can be provided by government (that is to say, hard decisions have to be taken), and a patient group and their representatives, advocates, and clinicians who understandably have strong views.

2.195 A lot of work was also carried out with medical experts in developing the application forms guidance and process for Stage 2 applications. These were then sent by Bob Stock to P Hayes by email on 18 August 2004 for his input before being finalised. In the email, Bob Stock explained the urgent need to finalise the forms:

> *"I have been working closely with Hugh Nicholas in the Department of Health over the last two weeks in an attempt to finalise the application form for the £25k payment that the Skipton Fund can make to those people who have already been found eligible for the basic £20k payment and who have cirrhosis, or liver cancer or have undergone a liver transplant (or are waiting for one). Finalisation is urgent now — as there are now quite a number of people who have received the first payment who will probably qualify for the £25k payment and will need the from [form] in order to be able to claim.*

The form itself is obviously based on the recommendations of the group of medical experts (of which you were part). We have retained the fundamental thinking of that group (I hope) but, in subjecting the underlying processes to detailed scrutiny, have made quite a lot of change to `around the edges' and we think it would be good to get a reality check from yourself to make sure we haven't changed something critical in away that will prove unacceptable or unworkable for the specialist doctors who will have to deal with it.

I attach what is effectively a final draft of both the form and the associated guidance. If you were able to come back to me by Tuesday with any serious concerns you may have about how this has turned out that would be tremendously helpful." [DHSC6701695]

Skipton Fund Appeals Process

2.196 I left DH around 6 months after the Skipton Fund become operational and started making payments to those infected with HCV. The appeals panel had not yet been set up, although I had been involved in various discussions about it. My successor William Connon took forward this work.

2.197 It was clear from the outset, that there would need to be an appeals mechanism for those who wished to challenge a decision to reject their applications for ex gratia payments. The appeals process needed to be fair, transparent and independent of DH. In an email dated 13 October 2004 to which I was copied in, Michael Brannon Science Communicator explained that DH had "*…committed to develop the appeals process in collaboration with the patients groups*". [DHSC0003458 _ 004]

2.198 On 21 July 2004 I received a memo from Nathan Moore (a member of the CJD/Blood Policy Group) [DHSC5344354]. Attached to the memo was an Annex which set out the proposed model of the appeals process that had been accepted by the devolved administrations:

"The stage 1 process as we see it is as follows;

• Applicant registers with the Skipton Fund for a formal application form.

• The completed application form is processed by the Skipton Fund and a decision is made on the claim.

• If the claim meets the criteria, the Skipton Fund will authorise the payment.

• If the claim does not meet the criteria, the Skipton. Fund will write to the applicant advising of the outcome and provide information about their opportunity to appeal against the initial decision.

• The applicant then has three choices at this point:
o The applicant can accept the outcome and take no further action,
o The applicant can appeal to the Appeals Panel who will review the papers from the first application, together with any new evidence submitted by the applicant, or
o The applicant can seek a judicial review.

Following previous consultation with the devolved administrations, we would envisage the appeal process as a panel of no more than five members (for stage 1 application appeals). There would also be a pool of medical. experts (primarily for stage 2 applications). The Skipton Fund would provide the secretariat for both the Appeals Panel and the Medical Pool.

The Appeals Panel would be constituted and convened consistently on each occasion that it met or deliberated cases. The Panel would be Chaired by a legal professional such as a QC and consist of lay representatives, a lawyer, a GP and a haematologist. We expect the

Appeals Panel to meet on a quarterly basis (at least for the first year or two) before a review of how the process has been working is carried out.

The pool of medical experts would consist of up to 5 Consultant Hepatologists who would be primarily involved in assessing stage 2 applications. However, the Chair of the medical pool would be co-opted to the Appeals Panel if it were required.

The benefits of this approach are;
• Stage I appeals and Stage 2 applications are kept separate.

• The Appeals Panel would be constituted formally for a defined period ensuring consistency in their approach to each case.

• The appeals received by the Skipton Fund would be forwarded to the Appeals Panel prior to each meeting. The Panel would provide their decision based on the evidence provided by the [appellant]. As a result, the administrative burden on the Skipton Fund is minimised.

• The Chair would have the casting vote after all Panel members had voted." [DHSC5344354]

2.199 The Annex also set out the principle that the Government should be removed from the operation of the Skipton Fund and the associated appeals process. In the same way, the appeals process should be distanced from the control of the Skipton Fund. It was our intention that the Skipton Fund would provide the secretariat for the Appeals Process and accept the decisions made by the Panel.

2.200 Additionally, in the memo, Mr Moore set out the latest position with regard to the Skipton Fund:

"1. As you are aware, the Skipton Fund (SF) has started to administrate the ex-gratia payment scheme for haemophiliacs infected with Hepatitis C via contaminated blood products.

2. It is anticipated that there will be a high number of initial applications declined. Within the scheme an opportunity for applicants to appeal against that decision is provided. Whilst declined applicants do not have to use the appeals process [they could go straight to the Courts for an appeal], they will be advised that the voluntary process is available to them.

3. The Government wishes to remain removed from the day-to-day operation of the SF and cannot therefore operate the appeals process. In order to maintain the neutrality of the fund, the SF also cannot operate the appeals process. However, the SF have agreed to provide a secretariat function for the appeals process.

4. The appeals process will be funded from the total budget provided to the SF and so the burden must be kept as low as possible. Expenses for panel members will have to come from the fund.

5. Our proposed model of the appeals process, which has been accepted by the devolved administrations, is attached at Annex A.

6. We believe that this would provide the SF with the least burdensome role, given their limited resource."

2.201 Nathan Moore then listed the issues to be resolved:

"7. It is still not clear whether or not the panel members will be public appointments. The SF is a private company limited by guarantee and is facilitating the distribution of public money. We need to seek clarification from SOL Employment on this point. Consideration needs to be given to the fees or expenses to be provided to the Panel members.

8. We have undertaken to share details of the appeals process with relevant patient groups. I anticipate that as soon as we have a steer from

SOL Employment, we will send a note to the devolved administrations asking them to share the appeals process with patient groups and to feedback any comments generated.

9. We should set out the terms of reference for the appeals panel so that the SF can work up procedures for handling appeals.

10. We need to seek nominations from relevant professional bodies so that SF can appoint the Panel."

2.202 The setting up of the panel was delayed due to a number of issues that were yet to be resolved. These included whether the appeals panel would be considered to be an NDPB and whether appointments to the panel would be considered to be public appointments. If so, the recruitment process would need to reflect this. I have seen documents that show there was a fair bit of correspondence on this point as the advice we received was contradictory.

2.203 Initially, we were advised these were not public appointments. This was the view communicated to Nathan Moore to Jerry Bird on 13 June 2004. This was forwarded to myself and David Reay on 14 June 2004:

"I think that the key points here are that these are not public appointments, and it is entirely up to you or the company to determine what you pay to the people involved, either in terms of remuneration for their time or for expenses incurred." [DHSC5339238]

2.204 Advice was later received that confirmed that appointments to the appeals panel, were in fact, public appointments as I explained in an email to Bob Stock on 9 September 2004:

"As to the Appeals system as you are aware we had legal advice, supported by Northern Ireland lawyers that they need to be public

> *appointment's. I have asked lawyers to revisit and they will advise this week. I will then move forward.*
>
> *I would just repeat what I said before the Summer break with David Reay's departure I have no staff to provide the support we have in the past. Things in the future will therefore clearly take longer to progress. If anyone wants to take on the responsibility for progressing the appeals process and the appointment of the Directors then I am more than happy to hand it over."* [DHSC5346956].

2.205 With David Reay's departure from DH, I knew less resource would mean that things would take longer. This is why, in the above email, I asked whether anyone else wished to take more of a lead on the appeals panel work.

2.206 The need for the appeals panel became more pressing as explained in an email to me from Peter Stevens on 4 October 2004 [DHSC0004520_059]. This advised me that five applications had been rejected and that there was a need to tell applicants who had been turned down something about the appeals process. The first formal letter of appeal was received on 14 October 2004 as notified to me and Bob Stock the same day [DHSC5349899].

2.207 The work on the appeals panel was still ongoing at the time I left my role at DH. On 12 December 2004, I emailed William Connon to provide answers to a couple of queries which had been raised, so he could progress work on the appeals panel when he started his new role as Head of Blood Policy:

> *"These question need to be answered before the appointment process for the appeal panel can commence. The answer to the questions are simple*

There is no statute against which the Fund will adjudicate - it will be the criteria and guidance produced by the four Health Administrations.
The obligation to accept the Appeal Panels decision is enshrined in the Funds Agency Agreement with the Department.
We envisage that it will take about two years for the bulk of the payments to be made including adjudicating on the Appeals. After that claims are anticipated to drift in in tribs and trabs but some might result in appeals and this fact should needs to be reflected in the terms of appointment.
I agree with Gill that an advisory classification may be more appropriate than an NDPB – it may also spped up the appointment process." [DHSC0041217_062]

2.208 I have seen a complaint from GRO-A dated 21 October 2004 about decision-making at the Skipton Fund. DH clearly received some complaints about the Skipton Fund I cannot recall the frequency. We always aimed to respond to such correspondence in a professional and empathetic manner and explain the rationale behind setting up the scheme. I do not recall the specific correspondence referred to by the Inquiry or how I dealt with it but it does demonstrate that DH did try and engage with potential recipients of the scheme. My team was inundated with work as there was much to do in order to set up the scheme. We also had other work streams which needed to be completed. I do recall that we had to request assistance from colleagues in other parts of DH to help with correspondence as we had a large backlog around the time of setting up the scheme and we needed help to clear this.

2.209 On 19 October 2004, I received an email from Anna Norris on behalf of Melanie Johnson requesting an update on the Skipton Fund as Melanie Johnson was concerned about reports of delays in processing applications and wanted "*reassurance that the Skipton Fund is running okay*". [DHSC5014739]. In my

response on 25 October 2004, I explained the reasons for the delays and also explained:

> *"The other issue which may cause some comment is the setting up of the Appeals Panel although this only appears to be an issue in Scotland. There is currently one request for a decision to go to appeal. This was the subject of correspondence between PS(PH) and the then Health Minister in Scotland Malcolm Chisholm. Work is now progressing on setting up the panel. The delay was caused by the need for legal advice on how the Panel should be set up. Whilst advising that the Skipton Fund was not a Non Departmental Public Body SOL advised that the appointments should be as if they were one. We have asked the NHS appointments Commission to take this forward together with the Scottish Appointments Commission. We have had to do this so that the process is seen to be transparent but more importantly independent of Whitehall. As Minister is aware there is a pressure group in Scotland which feels aggrieved that the Skipton Fund has been highjacked by London which is not the case." [DHSC5014739]*

2.210 I have reviewed a Ministerial Briefing from William G Connon, dated November 2005 [DHSC0041162 _058] in which it was noted that *'very limited departmental resources have delayed completion of the appeals process'*. Although this briefing post-dates my time in the Blood Policy Team by several months, I can very much relate to the sentiment expressed in relation to very limited departmental resources. Mr Connon was referring to "*very limited departmental resources*" delaying the establishment of the appeals panel. I think that with more resources in my team, the Skipton Fund could have been developed sooner and in operation at an earlier date.

Record Keeping concern raised by Mr Stevens

2.211 In relation to record keeping, the Inquiry refers me to the evidence from Peter Stevens [WITN3070003] and his account that the DH did not have a copy of the Eileen Trust founding documents. I cannot assist on this point. I have no specific recollection of this issue arising or of being unable to find the Eileen Trust founding documents.

How the AHOs were Run

2.212 Given the passage of time, it is very hard to recall points of detail or week to week events. However, doing my best to remember, I do not recall having any concerns about the way the Macfarlane Trust or the Skipton Fund were being run.

SECTION 3: vCJD

The introduction of recombinant Factor VIII

3.1. The Inquiry asks me to describe my role while Head of the Blood Policy Unit, in the decisions and actions taken by DH with respect to the introduction of recombinant Factor VIII.

3.2. In paragraph 11 of my first statement, I explained that one of the main areas of work in this role was "*introducing the recombinant factor concentrate treatment scheme".* I also note that in my Business Objectives 2003/2004, one of my objectives was listed as to "*Take forward the roll out of recombinant clotting factors for adult haemophilia in England"* [DHSC5067904].

3.3. In terms of the introduction of recombinant Factor VIII the minutes of a meeting of the Recombinant Clotting Factors Working Group (the 'Working Group') held on 19 March 2003 predated my involvement. But that meeting, which was attended by representatives of the UKHCDO, show that it had already been recommended, subject to the agreement of DH Central Finance and with Ministers, to prioritise the phasing of recombinant Factor VIII on an age-based priority starting with the youngest [HCDO0000111_167].

3.4. This approach appears to have been reflected in several subsequent documents such as for example, a note to Haemophilia Centre Directors from Frank Hill, the Chair of UKHCDO dated 15 April 2003 recording the allocation

of funding and the introduction of recombinant Factor VIII to patients aged 23 and over [HCDO0000111_169], as well as in minutes of a meeting of the DOH sub-group dated 22 April 2003 [WITN3289061]. It is also confirmed in an email to a number of stakeholders from Charles Lister dated 28 April 2003 [WITN5292028]. I note from these documents that it had already been agreed by DH that funding would be made available over three years in the following manner: 2003-04: £13m, 2004-05: £21.7m and 2005-06: £53.4m.

3.5. However, it was clear that with the appropriate funding being made available by DH over three financial years, further work on the practical implementation of the roll out was now required. In the handover notes from Charles Lister, to which I have already referred earlier in this statement, the material part on recombinants stated on page 6:

> *"We have £88m over the next three years to roll out recombinant clotting factors for haemophilia patients still receiving plasma derived products… 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…"* [DHSC0041246_45].

3.6. An email dated 23 May 2003 from Julia Stallibrass, Specialised Services Team Leader to various addressees, puts the role in a slightly different capacity: "*A working group has been established by the Department of Health to advise on the phased introduction of recombinant clotting factors…*" [DHSC0020737_053]. In essence therefore, the Working Group was advisory in nature but there was a close collaborative working relationship as we were all working together with the same goal of implementing the roll out.

3.7. When I took up my role, the Working Group had only met three times. The Working Group was comprised of a variety of stakeholders including representatives from the UKHCDO, the Haemophilia Society, a number of PCTs and other interested groups.

3.8. Accordingly, as the chair of the Working Group and as the head of the Blood Policy Unit, I attempted to drive forward the roll out of Factor VIII. Broadly speaking, this involved collaborating with the Working Group and chairing its meetings, providing updates, communications and meeting directly with other key stakeholders (such as the UKHCDO and the Working Group). Working with the Working Group we finalised the allocation of funds, agreed a national procurement contract and framework for the supply and ordering of Factor VIII and, where appropriate, clarified key messaging. I also agreed individual funding allocations to clinical centres on the basis of calculations supplied to me by the UKHCDO and unblocked difficult issues, such as the reinstatement of the budget allocation for 2004/05. I provide more detail on this issue below.

3.9. Shortly after my arrival in the Blood Policy Unit, I became aware of extant litigation; a judicial review case concerning the allocation of funding treatment for the claimant and the assertion that an overly rigid policy had been applied by the Newcastle PCT. As far as I recall, DH was not a party to this claim but the nature of the arguments being deployed, namely that "*the original Health Circular on recombinant which set the original 16 age limit was in breach of the Disability Discrimination Act",* would, if successful, have a bearing on our Factor

VIII roll out which was also age-based. Accordingly, this case had the effect of delaying DH's further efforts in the roll out as I explained in a letter to the Working Group dated 5 December 2003 [HSOC0021069].

3.10. On 8 July 2003, I took part in an interview with several other colleagues on the subject of centrally allocated funds. The interview appears to have been part of a wider review of some kind, the details of which I cannot recall and which may not be relevant. For present purposes, the note of the interview is useful because it set out a concise summary of the position reached and the tasks involved on the roll out of recombinants:

> *"The objective is to provide appropriate funds to Lead PCTs to distribute to designated centres for spending on clotting factors. This comes under the Delivery Priority of customer service.*
>
> *The Government has allocated £88m over three years (C. Lister estimate). £13m has been budgeted for 2003/04. Spending will start from September 2003.*
>
> *The programme was developed by a working group of representatives from PCTs, patients and haemophiliacs.*
>
> *Clotting factors will be obtained under a centrally negotiated procurement contract. Clotting factors will be available at designated centres around the country from September 2003. Funds will be passed to Lead PCTs for each designated centre for this purpose, through a resource limited adjustment.*
>
> *The Haemophiliac Doctors Association will establish a list of all haemophiliacs, which DH will use to calculate the monies to allocate to the Lead PCTs. The lists will be by age, covering the youngest first.*
>
> *The funding of these centres through Lead PCTs will continue for three years. After three years, DH should be aware of the requirements for each area, and so may be able to allocate within the general allocation.*

> *This is analogous with the HIV Treatment and Care budget, which was initially ringfenced, but is now in the general allocation. Cathy Hamlyn managed this for 3-4 years.*
>
> *This Friday, the implementation plan will be endorsed and Richard will commence with implementation.*
>
> *Richard and Vickie are working on a mechanism for monitoring the first wave.*
>
> *This Friday, the implementation plan will be endorsed and Richard will commence with implementation…Richard said that a risk assessment had been done as part of the implementation plan…"* [*DHSC0046981_008*].

3.11. A draft implementation timetable was prepared for discussion at a meeting of the Working Group on 11 July 2003 which I chaired for the first time [WITN5292029]. The Working Group tended to meet approximately every two months. I subsequently chaired meetings of this group (which changed its name to the Forward Planning and Monitoring Group on or around January 2004) on 9 September 2003 [WITN5292030], 18 December 2003 [WITN5292031], 26 April 2004 [WITN5292032], 5 July 2004 [WITN5292033] and 6 September 2004 [DHSC0004185_024]. I note that a meeting of the Working Group also took place on 9 February 2004 but I cannot ascertain whether I chaired this meeting [HCDO0000254_436]. I cannot recall who prepared the draft implementation timetable [HSOC0025689] but, I note that the secretariat agreed to revise it following discussions at that meeting.

3.12. I was involved in running and monitoring some of the tender bids and processes for Factor VIII to unblock any issues and this is evident from an email chain between me, DH colleagues and contacts at the NHS Purchasing and Supply

Agency ('PASA') (who were involved in organising the tendering process) between 15 and 24 July 2003 [WITN5292034].

3.13. I also routinely took departmental policy and legal advice on certain aspects relating to the roll out. For example, on 31 July 2003 I requested advice from policy colleagues that "*the age phasing decision is not causing them any problems"* and, separately, from the Departmental solicitors to *"advise on the human rights issue*" [DHSC0010257]. I infer from this request that I was concerned that all of the relevant angles were covered "...*especially as PS(PH) [Melanie Johnson] is keen to have some sort of press coverage when the money is distributed*". But this was also prompted by an anonymised letter presented to the Working Group that had argued that the policy was contrary to Article 14 of the European Convention of Human Rights.

3.14. I received a policy reply on the discrimination point on the same date (i.e. 31 July 2003) from Carl Evans, a policy colleague [DHSC0010255]. He gave an initial view on the proposed policy and suggested that it was potentially age discriminatory albeit this view was based on "*limited knowledge of the decision and how it was arrived at".*

3.15. A separate response was received from Ian Steptoe of I presume, DH legal on 6 August 2003 [DHSC0010254]. His view was that, in so far as Article 14 of the European Convention of Human Rights was engaged, any potential discrimination could be justified as long as it pursued a legitimate aim and the

treatment applied was proportionate to that aim. He suggested that "*there are certainly arguments that can be advanced to show that the decision is justified*" and provided examples of such arguments but noted that further information was required. I cannot remember specifically how this matter progressed, but at a meeting of the Working Group on 9 September 2003 I confirmed as seen in paragraph 4 of the minutes of that meeting, that I:

> "*…had consulted with lawyers about the decision to roll-out recombinant products by age group, and subsequent comments that the decision was discriminatory. The advice received was that the roll-out was not in breach of Article 14 of the European Convention.*" [WITN5292030].

3.16. An example of my implementation of the roll out and collaboration with key stakeholders can be seen from Frank Hill's email to me dated 4 August 2003, which contained a number of attachments. I had clearly assisted him with the content of a draft letter (to be addressed to me) which provided a draft plan for the roll out of recombinant products and contained a number of action points for DH and other onward messaging to Centre Directors [HCDO0000244_087]. In this regard, in a Working Group meeting on 9 September 2003 I proposed that I would:

> *"…set up a number of small sub-groups to address monitoring the roll-out, guidance to Centre Directors & Chief Executives and on the treatment for inhibitor patients"* [WITN5292030].

3.17. Moreover, on one occasion on 9 October 2003, I note that I tasked Zubeda Seedat with taking advice on a request from Frank Hill for a reimbursement of costs incurred by UKHCDO for roll out work which "*we would have had to have employed a consultant to have do it on our behalf*" [DHSC0004101_008]. I

duly chased and followed this up with Zubeda on 14 October 2003 [DHSC0004101_010]. I cannot recall the outcome of this request, but this illustrates some of the matters which I attempted to address and progress in this role.

3.18. On 17 October 2003, I wrote to the Working Group announcing a plan for awarding the national tender and seeking their endorsement so that PASA could place the relevant contracts, noting the work done by Frank Hill and Charles Hay (both of UKHCDO) to get to this stage. I can see from this letter that I proactively suggested the formation of a sub-group to look at the issues of stock holding and stock management to use up under spends in budgets and invited nominations to this sub-working group. I also noted that we would need to "*offer advice to Centre Directors and Chief Executives as to how the roll out will work in practice*" and offered to chair that sub-group and invited other nominations [DHSC0004101_088].

3.19. On 28 October 2003, I provided an update on the roll out and the progress made on the national contract through PASA for Melanie Johnson in case it would be useful for her meeting the following day with Michael Connarty MP and senior members of the Haemophilia Society which was scheduled in order to discuss the Hepatitis C Ex-gratia payment scheme to be announced on 29 August 2003 [DHSC0004101_032]. This update followed a ministerial submission that I put to Melanie Johnson on 27 October 2003 regarding this meeting. [DHSC0014997_092].

3.20. My role in implementing the roll out of Factor VIII can further be seen in an update I provided, by way of a letter, to the Working Group on 5 December 2003 [HSOC0021069]. I noted frustration at the delay caused by the ongoing judicial review given that "*products are in stock, individual centre allocations have been calculated and calculations are in hand to determine the Resource Limit Adjustment's for PCT's.*"

3.21. A subsequent email from Frank Hill to me dated 17 December 2003, attached a draft letter to the Haemophilia Centre Directors regarding the financial complications occasioned by the delay in the roll out [HCDO0000108_003]. However, the legal advice I had received suggested that the roll out should be paused until judgment was received [DHSC0016992] and a meeting to discuss the roll out on Wednesday 3 December 2003 appears to support this conclusion [DHSC0004101_020]. I also note that Melanie Johnson had "*expressed an interest in making an announcement on recombinant".* Looking at this document now I would assume that this was referring to the fact that there would be scope to provide an announcement on the good news that the roll out of recombinants had actually started, given the delays already occasioned.

3.22. In my letter dated 5 December 2003, I explained that litigation had delayed DH's commencement of the roll out programme but requested a meeting of the whole Working Group on 18 December 2003 given that judgment was expected imminently [HSOC0021069]. Prior to this, on 11 November, I provided an update on the litigation and my views to DH legal colleagues [WITN5292035].

3.23. It is clear from my letter of 5 December 2003 that I wanted to be able to share the good news, that the roll out programme could recommence or that we could try and find a pragmatic and alternative solution in order to begin roll out commencement. I note that a favourable judgment was received on 8 December 2003 [DHSC0041565]. I also note a remark from DH legal advisers that "*Counsel to the PCT asked me whether the Department would intend to further delay the roll out of the current planned phase for recombinant facto[r] products… until the outcome of any appeal. That is a process that may take some considerable time if pursued at all and I indicated that I would not expect the Department would wish to do this".* I cannot recall whether I had given instructions on this point, but I think it likely that I would have agreed in any event given my desire to recommence the roll out.

3.24. In response to my letter of 5 December 2003, I note a letter dated 17 December 2003 to me from Mick O'Donnell, Acute Services Lead of the West Midlands Specialised Services Agency, setting out various concerns and the need to identify and implement operational policies for the intended roll out [HCDO0000108_009].

3.25. Due to, I presume, concerns raised at the Working Group meeting on 18 December 2003 and in separate correspondence, I prepared a draft letter to the Chief Executives of PCTs [HCDO0000108_002]. This letter set out in broad terms, the efforts of DH and the Working Group to date and provided an update on the additional funding required by the relevant PCTs to pay for the necessary products for their patients to ensure that there would be a fair allocation from

the 2003/04 financial allocation. I can see from this letter that I also announced the creation of a new subgroup to the Working Group, in order to monitor the roll out programme and that Zubeda sent it to interested stakeholders for comment by way of an email dated 11 December 2003 [WITN52920036]. This also received legal input from departmental lawyers [DHSC0016984]. The final version was sent on 14 January 2004 [WITN52920037].

3.26. Melanie Johnson sent a letter to Jim Cousins MP on 14 January 2004 in response to his letter dated 16 December 2003. Melanie Johnson referred to the fact that on 8 January "*Haemophilia Centre Directors were advised that they may start to order recombinant products so that patients can be changed to recombinant products as early as possible*" [WITN5292038]. I can see that Zubeda took the lead on assisting with this response and canvassing views from stakeholders [WITN52920038]. At this point, I was heavily involved in MSBT meetings and the concern over the emergence of vCJD in previously transfused donors.

3.27. I further note that Sybil Hirsch was appointed as a project manager, funded by DH, to lead on and audit the implementation of the roll out [HCDO0000108_003]. Meanwhile I retained responsibility for liaising with PCTs especially in relation to the question of budget allocations and funding for the roll out as, for example, is seen in a letter to me dated 15 January 2004 from Mick O'Donnell, the Acute Services Lead at the West Midlands Specialist Services Agency [DHSC0014994_132]. I can see from a note dated February

2004, that once the UKHCDO had calculated costs to PCTs, DH would issue PCTs with resource allocation letters and that:

> *"the Recombinant Clotting Factors Working Group will be setting up a sub-group to monitor the roll-out programme and its first meeting has been scheduled for 9 February"* [DHSC0014994_096].

3.28. Reviewing the available documents, I am reminded that there were some, perhaps inevitable, difficulties with implementation and roll out and I worked to try and resolve these. For example, I have seen an email from Frank Hill dated 26 February 2004 to several addressees (including me) which noted that correspondence had been received suggesting firstly that PCTs were not proactively approaching Haemophilia Centres and secondly that Centre Directors were being constrained in what they were allowed to purchase under existing financial agreements [WITN5292039].

3.29. I also note an email exchange between Emily Costello at PASA and me and other Working Group stakeholders dated 25 March 2004, in which I approved the sending of a letter to the Haemophilia Centres to ensure full uptake of budget allocation and supply under the national contract [WITN5292040]. I also provided the text of a covering email message which stressed the urgency of purchasing the products and this was included in an email from Julia Stallibrass to stakeholders dated 29 March 2004 [WITN5292041]. I subsequently discussed this position with several of the stakeholders [DHSC0014994_080] and raised it in a meeting of the Working Group [WITN5292032].

3.30. Similar activity continued throughout the remainder of 2004. For example, I:

(1) prepared letters and correspondence to the Commissioners of Haemophilia Centres to ensure that full take-up of products could be achieved, queried PCT allocations [DHSC0020876_009] and [DHSC0020876_009];

(2) rebalanced budgets and dealt with reductions in funds available for the roll out (in the 2004/2005 financial year to £17m) [WITN5292042], [WITN5292043] and [WITN5292044]; and

(3) was aware of the need to keep Melanie Johnson updated, especially in respect of financial allocation letters. [DHSC0020876_009].

3.31. Despite my best efforts to implement the roll out, some key aspects were beyond my control such as the judicial review litigation delaying the roll out and proposed DH budget cuts. In respect of the budget cuts, an announcement had been made in or around July 2004 that the Department would reduce the budget for the recombinant roll out from £21.3m in 2004-05 to £17.7m. I recall that this was driven by finance colleagues in DH [DHSC0014994_044] and at the time I commented in an email to Natalie Howell of PASA dated 8 July 2004 that:

"*I fully understand people's concerns but cannot think of anything to say. As far as I understand it, the cut was arbitrary and one of many made to a large number of DoH budgets*" [DHSC0014994_044].

3.32. I considered this cut to be very unfair especially given the statement from Geoff Rees in an email to me dated 9 July 2004 that "*If you wish the budget reduction*

re-instated then the funding will have to be found from another budget within your directorate". I therefore endeavoured, to the extent that my position allowed, to get this decision reversed. This is confirmed in a letter from Frank Hill to all Haemophilia Centre Directors dated 9 July 2004 [HCDO0000254_604]. I also raised with finance colleagues the prospect that the proposed cuts may well lead to claims for breach of contract by the suppliers. Zubeda explains in an email to Geoff Rees of DH Finance dated 22 July 2004 that:

> "*Richard has already mentioned that suppliers may claim a breach of contract. The total volumes that can be purchased will be reduced compared to what was modelled by PASA for the National Contract and may affect the price per unit of recombinant product from some manufacturers. This means that we will no longer be able to reach the required threshold for maximum discount*" [DHSC0014994_044].

3.33. Zubeda's email set out a number of other very important representations on this point which included the fact that "*...the Minister has already queried this cut. By way of background, you should be aware that there is a high degree of Parliamentary interest in issues affecting people with Haemophilia and we are very likely to be lobbied as a result of this cut".* I cannot be sure but think it would have been very likely that I would have discussed the content of this email with Zubeda before it was sent.

3.34. I maintained pressure on this issue and subsequently engaged in a number of emails with the DH head of finance, Mark Thomas between 27 and 29 July 2004 [DHSC0038587_182], [WITN5292045]. In a response to an email from Mark dated 23 July 2004, I set out a lengthy reply on 27 July 2004 expanding on the

points raised in Zubeda's previous email and setting out, in clear terms, a number of the political, media and practical risks of the proposed budget cut. That email concludes with saying that I was "*Happy to discuss at a meeting if that helps*". I note that this email refers to the fact that, at the time, the proposed budget cut had prompted several letters of concern to Ministers from key interested groups (UKHCDO and the Haemophilia Society) [HSOC0028518] and [HCDO0000254_533]. It appears that it had also prompted a PQ from Lord Morris and I had suggested a handling approach to deal with this issue.

3.35. Mark replied to my email on 28 July 2004 [DHSC0038587_182]. He asked, assuming that the £4m was reinstated, what my confidence level would be that the money would actually be spent in 2004/05. He suggests in this email that depending on my answer, if the £4m is reinstated, a consequential cut would need to be found in another directorate if not mine and so a degree of certainty was required. I replied on 28 July 2004 to confirm that:

> "*We have been in touch with the United Kingdom Haemophilia Centre Doctors Organisation who are doing the calculations on our behalf who confirm that the full allocation will be spent this year*".

3.36. Mark confirmed on 29 July 2004 that "*the planned £4m cut has been reinstated for 04/05*". I was absolutely delighted with this result and am pleased that my efforts to get the budget reinstated had paid-off. I responded to Mark on 29 July 2004 saying that:

> "*… I am really grateful. I will of course keep you informed if we run into difficulties but the estimates at the moment are that all the money will be spent by year end…*".

3.37. Accordingly, I sent an email to the relevant stakeholders on 29 July 2004 confirming the restoration of the £4m budget and I thanked them for their support. On the same day, I was asked to send a letter to Roddy Morrison, the Chairman of the Haemophilia Society confirming that the existing agreed funding would remain at the same level and that "*Ministers are committed to the roll-out of recombinant for all adult haemophilia patients*" [HSOC0016812].

3.38. I recall that the reinstatement of the budget deficit was received well by stakeholders. For example, on 29 July 2004 Mick O'Donnell wrote to Zubeda and me to say:

> "*Richard/Zubeda – Thanks so much for your work in getting this money reinstated. This is really excellent news. Quite apart from obviously meaning a huge amount to the patients, it takes a lot of pressure off the Trusts and PCTs and means that we can concentrate on taking the national group forward in its wider scope, i.e. developing and using the UKHCDO database to support and develop more rational and informed planning for haemophilia services generally"* [WITN5292046].

3.39. In summary, upon joining the Blood Policy Unit, I continued to implement the roll out of recombinant Factor VIII and I was dedicated to trying to get "*money out to the PCTs"* as I stated in an email dated 29 July 2004 to Mark Thomas [WITN5292045]. In fact, by the time I handed over my role as the head of the Blood Policy Unit to William Connon in or around December 2004, we had published a report on the first year of the roll out on the DH website, we were looking ahead to procuring a new national contract to be put in place once the current contract expired in March 2006, we had reinstated the budget cut to the

recombinant budget and were looking ahead to agreeing the PCT allocations by January 2005 [WITN5292047]. I can see from the Working Group agenda set for 13 January 2005 that William Connon would have taken several of these aspects forwards [WITN5292047].

Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT)

3.40. I have been asked by the Inquiry about my position as an observer at meetings of the Advisory Committee on the MSBT and to explain the purpose of my attendance at those meetings.

3.41. As the Inquiry will be aware, the MSBT was an independent advisory committee chaired, at this time, by Professor Lindsey Davies. There were a number of MSBT members who, as I recall, had a scientific or medical background and were experts in their fields. There were also regular observers to MSBT meetings the majority of which seem to have been from DH, including those from the CJD policy team, but there were other regular observers as well. In addition, MSBT meetings also included a further category of visitors being those "*in attendance*". In the main, these appear to be experts invited by the MSBT to present or address particular issues.

3.42. I note from my Business Objectives 2003/2004, that one of my objectives was to "*Provide Secretariat support for the advisory Committee on Microbiological*

Safety of Blood and Tissues for Transplantation and to take forward work on its re-structuring as a non-departmental public body" [DHSC5067904].

3.43. However, as the Inquiry notes, I also regularly attended the MSBT as an observer alongside other DH colleagues. My attendance as an observer often sat alongside my secretariat role but was beneficial in a number of ways. Firstly, it meant that I could oversee the provision of effective secretariat support to the MSBT by Zubeda and Dr Linda Lazarus. Secondly, however, it was useful in my role to be aware of the detailed discussions taking place in this forum given that I was routinely involved in providing policy advice on blood safety and updating ministers.

3.44. As part of the secretariat team, we briefed the chair on specific elements of the agenda and indicated where DH required advice and a steer. Of course, the MSBT remained as a completely independent advisory body and could select its own issues for consideration, but it was, on occasion, specifically tasked by the CMO and I recall that the National Blood Service ('NBS') could also raise issues on which MSBT advice was requested.

3.45. Finally, as an observer I occasionally contributed to discussions, but these tended to be related to policy or operational matters rather than medical or scientific issues which were matters for the MSBT members and experts.

3.46. The Inquiry raises the issue of my attendance at MSBT meetings in the context of the MSBT's advice to exclude donors who had received blood transfusions from giving blood as a precaution against the onward transmission of vCJD. In this regard the Inquiry has referred me to the following documents:

(1) A note of an ad hoc meeting held at DH dated 15 December 2003 [DHSC0006827_006];

(2) A memorandum from David Harper to Nicola Hewer dated 22 December 2003 [DHSC0004072_048]; and

(3) Minutes of the 31st Extraordinary Meeting of the MSBT held on 22 January 2004 [NHBT0035101].

3.47. I have reviewed these documents and several others, as set out below, in order to aid my memory and interpretation of these meetings. In answering these questions, I believe it may assist the Inquiry if I make a few general observations before turning to the specific content and context of the relevant meetings.

3.48. Firstly, the MSBT would take decisions on the basis of reports and evidence supplied and presented by the relevant experts. Accordingly, to the best of my memory, I was not involved in any of the scientific or technical discussions, decisions or recommendations of the MSBT and this was consistent across the MSBT observers.

3.49. Secondly, I recall that whilst the MSBT was an advisory committee, its advice, decisions and recommendations on this and other issues often carried authoritative weight in terms of advice to other bodies, Ministers and consequential actions to be taken by DH. Where helpful, I have set out examples of this relationship between the MSBT and DH below.

3.50. The first meeting of the MSBT that I attended took place on 10 June 2003 and this appears to be consistent with the minutes of that meeting in which, I note, I was formally welcomed by the chair [NHBT0005599]. This would have been my second working day in my new role.

3.51. From my review of those minutes, whilst that meeting dealt with several issues such as screening blood donations for vCJD, protection of the blood supply from emerging viruses, the importation of US plasma and organ and the testing or organ and tissue donors, I cannot see a reference to the issue of excluding donors who had received blood transfusions potentially contaminated by vCJD. It may be that this issue had been raised in previous MSBT meetings, but this would have been before my time and I have no direct knowledge of them.

3.52. The meeting of the MSBT on 22 October 2003 was my second MSBT meeting [NHBT0034823]. I note that detailed consideration was given by the MSBT to the issue of the exclusion of transfused donors in Agenda Item 4. The salient features of this discussion seem to have focused on the NBS seeking "*definitive advice*" from the MSBT on vCJD risk reduction strategies such as whether

previously transfused blood donors should be excluded from donating blood and whether the NBS should move toward 100% apheresis platelet production.

3.53. The minutes of the meeting on 22 October refer to a risk reduction paper produced by EOR (being the Economic and Operational Research division of DH) together with NBS titled "*The Implications of vCJD for Blood Safety and Supply in England*". This had apparently been presented at a meeting of the MSBT in October 2002. I assume that I was forwarded a copy either shortly before or after this meeting. In any event, the MSBT minutes record at paragraph 18 that "*no further information had been received since then to change the conclusions*" [NHBT0034823]. As I infer from these minutes, the conclusions reached suggest that there was no new scientific evidence providing further information on the issue of the transferability of vCJD in blood donors and that no links between donors had been drawn to date. However, modelling still suggested an element of future risk and therefore the NBS had noted at paragraph 20 of their paper that "*a precautionary approach may still be needed*". These were, of course, matters for the MSBT to advise upon.

3.54. In paragraph 21 of the minutes, the NBS reported on the actions that France and Germany had taken in respect of the issue of deferral and recorded that "*France had deferred transfused donors over a period of two years but this had been done at a time when requirements for blood had not been increasing. Germany had made the decision to only recruit new blood donors who were previously untransfused, however this could lead to a perception problem by allowing existing donors whom may have bene transfused to continue to*

donate" [NHBT0034823]. However, those approaches were taken at a time when blood supply demand had not been increasing. The minutes record that whilst the NBS noted a reduced demand for blood in the UK, at the same time there was a shrinking donor base and very real supply risks. Consequently, in paragraph 22, it appears that the MSBT members agreed that "*at the present time, total and immediate deferral could lead to unacceptable risks to the blood supply and public health. This did not appear to be a proportionate response to a transmission risk that remained theoretical".*

3.55. Whilst I cannot speak for the MSBT, my understanding of the position that the MSBT reached is that it effectively undertook a balancing exercise; the fact that the existing transmission risk of vCJD remained theoretical had to be balanced against the detrimental effect that deferral or exclusion of transfused donors would have on blood supplies at a critical time. I suspect that this was why the issue of deferral or exclusion had not been taken at that time, but this would be a matter for the MSBT to confirm.

3.56. Nevertheless, paragraph 22 of these minutes record that "*The situation would need to be reviewed should a transmission by donated blood be discovered"* [NHBT0034823]. Moreover, I understand that whilst MSBT members agreed that a phased approach to the issue of exclusion might be needed, essentially more information was required on both the current situation and the phased approach taken in France and Germany. I can see from the minutes that this formed a specific action point for the NBS ahead of the next meeting of the MSBT. Again, however, these are matters for the MSBT.

3.57. I have been reminded from the papers supplied by the Inquiry that the next important meeting in the chronology of events was an ad hoc meeting to discuss vCJD and blood held on 15 December 2003 [DHSC0006827_006]. This ad hoc group was chaired by Professor Lindsey Davies and attended by a number of stakeholders including a number from DH policy teams and, for example, the National Blood Service. I attended this meeting together with Dr David Harper.

3.58. I can see from the notes of this meeting that the nature of the particular vCJD incident which led to the instigation of the ad hoc group were set out; namely that a patient who had received a blood transfusion from a blood donor who subsequently developed vCJD had died. I had been copied into Rowena Jecock's minute to the Chief Medical Officer on 9 December 2003 which had set out what was known about the case [DHSC0004087_003]. There had then been a ministerial submission from the CMO to Melanie Johnson on 12 December 2003 which was also copied to me. The CMO had suggested the convening of the ad-hoc expert group and that "*when the expert group has advised, which it will do quickly on a phased basis, Ministers will need to decide on how this matter will be announced"* [DHSC0004068_030].

3.59. I note that this ad hoc meeting recorded that "*while it would be impossible to be certain how the patient got vCJD, the probable route was via the blood transfusion"* [DHSC0006827_006]. Given the importance of this issue and the previous conclusions of the MSBT members, the meeting notes record that

"*One option already looked at would be to exclude recipients of blood transfusions from donating blood. In the light of the suspected case of blood transmission, it was agreed that this should be looked at again".*

3.60. This suggests that the conclusions reached in the MSBT's meeting of 22 October 2003 would need to be reconsidered given that the risks were no longer 'theoretical'. I further note that the implications of this incident on the security of blood supplies were also discussed. The note of the meeting further records that "*There was however a need to avoid measures which unmanageably reduced the blood supply".* Accordingly, the meeting note suggests that whilst there was now a need to revisit the issue, the potential impact of exclusion on the reduction of blood supplies remained an issue of concern.

3.61. I cannot recall what specific actions I took in the immediate aftermath of the ad hoc meeting. I recall and think it likely that any consequential action would have been reported by and dealt with by Rowena Jecock's team (the CJD team) as they had primary responsibility within my branch to advice ministers of CJD policy issues and implications. This can be seen in Rowena's note to Elaine Trewartha of the FCO dated 11 February 2004 concerning the identification of a German recipient of a blood transfusion from a British donor where the donor developed vCJD [DHSC0003556_009] as well as a similar update to the Secretary of State [DHSC0003556_010].

3.62. Of course, however, the CJD team and the Blood Policy Unit had clear areas of overlap, especially with regards to the effect of CJD on the security of blood stocks. This meant that sometimes, we would be working together on the same or interrelated issues. This approach is evidenced by the presence of members of the CJD unit (including Dr Philippa Edwards and often the Branch Head being, at first, Vicki King and then Ailsa Wight) at MSBT meetings, including the ad hoc meeting on 15 December 2003. I note that the Secretary of State gave a statement on 17 December 2003 announcing the death of the transfused donor HC Deb (17 December 2003) vol.415, col.1572.

3.63. I note that on 22 December 2003, Dr David Harper provided a note to the Secretary of State's Private Office on this issue; I was copied in [DHSC0004072_048]. This document appears to have been drafted in response to a query from Malcolm Chisholm, the Scottish health Minister, who had queried when "*decisions will be made about donation of blood by people who have themselves had blood transfusions".* Whilst this note does not appear to reference the discussions of the ad hoc group on 15 December 2003, it refers to the need for the MSBT meeting to be convened on 22 January 2004 which would provide the opportunity for the National Blood Service to provide evidence on the impact of exclusion of donors on the security of blood supplies.

3.64. From my review of the note of 22 December 2003 and, in particular, the final paragraph, I infer that Dr David Harper appears to suggest that the MSBT recommendations on 22 January 2004 would be directly "*considered urgently by the 4 CMOs".* I also note that Sir Liam Donaldson would advise the Secretary

of State of "*any actions in respect of the blood supply in England*". Again, this demonstrates the weight and authority of MSBT decisions.

3.65. I have reviewed the minutes of the MSBT's 31st meeting on 22 January 2004 [NHBT0035101]. This was an Extraordinary Meeting of the MSBT and given the importance of the situation, the number of attendees was larger than subsequent meetings. Gerard Hetherington (Grade 4 civil servant and my Head of Division) was also present as an observer with me.

3.66. I can see that in the introductory remarks, the Chair (Professor Lindsey Davies) explained that the meeting had been convened to "*discuss the implications for the UK Blood Services of a case of possible transmission of variant Creutzfeldt-Jakob Disease (vCJD) by blood transfusion*". This appears to have been instigated by the Secretary of State's statement in the Commons on 17 December 2003 in which he had asked MSBT to "*look comprehensively at whether further precautionary measures could be taken which would not adversely impact on the safety or availability of blood*" [NHBT0035101].

3.67. Paragraph 3 of the minutes referred to, the ad hoc group of experts meeting that had held on 15 December 2003 and that it was tasked to "*discuss the full details of the case and advise Ministers on the policy implications*" and "*had preliminary discussions on further options for safeguarding the security and safety of the blood supply*" [NHBT0035101].

3.68. Paragraph 3 of the minutes further record that the purpose of this extraordinary meeting of the MSBT was *"...examining the recommendations of the ad hoc group in more detail and providing advice to Ministers on what practical steps to implement, taking into account overall risk and safety considerations*". Moreover, at paragraph 5 of the minutes the MSBT members were reminded that, at the last formal MSBT meeting (i.e. 22 October 2003), the risk of vCJD transmission by blood transfusion had been a theoretical one, and the risks to the blood supply of deferring transfused donors was considered unacceptable. However, the MSBT noted that "*in light of the reported case, this position needed to be revisited*" [NHBT0035101].

3.69. I do not believe it would be helpful to the Inquiry for me to set out at length the discussions and conclusions of the members of the MSBT on the criteria for exclusion of previously transfused whole blood donors. I am however, reminded that the NBS presented on this issue on the basis of an updated paper tabled for the purposes of this extraordinary meeting being 'The implications of vCJD for blood safety and supply in England' which is referred to on page 11 of these minutes [NHBT0035101].

3.70. In terms of my understanding of the exclusionary criteria, based on the minutes of this meeting which I had attended, the specific exclusion criteria were set out in the NBS paper tabled at that meeting. This was tabled as MSBT31/2 and titled 'Exclusion of previously transfused blood donors MSBT submission' [NHBT0008157]. Section 4 of this paper set out, in detail, the nature and scope of the proposed exclusion criteria and the rationale behind it. Section 5

proposed an implementation date of 5 April 2004. This was clearly referred to in paragraph 11 of the minutes where it is said that "*... the paper provided an assessment on how a new policy of donor deferral could be implemented while minimising the risk to the blood supply*" [NHBT0035101]. Moreover, paragraph 14 of the minutes referred to the "*... key criteria determining the scope of the donor exclusion policy as listed in section 2 of MSBT 31/2".* However, the reference to section 2 of MSBT 31/2 must be incorrect as these criteria are set out in section 4. Section 2 refers to general points for MSBT consideration.

3.71. The proposed exclusion criteria are listed, summarily, at paragraphs 24 to 27 of the minutes of the meeting of 22 January 2004. I note, of course, that the exclusion criteria were not absolutely comprehensive and that several categories of donor (e.g. existing and new tissue donors, bone marrow donors etc) would need subsequent review and analysis before being considered for exclusion in the future.

3.72. My understanding of the proposed exclusion criteria is supported by two further documents: firstly, a subsequent report from Professor Linsey Davies dated, I presume erroneously, January 2003, sent directly to the CMO and copied to Dr David Harper, Gerard Hetherington and me. I cannot be sure whether this report was in its final form or not and whether or not I had any involvement in it or subsequent briefing to the Secretary of State. This report sets out the conclusions of the ad hoc group and the subsequent MSBT agreement on the exclusion strategy in the meeting on 22 January 2004 [DHSC5035016]. Secondly, a written briefing that I prepared and sent to Lord Warner via his

Private Office which is dated I believe, 15 March 2004. This briefing appears to have been written for the purposes of responding to a number of parliamentary questions. In particular, I would draw attention to paragraph 3 of that note. This refers to the fact that the "*CMO and SofS accepted this recommendation" [i.e. the MSBT's recommendations to exclude previously transfused donors on 22 January 2004]* [DHSC5333851].

3.73. In terms of subsequent decision making on the 'exclusion' issue, I have seen an email from Robert Finch (the acting private secretary to Melanie Johnson) to Dr David Harper dated 30 January 2004, which suggests that the CMO's advice would be sent to Melanie Johnson [DHSC6710786]. Moreover, reinforcing the point I made regarding the authority of MSBT advice, I have seen an email from Siobhan Jones (Assistant Private Secretary to the CMO) to Dr David Harper dated 4 February 2004 referring to the fact that the "*CMO has seen the note provided by Lindsey Davies of the advice of MBST. He agrees with the approach suggested. He has asked if you can provide a draft submission to send to PS(PH) on this as soon as possible"* [DHSC0038576_036]. This request was subsequently passed to Gerard Heatherington on 5 February 2004 [DHSC6245292].

3.74. I have seen from the papers several emails between the Private Offices of the Secretary of State and Melanie Johnson addressing who should clear it. I am unclear as to who, ultimately, cleared this submission save that, clearly, the Secretary of State had a copy of it in his box [DHSC5332262]. The submission itself is dated 10 February 2004 and is addressed to Melanie Johnson from the

CMO [DHSC5007636]. By an email from Robert Finch to Siobhan Jones copied to me dated 12 February 2004, I see that *"PS(PH) accepts CMOs recommendation to accept the MSBT advice"* [DHSC5332341].

3.75. In terms of the issue of implementation of the exclusion criteria, again, I am informed by the content of the minutes of 22 January 2004. I can see that an implementation date of 5 April 2004 was suggested for several reasons: *"to allow stock levels to build, to train donor facing staff; to update information in donor invitation letter and include relevant questions in the new Donor Health Check Questionnaire; and to give Trusts time to prepare contingency plans to manage blood shortages. Operational risks associated with earlier implementation… were also described"* [NHBT0035101]. This implementation plan appears to have been agreed to by the MSBT members, but it is noted that a detailed implementation plan would need to be agreed between the UK Blood Services and Health Departments.

3.76. As I have referred to above, the Inquiry will be aware that there were subsequent extensions of the exclusion criteria to other categories which, I understand, were approached using a similar methodology i.e. guidance by the MSBT and adoption by the Department of Health on the advice of the MSBT.

Notification to patients who may have received vCJD contaminated blood products

3.77. The Inquiry asks whether I had any input into the notification exercise announced by the Secretary of State Dr Reid on 9 September 2004 to notify patients who received blood products which may have contaminated with vCJD. The Inquiry raises a series of sub-questions if I was involved in this area:

a) What my role was;

b) What if any advice the Department took on the legal and ethical arguments for and against such notification;

c) What if any advice the Department took on the psychological impact such notification could have on patients, particularly those patients already infected with Hepatitis and HIV; and

d) What if any consideration the Department gave to providing psychological support to those notified.

3.78. My involvement in the notification exercise announced by the Secretary of State on 9 September 2004 (HC (09 September 2004) vol. 424, col 129)[1] was very peripheral. To the best of my recollection, the only substantive input I had was as part of the team which helped to draft the written ministerial statement given by the Secretary of State to Parliament and which Lord Warner gave to the House of Lords on 9 September 2004 (HL (09 September 2004) vol. 664, col. WS 105-106)[2]. I recall that, at that time, the lead on this exercise was taken by Dr David Harper and the CMO.

3.79. From my review of the relevant material, I note that there was a significant amount of email traffic and other correspondence on this issue between

1. https://hansard.parliament.uk/Commons/2004-09-09/debates/3ddf6004-54df-40e0-9f82-f5c38308b3e2/BloodDonationAndVcjd
2. https://hansard.parliament.uk/Lords/2004-09-09/debates/2e6df981-5bfc-476d-a953-76159515206a/BloodDonationAndVcjd

January 2004 and September 2004. I seem to have been copied into some of the emails for information given my role, but I have not been copied into all of them.

3.80. I have since reviewed a number of the documents provided to me in relation to this issue. I note, for example, that I was copied into an email from Michael Clarke, the Chief Press Officer in DH, to Helena Feinstein dated 7 September 2004 in which Michael stated "*Thanks to Gerard for doing the WMS*" [WITN5292048]. This email attached a handling plan for the proposed written ministerial statement and Michael appears to have suggested some changes to the written ministerial statement. It must, therefore, have been the case that Gerard Hetherington led on the production of the written ministerial statement. Whilst I cannot trace my specific input into it from the documents provided, I clearly recall being involved in some of the drafting. This is probably the reason why I was copied into the email from Michael Clarke.

3.81. For, I presume, similar reasons, I am copied into an email from Neil Townley to Michael Clarke, Helena Feinstein and Gerard Hetherington dated 8 September 2004 and which sets out what is, I believe, the final form of the written ministerial statement [DHSC0004570_030].

3.82. In any event, to the extent that this is helpful for the Inquiry, I have set out my understanding of events leading to, as I understand it, the Secretary of State's notification on 9 September 2004.

3.83. I was broadly aware of the notification issue from the start of January 2004 when I was copied into a submission from, firstly Ailsa Wight to the CMO and the Secretary of State on 9 January 2004 [DHSC0004114_003] and secondly a submission from Dr David Harper to the Secretary of State on 15 January 2004 [DHSC0032258_032] covering the same material. It may be the case that Ailsa Wight's submission to the Secretary of State was replaced with David's. In any event, these submissions set out:

"2. *The Ministerial statement on 17 December 2003 referred to 15 people in England and Wales who received donations of blood from donors who subsequently developed vCJD, and made it clear that all would be told and have the opportunity to discuss their case with expert counsellors.*

3. *In addition, Ministers noted that there were many patients, including haemophiliacs, who had received lower risk plasma products. The CJD Incidents Panel would advise, on a case by case basis, which of these patients should be contacted, as more information became available".*

3.84. I was also copied into an email dated 19 May 2004 from Nicky Connor to Ailsa Wight. This email set out the following:

> *"I would like to update you on our progress in preparing to inform patients exposed to plasma products manufactured from donations from people with vCJD. I discussed this with Rowena Jecock yesterday as we are working towards a suggested launch date of 21 June. Rowena…felt there may be a need for DH clearance of the 'umbrella approach' of the haemophilia patients…The message from David Harper and CMO so far has been clear – that this work should progress as quickly as possibly and that there were no further departmental decisions to be made, other than comments on the timing/press handling"* [DHSC5338310].

3.85. This email attached a memorandum drafted by Ailsa Wight to Nicky Connor dated the same date i.e. 19 May 2004 [DHSC0032258_062]. I can see that I was copied into it. The memorandum starts by recording: "*I called Rowena Jecock yesterday to discuss a possible date for informing patients about vCJD implicated plasma products. Rowena asked me to write to you explaining the current state of play and the proposed plan of action".*

3.86. This memorandum helpfully I think, puts the email of the same date into context. In essence, my understanding was that on the subject of notification, the CJD Incidents Panel had previously proposed to notify individual patients on the basis of individual risk assessment, in respect of those who had received implicated plasma products. However, the UKHCDO "*decided that they do not want to take this approach to patient risk management. Instead, they have proposed an 'umbrella' approach*". This 'umbrella' approach is helpfully explained on page 4 of the memorandum as follows:

> *"…any patient who has received UK sourced clotting factors in a defined time period would be placed in the 'at risk' group. All these haemophilia patients would be informed about this, and given the option to find out whether they had received implicated products and what their individual risk assessment was… the CJD incidents panel considered this 'umbrella' approach at a sub group meeting in April and again at the main meeting in May. The Panel has accepted this approach as a practical way forwards".*

3.87. In terms of the timing and next steps for notification, the memorandum appeared to have conveyed a slight tension and hesitation on behalf of the NHS

in respect of the 'umbrella' approach to notification. The memorandum noted that:

> *"On 12 May the HPA hosted a training day for haemophilia doctors, nurses and patient representatives. At this meeting, angry views were expressed that all information should be given to doctors and patients without delay… David Harper was clear that there were no further DH hoops to jump through or permission that was required and that we should simply keep the DH informed of our plans and progress. However, when I contacted Rowena Jecock yesterday, she said that the new 'umbrella' approach could have implications for the NHS and that I should write to you before proceeding with this strategy".*

3.88. The memorandum concluded by requesting: "*Please would you let Noel Gill and I know as soon as possible whether we can … proceed with the 'umbrella approach', and whether the proposed date of 21 June 2004 is acceptable".*

3.89. I note that on the same day, Rowena Jecock emailed Ailsa Wight to say that she was concerned about the HPA's 'umbrella' approach and noted the implications for the NHS delivery of services to other patients. This email concludes by suggesting that a meeting "*… with Pat Troop about CJD issues might be a good idea. I feel that we haven't yet succeeded in getting the HPA on the right track as far as CJD is concerned".*

3.90. Again, as I have set out, I infer from these communications that Rowena Jecock was, as head of the CJD unit, leading on this issue although I am sure that we would have discussed matters given my team's interest in vCJD and the security of blood supplies.

3.91. I can see that the email dated 19 May 2004 from Nicky Connor was subsequently and separately forwarded to me and Gerard Hetherington by Ailsa Wight (Head of Programme, General Health Protection) with the comment: "*I think DH has to engage, even if we shift the panel soon firmly to HPA"* [DHSC5337443]. A further email from Ailsa Wight to David Daley (Press Officer, Public Health Desk) dated 25 May 2004 and copied to Gerard Hetherington and me mentions that "*… it may be that as you say the June date isn't practical"* [DHSC0020789_029]. This is in response to David's email earlier on the same day on which he asks:

> "*Will a submission be going up to Ministers on the results of the risk assessment and the proposed action? I know that CMO is keen to push on with this but I'm just aware that it will probably need to go in the media diary (regardless of whether it's us announcing it, or HPA) and so the June 21 date may not hold"* [DHSC0020789_029].

3.92. Again, my recollection at this point is that Gerard Hetherington was leading on this aspect with contributions from me where necessary, and I have seen an email dated 2 June 2004 from Carole Dobson, the personal assistant to Dr David Harper in which David asks Gerard in respect of the notification issue: "*Please will you update me on this. (What action is being taken to resolve the problem)"* [DHSC5338310]. I would suggest that it is clear that Gerard was clearly in the lead.

3.93. I further note from an email from Carole Dobson to Rowena Jecock that Dr David Harper had a meeting with the CMO on 30 June 2004 and that David had

requested a briefing as to *"where we are with Scotland and vCJD"* [DHSC6709073]. Interestingly, this email attaches an undated email from Ed Davis to Carole Dobson stating that:

> *"the position is that with regard to haemophiliacs, their position is that they would wish to recommend to their ministers to take the umbrella approach. They have been waiting to see what England does, and clearly prefer we have a UK wide position on this. They are very pleased that our direction of travel is to recommend the umbrella approach to our ministers, but it would appear they would go it alone if we did not adopt this*".

3.94. I have now seen from an email to John Stewart (Assistant Private Secretary to the Parliamentary Under Secretary of State for Health) from Ed Davis dated 21 July 2004 stating that a submission was sent to Melanie Johnson MP in respect of "*vCJD and plasma products and the proposals for patient management and notification.* This version had been agreed by Dr David Harper and amended or modified a previous submission sent on 15 July 2004 [DHSC5058193]. By an email from Nathan Moore to a number of recipients (and copied to me) dated 23 July 2004, Melanie Johnson agreed:

"• *to an "umbrella" approach being taken for the management of the specific sub-group of people with haemophilia and other bleeding disorders who received UK sourced plasma products between 1980 and 2001 and an individual approach for others… However, Minister does not feel that there is a need to place this notification exercise into the public domain [sic] by way of a press release… As a result, we now need to ensure that the notification exercise moves forward as planned"* [DHSC6710801].

3.95. I note from this email that in terms of timing, these had to be kept consistent with the timings agreed between DH and HPA on 20 July and, as a result: "*We would expect to have seen the finalised project plan and timelines for the communications exercise by 28th July and the letters and information packs for both PID and Haemophiliac clinicians are ready to be distributed on 11th August".*

3.96. I cannot provide any helpful recollection on the timing of the eventual notification exercise. However, I have seen a letter addressed to the Secretary of State dated 4 August 2004 from Graham Whitehead, Chief Executive of the Haemophilia Society and David Watters, Chief Executive of the Primary Immuno-deficiency Association [DHSC5344200]. This letter expressed concern at "*the dates chosen for the notification process".* This is because clinicians writing to patients in the week commencing 23 August would result in under-resourced treatment centres to provide the support needed or that patients would "*return from holiday over the Bank Holiday weekend to find that letter on their doormat waiting for them".* The letter stresses that this is prime holiday time and such a time frame "*will be seen as hurtful and neglectful to the needs of the patients… and another two weeks is not going to make a significant difference".* The letter then urged the Secretary of State to defer the announcement to the week commencing 6 September 2004. I obviously cannot comment on whether this letter influenced the proposed timescales for the notification save that the eventual announcement was made on 9 September 2004.

3.97. In terms of the points raised with me by the Inquiry as to advice taken by DH on the legal and ethical arguments behind notification, the psychological impact of notification on patients particularly those already affected and any consideration DH gave to providing psychological support, I am afraid that I have no specific memory of the advice taken. However, given that my involvement on this issue was very peripheral and others were leading on this (such as Rowena Jecock, Gerard Hetherington and Dr David Harper) I would suggest that they, or others, would be best placed to address those matters.

Section 4: INQUIRIES AND REVIEWS

Calls for a public inquiry

4.1. The Inquiry asks what consideration I gave to calls for a public inquiry as Head of Blood Policy, and about my understanding of the Government's reasons for not establishing a public inquiry before now.

4.2. When I first received this aspect of the Inquiry's request, I did not have any significant recollection about the detail of the calls for a Public Inquiry, so I am particularly reliant on the documents in this regard although the documents have helped to jog my memory.

4.3. As I will address in the next sub-section of this statement, before I joined the Blood Policy Team, an internal review of the Department's self-sufficiency had been commissioned in 2002 by Yvette Cooper (when she was PS(H)). In my first statement I referred to the meeting on 1 July 2002 between Hazel Blears (who by then had taken over as PS(H)), and Lord Morris and Michael Connarty at which the internal review amongst other issues, was further discussed [WITN5292049]. I am reminded that part of the background to the commissioning of the internal review was the concerns raised by Lord Owen that the earlier commitment to self-sufficiency had not been honoured and that this, in his view, justified a public inquiry. Although the record of this meeting pre-dates my own involvement, it is relevant because it illustrates the view that was developing based on the (then) early stages of the internal review. At paragraph 3, Hazel Blears is recorded as explaining that on the basis of an initial

paper trawl, it did not look like there had been any misappropriation of the funds for self-sufficiency. Rather, there had been an exponential growth in the use of clotting factors and the aim of the UK self-sufficiency was therefore a "moving target", which the original allocation of funds had been unable to keep pace with.

4.4. In my first statement I also referred to Charles Lister's email of 10 June 2003 [DHSC5541395]. That email was sent right at the start of

my time in the Blood Policy Team. It can be seen from this that a draft of the internal review was already available by this stage.

4.5. I refer to these early documents because when I took over as the Head of Blood policy, the broad - but I think established - position was that:

(1) The allegations of failing to meet the commitment to self – sufficiency were being considered by the internal review;

(2) The early work on the internal review was not suggestive of culpability on the part of the Department;

(3) The Department had not been persuaded that there was a proper basis to consider that there had been past wrongful practices / culpability;

(4) However, what the Department had agreed to was an internal review. It probably stands to reason that the department would not be inclined to agree to a public inquiry whilst its own internal review was still ongoing, unless it was shown that this was very clearly warranted.

4.6. I think it is also relevant context to note that a decision to commission a Public Inquiry would have been a major decision far above my own level of seniority. Clearly, as the Team Leader of the Blood Policy team, I and my team did deal with correspondence, PQs and arguments in other forms calling for an Inquiry. At my level it would of course have been open to me to suggest a change in policy direction if new evidence came to light that this was clearly warranted. But a change in stance on a public inquiry (while ultimately a matter for Ministers) would been dealt with at officials level and at a far more senior level than me. As the Inquiry will be aware, while draft answers to PQs and contributions to debates etc., were often drafted at my level or by members of my team, (including those touching on public inquiry issues) they would be approved by Senior Civil Servants within the Division. For example, the available documents include a briefing note for an oral PQ drafted by me and approved by my Head of Division Gerard Hetherington dated 15 January 2004 [WITN5292050]. In response to a possible supplementary question on calls for a public inquiry the suggested line was that:

> *"A number of Pressure Groups have raised the question of a public inquiry into the infected blood issue. However, the Government does not accept that any wrongful practices were employed and does not consider that a public inquiry is justified. Donor screening for hepatitis C was introduced in the UK in 1991 and the development of this test marked a major advance in microbiological technology, which could not have been implemented before this time."* [3]

[3] I acknowledge that this and similar statements could have better reflected the findings of the Court in ***A & Others* [2001] EWHC QB 446**. However, I think that I would have been drawing on established 'lines to take' and the advice of others in the Department.

4.7. Without referring to all documents where a public inquiry was raised, I have set out below some illustrative examples of how correspondence and PQs raising this issue were handled.

4.8. In September 2003 I prepared a response to a Parliamentary Question (PQ08281) regarding the Government's consideration of a financial assistance scheme for haemophiliacs infected with Hepatitis C by the National Health Service blood products [DHSC0006217_027)]. Part of this briefing note addressed the Government's decision not to hold a public inquiry:

> *"Other Supplementary Questions*
> *Self Sufficiency*
> *Will you review your decision not to hold a public inquiry in the light of the Noble Lord Owen's public statements that when he was Minister of Health in 1975 he made a commitment to make the UK self-sufficient in clotting factors within 18 months?*
>
> *We have examined the Department of Health's files for that period. These indicate that the resources promised by the Noble Lord when he was Minister of Health were allocated to the then Regional Transfusion Centres to increase production of plasma for the Bio Products Laboratory.*
>
> *The money was linked to a target of 275,000 blood donations to be used annually for the preparation of Anti-Haemophilic Globulin concentrate and 100,000 donations for cryoprecipitate. This target was achieved within the 2 year timescale envisaged by the Noble Lord and, as a direct result, the Bio Products Laboratory increased its production of concentrate from 5 million international units in 1976 to 11 million international units in 1977. However, given the rapid growth*

in demand for these products at the time, this was not enough to achieve self sufficiency.

Although self sufficiency continued to be the aim of Ministers for a number of years, and NHS production of concentrate continued to increase, the rising demand for clotting factors meant that commercial products continued to be imported.

None of this evidence, which officials have now made available to the Haemophilia Society, suggests that Parliament was misled or that a public inquiry is warranted."

4.9. I would have been drawing here on established lines to take on this issue. The reference to an examination of the Department's papers within this briefing note reflects that the early drafts of the internal review were not suggestive of culpability.

4.10. On 2 September 2003, Jill Taylor emailed Neil Moors regarding correspondence that had been received from Carol Grayson of Haemophilia Action UK [DHSC0004074_028]. Jill's email noted that it was the primary aim of that group to secure an inquiry into contaminated blood products and its second aim was to achieve compensation for haemophiliacs infected with Hepatitis C. I recall that Haemophilia Action UK was one of the campaign groups that was most vocal in their calls for a public inquiry during this period.

4.11. On 9 September 2003, I was sent an article by Bob Stock of the Scottish

Executive Health Department. This reported on comments made by Malcom Chisholm, the then Scottish Health Minister, that he had refused to rule out a public inquiry and had an "*open mind*" about a possible inquiry. Mr Chisholm's comments were also significant because he had confirmed the intended amounts for the Hepatitis C payment scheme [DHSC5324779].

4.12. In response to these articles, Melanie Johnson's Private Secretary suggested that I should prepare a note for the Secretary of State to make him aware of Mr Chisholm's statements. Calls for a public inquiry were growing in Scotland at this time and so the Blood Policy Team, and the Department, will have been aware of the Scottish Government's approach to calls for an inquiry. [DHSC5324779].

4.13. On 19 September 2003, following an alert by Melanie Johnson's Press Officer, I emailed Graham Bickler, Head of Communicable Diseases Branch - Grade 6, and others, regarding calls for a public inquiry from the Haemophilia Action Group that had been reported by the BBC. The item was based on a document that was said to support the view the Department had knowingly allowed contaminated blood to be used in haemophilia treatment without informing patients of the risks WITN5292051[4] This is an example of how campaign

[4] In this email I assert the Department's position to be that "*...it was 1985 when non-hep A and b came to light and we started to take measures. We have a strong line in that the virus was unknown, it could not be grown and there was no test available. In addition it has to be remembered that at the time there was no alternative and not to have given Haemophiliacs the blood would have led to early and painful death*". I return to this below.

groups sometimes alighted on particular documents which they felt justified their calls for an inquiry, or at least helped justify their arguments for one. On this particular occasion, certainly at the time I was writing, we had not been provided with a copy of the document being relied upon and I commented that it was not in our files.

4.14. In the same email chain, on 19 September 2003 at 10:43, Mr Bickler referred to "*...prosecutions following HIV transmission via the blood supply...*" that had been brought in France. This comment is illustrative of the Blood Policy Team and other officials within the Department, monitoring the issues arising from the contamination of blood products in other countries during this period, including France. Mr Bickler's suggestion that we ensure we are on "*... [very] good grounds...*" suggests that the Department were being influenced by the approach of other countries to inform the UK's approach to the issue.

4.15. On 22 September 2003 Bob Stock emailed me a summary of the findings of the Irish Lindsay Inquiry Report 2002. This email also referenced the earlier Finlay Inquiry Report 1997[5]. Mr Stock pointed to some of the helpful conclusions of the Lindsay report, noting that,

> *"The Tribunal has formed the view from this evidence that the consensus which existed in the late 1970s and early 1980s that NANB hepatitis was relatively mild or benign did change as the results of studies became available showing the condition to have potentially serious consequences for some people infected by it. A number of*

[5] Mr Stock stated that the Finlay report *"...led to the Hepatitis C Compensation Tribunal Act 1997 and the current payment scheme compensation for HCV patients..."*. I now understand that the Irish compensation scheme actually pre-dated this report - the Irish government having committed itself to a compensation scheme in December 1994.

> *experts came to regard it as a serious disease with significant long term consequences, especially and increasingly in the period after approximately 1985. That view did not, however, come to be universally held in the relevant medical and scientific communities until after 1989".* [DHSC6701770].

4.16. As I have set out in my first statement, on 23 September 2003, GRO-A wrote to the Department to request an urgent meeting with Mr Reid. Within this correspondence, Mr GRO-A called for a public inquiry on the basis of his allegation that the Government was withholding information and that their offer of financial assistance for those affected by contaminated blood was insufficient, particularly when compared to *"...what other countries with similar or better safety records have given to Hepatitis C suffers".* Mr GRO-A went on to state that the Scottish Haemophilia Groups Forum has recently "*...acquired new documents which are even more incriminating for the Government...*" [WITN5292052].

4.17. On 1 October 2003, David Reay emailed Joanna Nicholson, a Department Legal Advisor, regarding the response to this letter and other correspondence raising similar points [WITN5292053 & WITN5292054]. His suggested reply included:

> *"As you mention in your letter, the Secretary of State has recently announced his intention to provide financial assistance to those inadvertently infected with hepatitis C. At this time, the size of the awards and many other details are still under discussion but we expect to make a further announcement about the scheme in the next few weeks.*

I think it is important to stress that despite the Department of Health's decision to make ex gratia payments, our position with regards to accepting liability has not changed. The payments are being made on compassionate grounds, and are not compensation. With this in mind, they cannot be expected to take account of loss of earnings or compare with punitive damages awarded by the courts, as was the case in a number of other countries, that admitted wrongful practices.

You have requested a meeting with the Secretary of State to discuss a public inquiry into this issue. As I have stated above, the Government does not accept that any wrongful practices were employed and does not consider that a public inquiry is justified. Donor screening for hepatitis C was introduced in the UK in 1991 and the development of this test marked a major advance in microbiological technology, which could not have been implemented before this time. The Secretary of State does not therefore feel that a meeting is appropriate."

4.18. On 2 October 2003 Joanna Nicholas replied to David Reay's email and proposed a number of amendments to the draft correspondence, including a suggestion to tone down the reference to punitive damages and wrong practices in other countries. These proposed amendments and the draft letter, were attached to the email [WITN5292053 & WITN5292054].

4.19. On 17 October 2003, Bob Stock emailed Zubeda Seedat regarding a draft Ministerial response to Lord Morris who had referred to an article published in the 'Scotland on Sunday' [SCGV0000262_ 116]. The substantive allegation arising from the article was that government officials were aware from as early as 1974 that treatment with blood clotting factor concentrates carried a risk of infection with Hepatitis C and therefore, steps should have been taken by the

Government to mitigate the risk posed to those treated with these blood products. Bob Stock's input into the draft response was as follows:

> *"I don't have any problem with your draft. However, you will see from the letter we sent to the Health Committee (which I am sure I have already sent to David and/or Richard) that the main reason we dismissed the Scotland on Sunday allegations was that they have to be viewed in the context of the general professional consensus at that time that NANB was a benign non-progressive condition. You might want to take that on board - as Morris and co. are likely to rubbish the arguments about the lack of a test and the fact that the virus hadn't been identified. I have sent the offending document to Richard and I realise that you might not wish to concede in the reply that you have seen it. But the main issue is that it shows that the risk of NANB was known to be much greater in commercial products than in NHS products. The fact that the virus hadn't been identified then and there was no test aren't good arguments against that - since it would still have been possible (within the constraints of UK NHS capacity to produce F8) to use proportionately more NHS product than was in fact used. The accusation that follows behind that is that we should have achieved self sufficiency before we did - so the 'non dangerous' argument is central to refuting all this.*
>
> *Scotland achieved self sufficiency before England but Scottish haemophilia directors continued to prescribe commercial products in preference to SNBTS right up to 1992 (and probably beyond). You can only defend such behaviour on the basis that the advantage outweighs the risk - and the risk being thought to be negligible is central to that. You can also defend their behaviour on the grounds that the commercial products were licensed by MCA – but that just opens up another can of worms and, more importantly, detracts substantially from the main argument about low risk.*
>
> *It is also possible to mis-read into the document (and this is hinted at in the SoS article) that one of the commercial F8 products (Hemofil) was much more likely to carry NANB than the others - but if you read*

the whole document you will see that the preamble warns against this misinterpretation of the data."

4.20. Reviewing these documents now, I think it reflects that Bob Stock's input was correcting my earlier misapprehension, or poorly worded statement, that '*it was in 1985 when non-hep A and B came to light*'. The substance of Mr Stock's input and argument remained supportive of the case against an inquiry on the basis that while risks associated with NANB infection were known to be higher for imported products, the severity of NANB was not as well understood as it later became, and this had to be judged against the advantages of the treatment.

4.21. On 15 December 2003 I received an email from Bob Stock in which he discussed the Australian Government's intention to establish a public inquiry, following the Canadian inquiry and litigation arising out of it about surrogate testing. [DHSC5329961]. Mr Stock provided an analysis of what he believed to be the Canadian Inquiry's key findings. Again, I think we were receiving this helpful analysis from the Scottish Executive Health Department because of the particular prominence of calls for a public inquiry in Scotland.

4.22. On 5 February 2004 Lord Warner, when responding to a parliamentary question on the HCV payment scheme for patients infected by contaminated Nation Health Service blood products, was asked by Lord Roberts of Conwy:

"...have the Government compared their proposals with the scale available, for example, in Canada, which is much more generous?"

and Lord Warner responded:

> *"My Lords, the awards that were made in Ireland and in Canada followed public inquiries or criminal charges which established that wrongful practices were employed. The payment structures of those schemes were therefore based on claims for punitive damages. We do not acknowledge any such wrongdoing in England, so it is not fair to make a comparison between those schemes. The Macfarlane Trust will be involved in the administration of this scheme, but there are significant differences…"* [WITN5292055]

4.23. On 1 March 2004, the Blood Policy Team was referred to two media articles regarding the recent ex gratia HCV payment scheme. The complaint in the article was that it was a less generous payment scheme than that of the Republic of Ireland. The articles also alluded to a threat to take the government to the European Court of Human Rights ("ECHR") on the basis of discrimination and challenged the accuracy of DH's distinguishing the position in the Republic of Ireland [DHSC6259005].

4.24. David Reay forwarded these articles to Bob Stock highlighting the Department's intended lines of response – namely that there was a distinction to be made between the payments made in Ireland and Canada and those in the UK. This position was formulated on the basis of the schemes in Ireland and Canada having followed on from public inquiries, or criminal charges, which established wrongdoing, and the payment structures of the schemes therefore being based on punitive damages. We did not acknowledge any such 'wrongful doing' in England. I am now aware that the Department of Health's reliance on the understanding that the Irish compensation scheme came after findings of

culpability in inquiries in the Republic was successfully challenged in a subsequent judicial review. In that regard I think I can only emphasise that I had noted in my email to Gerard Hetherington of 1 March 2004 that we had, *"...double checked our lines with the Irish Department of Health late Friday and they confirmed that what we are saying is correct."* [DHSC6259005].

Throughout my time on in dealing with this issue, I understood that there was a ground to distinguish the Irish scheme on the basis that their more generous scheme had followed after findings of fault. On 19 March 2004, David Reay emailed Ann McGrane, to seek further corroboration from the Irish Department of Health in respect of this position [DHSC6701497].

4.25. On 27 April 2004, Melanie Johnson wrote to Sir Michael Spicer MP. Ms Johnson confirmed, in response to a call for a public inquiry into the issue of the Government's decision to make ex gratia payments arising from infected blood products, that "...*The Government does not accept that any wrongful practices were employed and does not consider a public inquiry justified, as we don't believe that any new light would be shed on this issue as a result*." [DHSC0003606_105]. As discussed above, I recall that this position was maintained by the Department throughout the period I held the position of Team Leader of Blood Policy Team.

4.26. On 15 June 2004 David Reay emailed Sandra Falconer in the Scottish Executive Health Department providing the DH line to take where correspondents were

seeking disclosure of internal documents or accusing the Government of a cover up [SCGV0000046_088]. The line to take was

> *"…In order to fully respond to his/her comments, I feel it is prescient to wait for the completion of an informal review of internal papers commissioned by my predecessor Yvette Cooper in 2002. This review is being undertaken by the Department of Health to clarify the facts surrounding the drive for self-sufficiency in blood products in the UK in the 1970s and 1980s. The review is based on papers available at the time.*
>
> *A draft report has been prepared but there remain a number of outstanding issues that need to be addressed before it can be finalised . I am aware that it has been some time since the review was first commissioned and have therefore asked officials to take forward further work so that the report can be completed as quickly as possible..."*

This reflects that the Department's position at the time, that Ministers were not inclined to hold a Public Inquiry and would want to await the final version of the internal review.

4.27. On 1 September 2004 I emailed Gerard Hetherington about an article in the Sunday Herald on self-sufficiency and a public inquiry. I noted in that email that "… *we have just received the report we commissioned on this whole issue and we could attempt to finally nail this long running saga".* [DHSC6258608][6]. In referring here to the report being received, the available documents show that what we had received at this time in September 2004 was a further version of

[6] Please note that correspondence is also considered in my first statement at paragraphs [46 to 48], and [73 to 78].

the self-sufficiency report which had received the input of external medical writing services from Dianthus Medical Limited (I return to this later in this section of my statement). On the draft report's findings I noted:

> *"…The new Report we commissioned concludes that the Government did pursue the goal of self sufficiency in factor VIII during the 1970's and most of the 1980's in line with WHO and EC recommendations and this is documented publicly. Therefore despite the loss of Lord Owen's papers his policy was not neglected. On the question of use of contaminated blood the report concludes that it is reasonable to suppose that the Government would have known of the risks of contracting hepatitis from blood products but that the virus in question (NonA NonB Hepatitis) was perceived as mild, and often asymptomatic disease and the advantages of treatment with factor VIII concentrates far outweighed its potential risks. This view was supported by patients, their physicians and the Haemophilia Society as always a balance needed to be drawn to weigh the improvements in quality of life and the and the dangers of bleeding against the risks of treatment. The report also states that doctors did in fact explain these risks to patients which again counters claims that they were not told.*
>
> *On the question of BPL the report agrees that it was not operating to a minimum acceptable level. The MCA at the time stated that the continued production could only be tolerated owing to the essential nature of the products and only if immediate improvements were introduced. As a consequence Ministers agreed immediate upgrades whilst production continued. Along with other reasons such as the superiority of the BPL product over commercial equivalents, documented problems with HIV contamination of imported Factor VIII the decision for BPL to rely on Crown Immunity to remain in operation is defensible.*
>
> *All this I believe gives us a strong base to pursue our consistent line that a public enquiry is not warranted…"*

As will be apparent from the above, I did believe that the emerging findings of the internal review which had been commissioned strongly supported the line against a public inquiry.

4.28. On 29 September 2004, I emailed my Branch Head Ailsa Wight regarding a letter from Carol Grayson. Ms Grayson was calling for an independent inquiry into self-sufficiency in blood supply [DHSC5041563][7]. In the penultimate paragraph of that email I said:

> *"On the question of an enquiry our line is that we have no evidence to show that there was any wrong doing at the time and that an enquiry was not justified. We recently commissioned further work, following agreement by Melanie Johnson, into the allegations being made. That report, which is currently being peer reviewed, has concluded that the government at the time acted reasonably. We will therefore be putting a submission to ministers in the near future on how the conclusions of the review can be made public".*

4.29. In a Health Protection Divisional Update regarding Blood Policy dated 15 September 2004, in a section subtitled "Shredding of Lord Owen's Papers / Call for a Public Enquiry", it was recorded that:

> *"Shredding of Lord Owen's Papers/Call for a Public Enquiry*
>
> *Following our meeting with PS(PH), the consultant has now produced a first draft of the report, which concludes that the Department acted*

[7] On 26 April 2004 Ms Grayson sent me a letter regarding allegations of misinformation coming from the department of Health in relation to the ex-gratia payment scheme established in the Republic of Ireland **[DHSC0004520_009]**. On 10 June 2004 I sent a detailed response to Ms Grayson's letter dated 26 April 2004, addressing the issues she had raised. **[WITN1055115]** I believe that this is the letter referred to in the first paragraph of my email to Ailsa Wight on 29 September 2004.

> *reasonably at the time in terms of known infectivity of blood. This reinforces our position that a public enquiry is not warranted. A submission is in preparation for PS(PH) on handling and making the results of the analysis of the papers public, particularly the loss of Lord Owen's papers."* [DHSC5042710].

Again, I believe this reflects our assessment that the emerging findings of the internal review strongly supported the line against a public inquiry. The same update was re-produced verbatim in Health Protection Divisional Updates regarding Blood Policy, dated 29 September 2004 [DHSC5349579], 28 October 2004 [DHSC5351261] and 11 November 2004 [DHSC5215324].

4.30. On 4 October 2004, Linda Percival, Head of Customer Service at the Department of Health had chased Ailsa Wight for draft replies to correspondence which were overdue from my team [DHSC0041333_004]. In my reply I explained why the responses to the various correspondence had taken time. In relation to one of the outstanding pieces of litigation (being handled by Zubeda Seedat) I noted that the correspondence was part of the ongoing campaign calling for a public inquiry. And I again referred to the internal review:

> *"...with the agreement of PS(PH) we have just concluded a review of documents at the time and the preliminary conclusions reached are that the Government at the time acted reasonably and a public enquiry is not warranted. This will form the subject of a submission to PS(PH) in the near future"*

4.31. As I set out in my first statement at paragraphs [53 – 61] in October 2004, GRO-A GRO-A had emailed the Scottish Executive Health Department who in turn were in communication with my team. Within GRO-A correspondence he sought to rely on a "*...Westminster funded a secret report...*" from 1979 as justification for his renewed calls for a public Inquiry. As I set out in my first statement, I now

understand that this 'secret report' may have in fact been the "Haemophilia Centre Directors' Hepatitis Working Party Report for the year ending 1980-1981". Within GRO-A 's correspondence I note he referred to the Haemophilia Society's intention to "*...[step] up its campaign for a public inquiry*" [DHSC0200028]. I think this is another example of how campaigners would sometimes alight on particular documents which they felt particularly justified their calls for an inquiry. If the documents were not immediately being provided to us in correspondence, we would (as here) try to identify what was being referred to.

4.32. As I also set out in my first statement, on 26 October 2004 Bob Stock emailed me regarding further correspondence that had been received from GRO-A [WITN5292056]. I replied the same day. This exchange was also considered in my first statement at paragraphs [54 – 58]. It reflects, I think, the working level cooperation between the respective health departments including on the public inquiry question. On the public inquiry issue, my email reply to Bob Stock of 26 October noted that,

> *"...On the generic question of the justification for a public enquiry the report into self sufficiency we commissioned has now been peer reviewed, and I will be going to Minister next week on how to make the findings public. In brief it concluded that there was no cover up and the Department acted reasonably and in good faith at the time. I will let you all see a draft before it goes up."*

4.33. On 29 October 2004, Lord Warner responded to an oral PQ from Lord Morris which was on information given to patients who had received blood or blood

products from donors who went on to develop vCJD. In supplementary questions, Lord Morris raised the question of a public inquiry. Lord Warner stated that *"...The government have been transparent in their actions and in putting information on variant CJD in the public arena and before Parliament, and we will continue to do so. Wrongful practices have not been employed; we do not believe that a public inquiry is justified"* [DHSC0038587_112].

4.34. In conclusion, I think that the Department and the Blood Policy Team appreciated that there were campaigners and campaign groups during this period that held strong views and were calling for a public inquiry. But the issue most frequently and forcefully raised was the UK's failure to achieve self -sufficiency earlier – an issue that was already being considered by the Department's internal review. Whilst the internal review was ongoing, and in the absence of any evidence that was suggestive of wrong-doing on the behalf of the government, I don't think that the Department or the Blood Policy Team felt that there were grounds to warrant a public inquiry during this period.

Other Countries

4.35. The Inquiry has also asked me to consider what part the establishment and findings of inquiries in other countries such as Canada, France and Ireland, played in the Government's decision not to hold a full public inquiry during my time as the Head of the Blood Policy Team.

4.36. In the chronological examples set out above, I have referred to instances where the outcome of the Irish and Canadian inquiries were referred to and considered. However, we were I think conscious that the situation in other countries was often not directly comparable. For example, in Bob Stock's email of 15 December 2003 addressing the Canadian Inquiry (see paragraph 4.21, above), he was careful to point out the need for caution before transferring conclusions of one country's experience to another country. He said,

> *"* Not surprisingly, the fundamental issue is that of making a valid risk/cost benefit assessment , and both the risks and benefits (or disbenefits) turn out to different in different countries. This ties in nicely with what is said in the Irish 'Lindsay' inquiry, which found the Irish BTS at fault for not introducing surrogate testing but was at pains to point out that this conclusion was not necessarily transferable to other countries.*
>
> ** As regards the HBc test, there appears to be significant disadvantages to using this if the raw material for plasma products is whole blood donations . Deferring donors who test +ve for HBc apparently is a significant disadvantage because anti-HBs exist at the same time as antiHBc so screening one out screens them both out.This is undesirable because anti- HBs are required to be present for immune globulins to be effective .This is important in the context of the decision by the US to use surrogate tests because most of their raw material for plasma products was produced by plasmapheresis - not from whole blood donations - so they were not affected by this disadvantage.*
> *It is for this reason that most European countries that introduced surrogate tests only used the ALT test. It is therefore inappropriate to quote the combined efficiency of using both HBc and ALT tests (as was done in Mr Justice Burton's notes) . [The Canadian inquiry quotes the main US study (the TTV study) as showing combined efficiency of 39% and the efficiency of ALT alone as 30%.]*

> * *As regards the ALT test , the incidence of NANB was much lower in the UK than in the US, Canada and many other countries (2 .5% compared with figures ranging from 4% up to 26% in different parts of France) so that the cost benefit of introducing ALT in the UK was very unattractive compared with many other countries."*

4.37. While reports from other countries were considered and referred to in correspondence, they did not - in our assessment at this time - undermine the Government's approach of conducting an internal review into self- sufficiency, nor the assessment that there had not been any findings of wrongful practices in relation to what had happened in the UK.

The Department of Health Internal Review In Relation to Self Sufficiency

4.38. The Inquiry has raised a number of questions about the Department internal review commissioned in 2002 into self-sufficiency. I have referred to this review a number of times in the sections above dealing with the public inquiry issue, but I deal here with the Inquiry's separate questions about the internal review. As I set out in my first statement at paragraph [11], the self-sufficiency report was one aspect of the varied infected blood issues covered by me and my team. Before reviewing the documents however, I had little active recollection about it and am again heavily dependent on the written records.

Authorship of the report

4.39. From the documents, I am reminded that the report was initially prepared by Peter Burgin, who was an official within the Department[8]. This led to the report being frequently referred to in internal Department correspondence during this period as the 'Peter Burgin Report' or the 'Burgin Report'. It is clear that Peter Burgin had started his work on the Self Sufficiency Report, and had already prepared a draft of the report, prior to my appointment as Team Leader of the Blood Policy Team. This is evident from the email sent by Charles Lister to Zubeda Seedat on 10 June 2003 [DHSC5541395]. The background to this correspondence is set out at paragraphs [18-21] of my first statement to the Inquiry.

4.40. In terms of others who had input into the report, on 6 May 2004 I emailed the director of my Division, Gerard Hetherington, and recorded our agreement that we should "*...pursue appointing a medical writer to redraft the [Self Sufficiency] Report in a more robust form*" [DHSC5336358][9]. I can see that within the same correspondence, I explained that I had hoped that Dr Hugh Nicholas an experienced Senior Medical Officer in the Department, might be able to assist

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[8] I am not able to recall Mr Burgin's specific role within the Department of Health or his Civil Service grade.

[9] On review of the documents available to me, it is my recollection that we decided to instruct a medical writer to address the outstanding drafting issues that Charles Lister had identified in his email to Zubeda Seedat dated 10 June 2003 (as discussed 4.44 below). This is what is what I mean in my email dated 06 May 2004 mean when I say "*...redraft the [Self Sufficiency] Report in a more robust form*"

with this redrafting process, but he did not have the necessary capacity at that time due to commitments on other projects. I have set this email out more extensively below in addressing the timescales involved in work on the report.

4.41. On 7 June 2004, I signed an agreement for medical writing services provided by Dianthus Medical Limited. This agreement provided for Dianthus Medical Limited providing *"the services of one or more of its medical writers to the Department of Health to improve the quality of referencing in a report of hepatitis C and blood transfusions"* [WITN5292057]. I have also seen a briefing for a Parliamentary Question dated 23 May 2006 which records, in response to the question "Who undertook the review?":

> *"A DH official (Peter Burgin) was employed for three months to undertake the review of papers. A draft report was submitted to the Blood Policy Team in January 2003. The report was completed by Medical Consultants from a company called Dianthus Medical Limited. The company specialises in medical writing, statistical consultancy and clinical data management services. The consultants that assisted were*
> *Dr Shanida Nataraja and Dr Adam Jacobs*."
> [WITN5292062 (pg 24)]

4.42. Although the 23 May 2006 briefing note was produced after I had left the Blood Policy Team, this confirms my recollection that the report was further edited in readiness for publication, by third party consultants who were contracted from outside of the Department.

The time taken to complete the Review

4.43. The Inquiry has asked me to explain why the review was not published until 2006 and to explain any reasons for the publication being delayed.

4.44. As set out above, it is apparent that a draft of the Self Sufficiency Report had been prepared prior to my appointment as Team Leader of the Blood Policy Team. The email from Charles Lister to Zubeda Seedat on 10 June 2003 [DHSC5541395] suggests that what needed to be done before making the report "*… more widely available*" was:

(1) The addition of an executive summary;

(2) References added to the documents quoted;

(3) References added to back up the statements which otherwise remained unsubstantiated;

(4) Giving Ministers the option of releasing documents that corroborated the statements made in the report; and

(5) Consider sending – with Ministers' agreement – a final draft to some of those consulted in the report (eg Frank Hill, Terry Snape, Karin Pappenheim) for comments on factual accuracy.

4.45. As I mentioned in my first statement, on 15 December 2003 I minuted John Hutton's Private Secretary on the self-sufficiency report and comments by Lord

Owen about the destruction of his papers [LDOW0000350]. This was copied to Gerard Hetherington and Vicki King among others. Within this note, I set out the Self Sufficiency Report's background, history and progress. In the final paragraphs of the note I explained that:

> *"6. A report was submitted to officials in the blood policy team earlier this year, however there are a number of outstanding issues which need to be resolved before the report can be finalised and submitted to Ministers.*
>
> *7. PS(PH) is aware of the background to this review. Earlier this year, officials agreed to conclude the review as soon as practicable. Unfortunately we have been unable to make any progress during the year."*

This was a candid acceptance by us that we had simply not progressed the report further during the year. Speaking for 'my half' of 2003, this reflected I am afraid, the very great pressures that my team were under.

4.46. In an email dated 1 March 2004 to Gerard Hetherington, I sought his views in response to media articles on the newly announced ex-gratia payment scheme for haemophiliacs and the potential publication of the Self Sufficiency Report. In that email I stated:

> *"...We commissioned a review of the papers which show that Lord Owen's papers are missing - we believe they were shredded by Solicitors during the HIV Litigation. We agreed that we would meet with Melanie Johnson to discuss how best to make the findings of the Review public - she was fairly robust about coming clean last time I spoke to her. I would like to bring someone in to finish off the Report in the sense of producing a chronology, cross referencing the documents referred to and clearing it with those consulted during its production. In addition we need to produce an Executive Summary which could be published. It would also be useful if at the same time*

> *someone ie Hugh Nicholas, could produce a subsid[i]ary report on the issue of when Non A, Non B, and Hepatitis C was first identified and what decisions were taken at the time and for what reasons. This would give us an extra degree of confidence in our line that we dealt with Hepatitis C as soon as we became aware of it.".* [DHSC6259005].

4.47. On 17 March 2004, Melanie Johnson wrote to Lord Owen regarding the Hepatitis C payment scheme and the Self Sufficiency Report. Within that letter Ms Johnson confirmed that a draft of the report had been prepared, but there were a number of outstanding issues that needed to be addressed before the report could be finalised. The letter went on to confirm that the Minister had asked officials to commission further work so that the report can be completed as quickly as possible [HSOC0010692]. As set out in my first statement to the Inquiry at paragraph [44], this letter is identical to the draft I had attached to my note on 9 March [WITN5292058].

4.48. I have already referred to my email of 6 May 2004 to Gerard Hetherington. In that email I said,

> *"When we last met Melanie Johnson she gave us three months to sort out the problem of accusations of self sufficiency of blood and the shredding of Lord Owen's papers. We have a report produced - the Burgin Report - but it is not in form to be published or conclusions drawn from it. We agreed I should pursue appointing a medical writer to redraft the Report in a more robust form. I am meeting Adam Jacobs from a medical consultancy next Friday to see whether they are able to take on the work. Ideally I would have liked Hugh Nicholas to get involved in assessing whether the decisions made at the time stand up in the light of the knowledge at the time and the information*

> *available. Unfortunately he is tied up with work on the Hep C Strategy and the Hep C Payment Scheme Application Form. If the Consultancy Firm feel that they are able to do the work the same question then applies, have we the money"* [DHSC5336358].

The suggestion that the report was "*not in a form.... [for] conclusions to be drawn from it*" appears to me to relate to the drafting of the report as opposed to its substantive content. This is because, as explained earlier in my statement - see 4.40 and 4.44 above, I was at this time exploring the instruction of a medical writer to ensure that the outstanding drafting issues identified by Charles Lister in June 2003 were resolved prior to the report's publication. The preliminary findings of the draft report were being relied upon internally by the Department as early as September 2003 (see 4.9 above). Had I thought that there was any prospect of the draft report's substantive conclusions changing, I believe this would have been discussed in my email.

4.49. As noted above, see 4.41, on 7 June 2004 I signed the agreement with Dianthus Medical Limited.

4.50. As addressed above at paragraph 4.27, my email to Gerard Hetherington on 1 September 2004, I indicated that we had "… *we have just received the report we commissioned on this whole issue…"* [DHSC6258608]. Seen against the above chronology this was clearly a reference to the fact that we had the version of the report back from Dianthus Medical Limited. In the final paragraphs of my email to Gerrard Hetherington I started to address the necessary next steps:

> *"All this I believe gives us a strong base to pursue our consistent line that a public enquiry is not warranted. The key is how we take this forward. Do we react to a Lord Morris question or a make a proactive move. Do we release the Executive Summary of the Report or just the Conclusions or the Report itself. We will need to engage MHRA because of the licensing issues.*
>
> *Can we therefore meet to discuss handling. If you agree can one of your*
> *PA's please set up a short, I would say 1/2 hour, meeting. Thanks."*

As discussed at paragraph [52] of my first statement, I cannot recall having a meeting on this specific topic, but I do recall that my preferred way forward was to place the self-sufficiency report into the Libraries of House of Commons and House of Lords, once it had been agreed by Ministers.

4.51. In my email to Ailsa Wight of 29 September 2004, (see paragraph 4.28, above), included was the indication that it was our intention to prepare a ministerial submission discussing how the conclusions of the review could be made public [DHSC5041563]. To similar effect was:

(1) The Health Protection Division updates starting on 15 September 2004 to which I have referred at paragraph 4.29, above. As already noted, these stated that *" A submission is in preparation for PS(PH) on handling and making the results of the analysis of the papers public, particularly the loss of Lord Owen's papers".* DHSC5042710].

(2) My email to Linda Percival on 4 October 2004 in which I again referenced the intended submission to Melanie Johnson (paragraph 4.30, above) [DHSC0041333_004].

4.52. Between the 26 and 27 October 2004 in an email exchange with Bob Stock, I noted that "*...the report into self-sufficiency we commissioned has now been peer reviewed, and I will be going to minister next week on how to make the findings public...*". [WITN5292056].

4.53. Unfortunately, and despite these indications that a ministerial submission was imminent, so far as I have been able to see from the available papers we did not get that submission put up to Melanie Johnson on this before I left the blood policy team around December 2004.

4.54. Viewed against an objective standard, I entirely accept that work on the internal review took far too long and we made inadequate progress when I was Head of Blood Policy. The Inquiry may well conclude that – again judge by objective standards - it did not get the priority it deserved. I would not seek to argue against that. What I do wish to convey however, is that my team worked exceptionally hard and were under huge pressures. I touched on how busy we were and the volume of our work in my first statement. But some sense of our over-work and professional frustration can be seen from a contemporaneous email I sent to Alan Doron on 5 March 2004 [DHSC5217556]. The context was that we had been 'named and shamed' as one of the consistent worst offenders in being late in providing responses to correspondence. I said as follows,

> *"...As one of the consistent worst offenders I feel obliged to respond. To put the record straight you state that all the previously quoted correspondence has now been dealt with - that is not the case as far as the blood team is concerned. 1038927 is still outstanding and will remain so for a while. It dates back to November of last year and I*

make no apologies for that. It is a very tricky PO [Private Office case] from George Kennedy involving a request for sight of government papers going back over 30 years including an allegation that Ministerial papers had been deliberately pulped. It is part of an orchestrated campaign calling for a public inquiry into the Department knowingly allowing contaminated blood to be used. As Melanie Johnson once said to me "reply in haste regret in the future" (something like that anyway).

That brings me to the first of our problems which is the complexity of some of the issues. We get very few easy bog standard questions which can be easily disposed of. A large amount require a degree of research or requests for advice from third parties. When we were on the receiving end of an orchestrated campaign instigated by the Haemophilia Society our request for help was turned down by the Correspondence Unit. The Society posted a letter on their website requesting all their members to send it to all Ministers and the Department direct and also via their MP's. We therefore received a large amount of these letters from various sources. We agreed a standard response with Minister and asked Correspondence Unit to deal with the correspondence for us. We were told as it was not to do with cancer or dentistry they could not help.

This neatly brings me to the second of our problems which is sheer volume. As soon as we deal with 5 cases another 8 come in. We do have other work to do besides correspondence. For example in the last year alone we had to answer 152 PQs, deal with debates in the House and drive forward a number a key Ministerial Initiatives. I understand the importance of The Whitehall Standard but it needs to be looked at in context of what all policy branches in the Department are having to cope with on a day to day basis. I hope that under the change management structure our [correspondence] workload will decrease but as far as blood policy is concerned I doubt that Linda Percival's estimate that only 20% of cases will require policy lead input will actually materialise. When we receive our lists of [outstanding] cases on examination we find that a number have in fact been answered. What is holding up the process is putting the case on the

template - I was told once that it took half a day to put 18 cases on the system. Perhaps some sort of streamlining is needed. I will not waste time here arguing about how extra resources would of course help.

Lastly the system of naming and shaming and constant reminders of outstanding cases is irritating, counter productive and does not improve the speed at which cases are dealt with. The system does not appear to be capable of recognising when great efforts have been made to clear backlogs as happened in my Team over Christmas."

4.55. I also recall that Linda Percival raised concerns at ministerial level about the slowness of the correspondence returns from my team. I recall that ministers were somewhat protective of me and my team because they were conscious of the significant workload that my team were carrying during this period.

4.56. There is no question of there having been any deliberate delay or stalling of the Self Sufficiency Review. The slow progress, unacceptable though it now appears, was caused by our sheer workload. As the Inquiry will appreciate, the heavy demands of the Blood Policy Team were running in parallel. So, the work on the Self Sufficiency Review was vying in priority with many other important areas of work, including but not limited to:

- The Skipton fund – We were working on the fund's formation and establishing the framework for payments being made as quickly as possible
- The role out of recombinant factor concentrate
- Setting up the Competent Authority under the Blood Directive
- Overseeing the work of the National Blood Service as Accounting Officer

- Providing Secretariat support to the Advisory Committee on the Microbiological safety of Blood and Tissues for Transplantation MSBT
- Responding to correspondence and media coverage relating to individuals who were potentially exposed to vCJD by blood transfusion

4.57. As set in my first statement to the Inquiry, I moved onto a new position in Medicines and Healthcare Products Regulatory Authority. Accordingly, I would not have been involved with progressing the Self Sufficiency Report for publication after my departure from the team and this would have been taken forward by William Connon.

Self Sufficiency Review's Terms of Reference

4.58. The Inquiry has asked why the Self Sufficiency Review did not include consideration of how and when documents from the relevant time period were destroyed.

4.59. Charles Lister's email to Zubeda Seedat of 10 June 2003 summarised the remit of the review as being

> *"...to review surviving documents from 1973 to 1985 to address a number of issues to review surviving documents from 1 973 to 1985 to address a number of issues , chiefly:*
> *- how the Department implemented the policy of UK self sufficiency in blood products begun in 1973 (Lord Owen has said publicly that officials did not carry out his wishes) ;*
> *- to chart the developing understanding of the seriousness of non A/non B hepatitis (later identified as hepatitis C);*

> - *to examine the extent to which problems at BPL delayed the achievement of self sufficiency;*
> - *whether the achievement of self sufficiency would have led to fewer cases of hepatitis C in haemophilia patients.*
>
> *It was not set up to address Lord Owen' s allegation, dating from the late 80s, that the papers from his period as a Minister had been "pulped".* [DHSC5541395]

4.60. Lord Warner answered the PQ (PQ06314) on 18 June 2003 [DHSC0020829_204] as follows:

> *"Lord Clement-Jones asked Her Majesty's Government: What review has been carried out of the circumstances in which files relating to liability for the supply of blood products, which were compiled while Lord Owen was Health Minister, went missing; and what has been the outcome.*
>
> *Lord Warner: An informal review is being undertaken by the Department of Health to clarify the facts surrounding the drive for United Kingdom self- sufficiency in blood products in the 1970s and 1980s. The review is based on papers available from the time and is not addressing allegations that files from that period went missing."*

4.61. The remit of the self-sufficiency review was set before I was involved, but it is clear from the above that it was focussing on an analysis of the surviving documents not carrying out an audit or investigation into papers that had apparently been lost or destroyed.

4.62. In my first statement I set out the series of exchanges in which both Melanie Johnson and John Hutton had been consulted about the terms of the response to correspondence with Lord Owen (*see paragraphs [32 – 44] of my first statement*). In the course of that I had provide a briefing note dated 15

December 2003 in which I set out that the report had not been "*...set up to address Lord Owen's comments dating from the late 80s that the papers from his period as a minister had been "pulped"*. As also set out in my first statement, on 2 March 2004 Mr Hutton's had responded "Why not!?" to this comment [WITN5292060].

4.63. So far as I can tell from the available documents, this issue was resolved when my team met with Melanie Johnson at the meeting on Monday 8 March 2004. After the meeting, Robert Finch emailed Zubeda Seedat to confirm that Mr Hutton's office were content for Melanie Johnson to deal with the reply to Lord Owen's correspondence [WITN5292061]. And on 17 March 2004 Melanie Johnson wrote to Lord Owen, including the statement that the review was not addressing the destruction of his papers:

> *"I am aware that an informal review of internal papers was commissioned by Yvette Cooper n 2002. I have been advised that the review is being undertaken by the Department of Health to clarify the facts surrounding the drive for UK self sufficiency in blood products in the 1970s and 1980s. The review is based on papers available from the time. The review does not address why papers from your Private Office at the time may have been destroyed".* [HSOC0010692].

4.64. My understanding and knowledge of the reasons for the destruction of Department of Health papers from the relevant period is already discussed in my first statement at paragraphs [63 – 78].

4.65. I cannot recall any details about the meeting with Melanie Johnson on 8 March 2004. It is apparent that she required us to make progress with the self - sufficiency report, but she must also have been satisfied that it was not looking into the destruction of documents hence her approval of the response to Lord Owen.

Whether an inquiry should have been established before now

4.66. The Inquiry refers me to the oral evidence of former Secretary of State for Health, Lord Norman Fowler [INQY1000144; INQY1000145] and has asked me to provide my present view on the observations that the government should have established a public inquiry before now.

4.67. Having considered the documents made available to me even with the benefit of hindsight, given the position and information available to me at the time, I do not believe that there were grounds for an inquiry to be established during my time as Team Leader of the Blood Policy Team.

4.68. After I left the role of Team Leader, I was not aware of what further information or concerns came to light and accordingly, I am not in a position to comment or provide an opinion on whether an inquiry should have been established after my departure from the Blood Policy Team.

Statement of Truth

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

Signed ____ _____

Dated _____11.05.2022_____