Witness Name: ROWENA JECOCK
Statement No WITN0823003
Exhibits: WITN0823004 - WITN0823047
Dated: 27/05/2022

INFECTED BLOOD INQUIRY

THIRD WRITTEN STATEMENT OF ROWENA JECOCK

I, ROWENA JECOCK will say as follows:-

1. Introductory Remarks

0.1 I have been asked by the Inquiry to set out my understanding of a number of issues related to infected blood and blood products and the Inquiry's Terms of Reference. As set out at paragraph 65.4 below, I retired from the Department of Health in January 2017. Before that, I held a number of roles which related to policy on infected blood and blood products, starting with involvement in vCJD-related issues in 2002. The Inquiry's R9 Statement Request therefore covers a wide span of time, and inevitably I have only a limited and usually very general recollection of events. I have reviewed material to assist with my answers. This has either been supplied by the Inquiry itself or by my advisors, who have assisted with retrieving information still held by the Department of Health. However, there are limits on what has been made available to me. Some material is no longer available. For example, I asked to review my personnel files as I wanted to clarify the roles that I had held that were relevant to the Inquiry's Terms of Reference, but I was informed that this file is no longer accessible because of a change to the electronic records system.

0.2 Most significantly, I understand that to date there have been significant constraints on the information accessed from the Department's most recent information management system, Information WorkSpace (IWS), operational from 2013. I have been told that general document searches on IWS or searches for batches of documents are very challenging to deal with and not very useful. In addition, broadly defined search terms will return much material that is irrelevant to the Inquiry.

0.3 As a result of this and given also that the R9 Statement Request specifically asks me to focus on matters within my own personal knowledge, I understand that searches to retrieve relevant materials linked to my name have been conducted and information from that is being checked against the questions asked; but that process at the time of drafting is still ongoing. Further, when questions range more broadly over policy areas, this has not always resulted in all the relevant material being made available to me, to date. Where I have identified that this is an issue, I have tried to highlight it in the statement, sometimes identifying that there are others who would be better placed to speak to an issue.

0.4 My statement needs to be read subject to these caveats on the information that I have been given to review. I would be happy to look at additional material and to assess whether revisions were needed, if it is supplied to me.

Section 1: Introduction

1.1. My name is Rowena Jecock. My address is known to the Inquiry. I was born in 1959.

1.2. I have been asked to set out my professional qualifications, insofar as relevant to my roles in the Department of Health ("DH"). My highest qualification is a PhD from the University of Liverpool (see my answer to Q2 below). However, although my academic training was in the biological sciences and therefore provided useful background to my roles in DH, I was employed in policy roles as a generalist and not as a scientist, so my qualifications were not directly relevant to my work.

Q2. Employment History

2.1. My employment history is as follows:

- 1981-84: Science teacher working in secondary education;
- 1984-86: MSc from the University of London;
- 1986-91: Research assistant at the University of Liverpool, during which time I worked towards a doctoral qualification, which was awarded in 1991;
- 1992-95: Research Associate at the University of Birmingham;
- 1995-98: Education & Training Officer at West Midlands Regional Health Authority, subsequently the West Midlands NHS Executive Office of the Department of Health;
- 1998-2017: Various Team Leader roles at the Department of Health in London: see further below, Q3.

Q3. Positions at the Department of Health

3.1. I have been asked to set out the positions I held during my career in DH and their responsibilities.

3.2. As stated in my introductory remarks, I do not have complete information from my personnel record, and so I can only provide my best assessment of when I held specific positions in DH.

3.3. The following roles are of relevance to the Inquiry's Terms of Reference:

- From late January 2002-around mid-2004, I was Head of the CJD Team, with responsibility for ensuring that advice to Ministers on public health policy decisions regarding transmissible spongiform encephalopathies (of which CJD is one) was based on expert scientific advice.

- From mid-2004, following divisional restructuring, I became responsible for Detection and Diagnostics "Infectious Diseases", and continued to work on this aspect of vCJD policy. I contributed to other aspects of work involving vCJD as and when required.

- In around 2005, I took on additional responsibility for supporting the expert advisory committee on the Microbiological Safety of Blood and Tissues (MSBT, then MSBTO, followed by SaBTO from early 2008). At this stage, I believe the Blood Policy Team was headed by Richard Gutowski, who was succeeded by William Connon.

- In late 2008 or the start of 2009 I became Head of Blood Policy, responsible for policy on blood safety and supply. Responsibility for policy on CJD also resided with my team. I also managed the sponsorship relationship with NHS Blood and Transplant (NHSBT) for nearly four years until late 2012, when NHSBT sponsorship transferred to another Branch. In October 2011, I was asked to take over sponsorship responsibility for the Alliance House Organisations (the AHOs), following the retirement of Jonathan Stopes-Roe and the subsequent re-distribution of his Branch's work. In the Spring or early Summer of 2016, I took over management of the environmental hazards work of the Branch until I retired in January 2017, but I continued to assist with some blood policy matters during this period.

3.4. I have attached a Table prepared by my legal advisors, which summarises information on those in post with roles related to the AHOs, across this period [Table attached at WITN0823004).

Q4. The Place of the Blood Policy Unit within the Department of Health

4.1. I have been asked to explain how the Blood Policy Unit and other Units relevant to the Inquiry's ToR fitted into the structure of DH. I should explain that the terms "unit" and "team" were used interchangeably. Both the CJD Team and Blood Policy Team were part of the Health Protection Division within the Public Health Group. As I remember, the reporting line to Ministers on CJD matters was through Professor Sir Liam Donaldson while he was the CMO; although I think this changed in subsequent years and by the time Professor Sally Davies was appointed as CMO (2010), the CMO role had changed. The reporting line on CJD and blood policy matters was then via the Director General responsible for public health matters, although CMO's office was kept informed.

4.2. The Inquiry has referred me to [MACF000023_055], which is a letter written by Dr Ailsa Wight (Deputy Director of Infectious Diseases and Blood Policy) to Martin Harvey (Chief Executive, the Skipton Fund) and dated 30 September 2011. The letter summarises a number of changes to roles and responsibilities that were being made within the Health Protection Division on 3 October 2011, following the retirement of Jonathan Stopes-Roe. Dr Wight explained that she would be taking over as Deputy Director responsible for sponsorship of the Macfarlane Trust, the Eileen Trust, Skipton Fund Ltd, MFET and the Caxton Foundation. Nannerl Herriot was to hand over sponsorship business to myself, to enable sponsorship and policy to be aligned within a single team. As far as I remember, the work of Mr Stopes-Roe's Branch was re-distributed across the Division.

Q5. Colleagues with roles relating to blood and blood products.

5.1. I have been asked to name senior colleagues involved in decision-making and advice about blood and blood products and related risks, during the time I worked at DH. During the period in which I was Head of the CJD Team, my

recollection is that Dr David Harper was initially Head of Division, but moved up to the Director General post and was succeeded by Gerard Hetherington. Dr Pat Troop was the Deputy Chief Medical Officer with responsibility for my area of work at that time, and Professor Liam Donaldson was the Chief Medical Officer. By 2009, Elizabeth Woodeson was Head of Division, followed by Clara Swinson in 2010 and Helen Shirley-Quirk in 2013. Professor Sally Davies replaced Professor Donaldson as CMO in 2010, and I believe Dr Felicity Harvey took over from Dr Harper as Director General in 2012. Dr Ailsa Wight was my line manager from around 2002 until I retired in 2017.

5.2. Health Protection policy matters were within the portfolio of the Minster of State for Public Health, or MS(PH). Following the 2010 general election, I recollect that the ministerial post changed to Parliamentary Under-Secretary of State for Public Health (PS(PH)). Submissions were also sometimes directed to the Secretary of State, for example, when referring to significant parliamentary matters, or decisions with major implications for the Departmental budget.

5.3. I refer back to the Table mentioned at paragraph 3.6 for further names and details.

Q6. Membership of relevant committees, etc

6.1. I have never been a member of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference.

Q7. Retirement

7.1. I confirm that I retired from DH on 31 January 2017. I have not since undertaken any paid work or voluntary activity which is relevant to the Inquiry's Terms of Reference.

Q8. Involvement in other Inquiries or Litigation

8.1. I have been asked by The Inquiry whether I have provided evidence to, or have been involved in, any other inquiries or litigation related to blood or blood products.

8.2. As part of my DH role, I had some involvement in a number of judicial processes and inquiries. I do not have access to a complete list, but there were a large number of challenges brought against the Department, or in which it had an interest, over the years. Some examples that I can remember include:

- A 'best interests' civil case which was brought in the High Court for experimental treatment of a patient with variant CJD in 2002, which although against the NHS involved the DH in the arrangements to provide treatment [DHSC0006543_139].

- A challenge brought in relation to eligibility requirements for the Skipton Fund, *R(Moore) v Skipton Fund Ltd* (2010); Dr Wight provided a witness statement.

- *The Queen (on the application of Andrew March) v the Secretary of State for Health* [2010] EWHC 765 (Admin) in which my colleague Ms Webb provided a witness statement; see further Q63 below.

- A potential discrimination claim directed at securing reform of the Schemes received in early 2015.

8.3. Generally, I was involved in providing briefing, advising Ministers and drafting statements for challenges which related to my policy areas. But I cannot recollect being the signatory to any witness statements and none have been supplied to me for this Statement.

8.4. In 2009, I was also responsible for providing assistance to the Penrose Inquiry in Scotland on behalf of DH. As far as I remember, my involvement primarily entailed acting as point of contact with the Inquiry team, seeking legal advice from the Department's lawyers, giving Lord Penrose's team access to DH files, and keeping Ministers/senior officials updated on progress.

2. Section 2: The Alliance House Organisations

Q9. My involvement with the Alliance House Organisations (AHO)

9.1. I have been asked by the Inquiry to explain the role that I had with respect to the AHOs whilst at DH.

9.2. I had some involvement with the AHOs from 2009, when I became responsible for preparing the Government response to the Archer Report, until October 2011 when I took over the AHO sponsorship role. During this first period, I attended meetings with the AHOs and their sponsor team in order to understand first-hand some of the issues relevant to the payment schemes. In October 2011, following the re-distribution of business to which I referred in my answer to Q4, my team became the formal point of liaison between the Department and the AHOs. This role was referred to in the Department as "sponsorship". It involved managing the Department's relationship with the AHOs, including oversight of AHO business, ensuring that they were delivering against the objectives for which they were funded (for example, via annual review meetings), as well as bidding (through the internal DH financial allocation process) for funding for each AHO. I have addressed my role in relation to the AHOs further, including on the topic of the extent of DH involvement in each, when responding to the questions from the Inquiry on this topic in this section of my statement.

Q10. Meetings between each of the AHOs and DH

10.1. I have been asked to describe the pattern of meetings between each of the AHOs and the DH. I have done so by reference to 2011 onwards.

10.2. The Department of Health would hold annual formal review meetings between DH and each of the AHOs at which they presented their annual report and accounts (albeit, I think, sometimes in draft format).

10.3. There were also often informal meetings with each AHO. The frequency and regularity of these varied, according to prevailing factors, for example, business needs on either side, requests for DH advice/input from an AHO, reports of beneficiary dissatisfaction, whether a DH review of all or part of the

support system was underway, and the degree of parliamentary activity relating to each.

10.4. As far as I remember, the most frequent informal meetings were with the MacFarlane Trust (MFT), which had ongoing levels of beneficiary dis-satisfaction, and also with the Skipton Fund (SKF), which had the largest budget. There were less frequent meetings with the Eileen Trust, which had a much smaller number of beneficiaries, and where there were higher levels of satisfaction amongst its beneficiaries for the support provided. Relatively few informal meetings were required with MFET Ltd as it made fixed payments on a regular basis.

10.5. When the Caxton Foundation was established in 2011, I recall there were several meetings during the first year of its activity, as the Trustees determined beneficiary needs and introduced policies and systems of support, and also during 2014 when beneficiary numbers increased significantly as a result of the exercise to extend the payments scheme to the estates of people who died before the original 2003 cut-off date.

10.6. In addition to the formal meetings there was also lots of contact throughout the year on a more informal basis, including by telephone and email.

Attendance

10.7. I have been asked who would attend the meetings I have described; again I qualify that I am referring to post-October 2011, when I assumed the sponsorship role.

10.8. Formal annual review meetings were chaired by my DH Deputy Director, Dr Wight (a senior civil servant). I would attend as the Head of Sponsorship, and there would be one or two other colleagues from my team, usually our Senior Policy Manager and our Finance Liaison Officer. Sometimes, a representative from the DH Central Finance Group would attend.

10.9. For the AHO, the Chair or Director would attend, together with the Chief Executive and one or two members of their team, again usually including their Finance Officer.

10.10. The minutes of the meetings provided to me by the Inquiry provide some accurate examples of the attendee lists at these meetings. For example, I can see from the minutes of the meeting of the Macfarlane Trust Annual Review 2011/12 on 26 November 2012 [MACF0000061_081] that Dr Ailsa Wright (Deputy Director, Infectious Diseases and Blood Policy), myself (in my role as Head of Policy, Blood Safety and Supply), Ben Cole (Policy Manager, Contaminated Blood), Naomi Balabanoff (Policy Manager, Contaminated Blood Payments) and Eleanor Gill (Finance Business Partner) attended from the DH Central Finance Group.

10.11. From the Macfarlane Trust, Roger Evans (Chair of Trustees), Linda Haigh (Finance Manager) and Roz Riley (Welfare Manager) attended. The list of attendees at the corresponding meeting a year later is the same from the DH perspective, save that Harry Haralambous attended from DH Finance, rather than Eleanor Gill. Just Roger Evans and Jan Barlow (CEO) attended from the Macfarlane Trust (see [MACF000061_069], minutes of the meetings of the Macfarlane Trust Annual Review of 2012/13).

10.12. Likewise, I have been provided with some minutes of meetings between the DH and the Caxton Foundation Trustees. I can see that from the DH, these meetings were attended by Ailsa Wight, myself and Julie Lucas and from the Caxton Foundation, trustees: Peter Stevens, Linda Haigh, Mary Leadbeater and Roger Evans (see [CAXT0000108_075] (minutes of meeting on 13 October 2011) and [CAXT0000108_126] minutes of meeting on 5 December 2011).

Agenda-Setting

10.13. The agendas for meetings between the Department of Health and the AHOs were set jointly. The AHO would be asked if they had items they wished to discuss. The Department also raised items for the agenda.

Information-Sharing

10.14. I have been asked what kind of information was shared by the AHOs with DH. I have already described the formal annual reviews, in which annual reports and accounts were shared.

10.15. Beyond that, information from the AHOs covered a wide range of matters relating to their activities, such as information on changes in their beneficiary profile, actual or planned changes to their disbursement policies (for the charities only), in-year spending, beneficiary engagement activities, and service delivery issues including staff recruitment and office accommodation changes and costs (see for example, item 3 of the minutes of the meeting of the Macfarlane Trust Annual Review 2011/12 on 26 November 2012 [MACF0000061_081]).

10.16. Examples of information we requested included anonymised information about numbers of new beneficiaries [MACF0000015_010] or details of the rationale underpinning the Trust's disbursement policy as evidence of the needs of the Trust and the beneficiaries (see item, "Action 6" of the minutes of the meeting of the Macfarlane Trust Annual Review 2011/12 on 26 November 2012 [MACF0000061_081]).

10.17. Information about individual beneficiaries might also be shared when eligibility decisions had to be taken by DH; this was the case for the Eileen Trust, for example. There are examples of this discussed in answer to the Inquiry's Question 14, about eligibility decisions. Equally, beneficiaries might write directly about issues to the DH, even if the Trust concerned was the decision-maker, and those issues might be raised with the Trust.

Reporting obligations

10.18. As far as I can recollect, the reporting obligation on each AHO was to provide an annual report and audited accounts to DH, and to attend an annual review meeting at the Department. Following discussion with DH Finance, we also instigated a statement of financial procedures, with which they were expected to comply (from 2011, in the case of the Caxton Foundation

[CAXT0000108_075],[CAXT0000065_010], [DHSC5003907] and perhaps a little later with the established AHOs; see [I MFET0000004_032], the notes of the discussion of this document with MFET in July 2012).

Minute of meetings

10.19. I have been asked by the Inquiry about whether minutes of the meetings were taken.

10.20. Formal Meetings would be minuted by the Department and shared with the relevant AHOs. I believe that the AHOs often also took their own notes of the meetings and indeed that is evident from the documents that have been provided to me by the Inquiry.

10.21. I have been asked by the Inquiry about where the minutes might be located. I believe that all of the minutes of the meetings between the Department and the AHOs should have been kept on the file for each AHO. I have set out information about file descriptions below; it may be that further searches using these terms could assist in locating any missing minutes.[1]

Q11. Ministerial Meetings

11.1. I have been asked by the Inquiry about the frequency of meetings between the AHOs and the Minister.

11.2. There were no regular scheduled meetings, but meetings with Ministers did occur from time to time. Sometimes the Ministers would ask to see the AHOs, or one of them, and sometimes we would suggest to the Minister that they should meet with the AHOs. I cannot now recall how many meetings there were during my tenure, but it would not have been a large number. I believe that there should have been minutes of such meetings.

[1] Up until October 2011, I would have expected the file prefix to be SLN (Strategy & Legislation Branch). After this date, when AHO sponsorship moved to my team, it would have changed initially to GHP (General Health Protection Branch). All Blood Policy team files were identified as GHP/005, and later IDBP/005 (Infectious Diseases and Blood Policy). There may still exist a master list in DH that sets out the file structure beneath that prefix. When we moved from paper to electronic filing, we retained a system of file location. The meeting minutes should be in the relevant file(s) for each AHO.

11.3. Ministerial meetings were minuted, usually by an Assistant Private Secretary, and the note would have been sent to the Blood Policy Team, where it should have been filed as I have described above.

11.4. The Inquiry mentions a meeting between MFT and the Minister on 4 November 2014. I have been referred to [MACF0000061_067], which is a letter from Roger Evans to me, dated 5 November 2014, in which he asks that DH consider increasing MFT's funding for the 15/16 Financial Year. He does not refer to a Ministerial meeting the previous day, and nor is any recent meeting with PS(PH) referenced in the Annual Review minutes of 12 Dec 2014 [MACF00000061_057], although 4c of that minute notes that "...if the allocation is to be reduced, MFT expects to meet with the Minister". Although I am not in a position to query this date, still neither of those docs gives the impression that there had already been a recent Ministerial meeting.

Q12. Attendance at Board Meetings

12.1. I did not attend the board meetings of the AHOs, save occasionally by invitation from the Board. Thus, I recall that I may have attended for specific items at one or two such meetings: for example, to talk about parliamentary business and activity; but I certainly did not attend regularly.

12.2. The Inquiry has provided me with a copy of the minutes of the meeting of the Board of Directors of the Caxton Trust held on 19 November 2013 at Alliance House [CAXT0000110_074]. The minute records that I attended in relation to a short part of this meeting, to provide a more detailed briefing about a debate in Westminster Hall and about a recent meeting with the Prime Minister about contaminated blood (page 2). This is consistent with my recollection of the sorts of invitations that I would have received.

Q13. Working Relationships between the AHOs and DH

13.1. I have been asked a number of questions about the relationship between the AHOs and the DH.

a. Reporting obligations.

13.2. This has been addressed at paragraph 10.8 above.

b. Independence of Government.

13.3. I have been asked by the Inquiry whether the DH considered the AHOs to be independent of government. Those AHOs which were charities were independent of Government; their duties and the scope of their work were set by their Trusts Deeds. They were required to act in accordance with these Deeds, in the interests of their beneficiaries. Their policies and payment schemes were determined by their Trustees. But because they were established and fully-funded by DH, they also had a degree of accountability to DH, e.g. on issues that related to the Trustees' ability to manage spending within the funds that had been made available to them. I would also say that the Department had a right to understand what the AHOs were doing and wanted to make sure they were doing what they were set up to do, given the Department's ongoing financial role as funder from year to year, including the pressure – speaking very generally – to increase the funding allocations. I believe that aligns with Charity Commission guidance on accountability to funders, as I understand it. There were also accounting procedures within DH (perhaps even involving the National Audit Office) which had to be taken into account: see for example [DHSC5003907], which is a record of meeting between the Blood Policy Team and DH Finance, discussing the statement of financial procedures for the Caxton Foundation on 24 November 2011. I have commented, in response to questions relating to financial procedures, that these are issues which financial colleagues should be able to speak to.

13.4. Clearly this resulted in tensions in the relationships between the charities and the Department, and, as I understand it, the charities' accountability to DH in this regard was a contributing factor to some significant difficulties with their relationships with their beneficiaries, notably for MFT, and later for the Caxton Foundation.

13.5. The companies, Skipton Fund and MFET, were established to make fixed lump sum/regular payments, and were not considered to be independent of Government. My recollection is that the Skipton Fund was regarded as an Executive Non-Departmental Public Body, and its expenditure was captured in the DH Annual Accounts.

13.6. I would add that after the financial crisis of 2008 and the subsequent pressures on public expenditure, there was much greater scrutiny of expenditure within the Department. The Central Finance team became much more directly involved. This was right across the Department, not just in relation to this area of policy; but it affected the relationship between the DH and the AHOs, dependent as they were on public funding. If the Inquiry wanted more information on these overall pressures, it is possible that Richard Murray, who I believe was a Director or Deputy Director in the Finance Group, might be able to provide further information.

13.7. There are frequent references in the minutes of review meetings about the difference between the AHOs' bids for further resources and the DH's perspective, upon finite resources. An example is [MACF000061_081], the Minutes of the Macfarlane Trust Annual Review 2011/12 on 26 November 2012, where it is said under Action 6 d: "*RJ repeated from previous meetings that there is an ongoing downward pressure on budgets across DH, and the Trust would have to live within its means. RJ pointed out that the amounts paid to individual beneficiaries have increased far above CPI or RPI".*

13.8. Despite these tensions, I nevertheless understood why DH chose to use "arms-length" vehicles to provide support for people whose health had been seriously harmed; other examples include the Thalidomide Trust and the vCJD Trust. I felt that when I was working at DH that the Department had neither the skills nor the resources to deliver services directly itself. Furthermore, the great benefit of a charitable vehicle was that available funding could be prioritised for those whose need was greatest – although I accept that this process of determining relative needs was unpopular.

13.9. I might add it seems to me that whatever structures or vehicles were put in place to deliver support were to some degree secondary. It was clear to me when I was in post that the funding allocated by Government over the years was not sufficient to either meet the needs of those affected, or to satisfy their wishes for further support - which was understandable given the devastating impact of HIV and hepatitis infections on so many people and their families. I (and I believe several of my colleagues) knew that the only thing that would

help would be large sums of money without having to prove a claim to need assistance.

Lobbying and Campaigning by the AHOs

13.10. The Inquiry have asked whether it was acceptable to DH for the AHOs to campaign or lobby for a change in government policy to benefit its beneficiaries.

13.11. I do think that it was reasonable for the AHOs to lobby DH for a change in government policy to the benefit of their beneficiaries - especially now, having reflected on these matters over time. My own view is that large sums of money were needed for people to enable them to get onto their lives (see paragraph 13.9 above).

13.12. As I remember, the AHOs pressed DH frequently for changes to be made. Mostly, I think this related to seeking increased funding (see my comments above), but I also remember them suggesting structural system changes.

13.13. Again, this reflects the tension in the relationship between DH and the AHOs. They had a responsibility to work for what they considered to be the best interests of their beneficiaries. That said, we did not expect them to "rock the boat" by campaigning more publicly. They were not funded to be campaigning organisations. Of course, we recognised that if asked for their views, e.g. by parliamentarians, they would and should give them, but I think that on the whole, they managed to maintain a balanced position.

Views of the All-Party Parliamentary Group

13.14. I have asked by the Inquiry whether I would agree or disagree with "what was noted in the APPG's report, the 'Inquiry into the current support for those affected by the contaminated blood scandal in the UK' [CAXT0000111_029], that the relationship between the DH and the AHOs was "cosy". I would disagree that the relationship was 'cosy'. I think this language is a gloss on the report as the APPG did not actually use this term, albeit that it was critical of the apparent closeness of the relationship between DH and the charities.

For my part, I would describe the relationship as business-like and constructive; I have already acknowledged that there were some areas of disagreement that resulted in tension, but on the whole the relationship was cordial.

Q14. The Identification of beneficiaries of the AHOs

14.1. I have been asked to set out the Department of Health's role in identifying beneficiaries for each of the AHOs. In answering this question, I reiterate that although I was dealing with blood policy issues from 2009 and had some involvement with issues of AHO policy, still the business of the AHOs only became my direct responsibility in October 2011 when I took on the sponsorship role.

14.2. It may also be useful to point out that there are various aspects of 'identifying beneficiaries'. There is the issue of publicity (bringing the scheme to the attention of those who might qualify); there is the issue of trying to identify individuals who might wish to apply and enabling them to submit an application; and there is the issue of the assessment and approval of eligibility, to determine who should qualify.

14.3. My recollection on these issues is as follows:

14.4. Applicants to the Macfarlane Trust: as far as I can remember, DH had no role in identifying potential beneficiaries, which I understand was primarily done through NHS Haemophilia Centres and the Haemophilia Society.

14.5. The Eileen Trust: DH appears to have been central in both identifying and approving beneficiaries for the Eileen Trust when it was established in 1993. From the Scheme of Payments [EILN0000016_001] it can be seen that DH proposed to use communicable disease surveillance records, Blood Transfusion Service records, contacts with solicitors involved in HIV litigation, as well as a press release. I have no knowledge of whether all of these routes were used. I address the question of what steps were taken to assess an applicant's eligibility and how it changed over the years in paras 14.15, onwards below.

14.6. The Skipton Fund: I believe that eligibility criteria for Stage 1 and Stage 2 payments (as well as the level of awards) were set by DH. Eligibility changes that are discussed elsewhere in this statement (Q63) include those announced by the Secretary of State in January 2011. The applications, however, were handled by the Skipton Fund itself.

14.7. To my knowledge, DH had no role in identifying potential beneficiaries for SKF, but I believe the Department was central in publicising the Skipton Fund when it was established in 2004. Others may be able to provide details. When changes to the Fund's payment regime were announced in 2011, DH publicised the scheme through a wide range of routes, identified in Dr Cole's submission of 26 April 2011; I refer to my answer to Q20.

14.8. When the Minister, Ms Milton, met with members of the Haemophilia Society and other charities or campaign groups on 29 June 2011, one of the points that was made was that the 'balance of probabilities' test was not being properly applied. It was said that the Skipton fund application process should be reviewed as the appeal process was very distressing for applicants. *"It would be helpful to have some medical input during the initial assessment of an application"* [DHSC6606436].

14.9. I believe that the Skipton Fund subsequently appointed its first Medical Director. I have not yet been supplied with any internal DH papers on this, but the Inquiry's presentation on the Skipton Fund (22 March 2021) noted that Professor Thomas was appointed to the Board of Directors in December 2012 and joined his first meeting in March 2013,[2] with Professor Dusheiko joining in March 2015.

14.10. The Minutes of the Annual Review of the Skipton Fund on 8 October 2015 record: "*Applications which are not straightforward are considered by the medical Directors of the Fund. There were also more borderline Stage 2 applications, which are often deferred based on the evidence provided. Such applications are also often considered by the medical Directors, whose expertise is appreciated. Where history is less clear, fibroscan levels, and*

[2] CTI Presentation of 22 March 2021, para 11.2.

other evidence, are considered, and the medical directors give an expert view, taking all evidence into account." There was a further note that the Appeals Panel *"met three times last year, considering about 15 cases each time. The caseload for the appeals panel has dropped since the appointment of medical Directors to the Fund"* [WITN0823005].

14.11. MFET Ltd: When established in 2010 to make recurrent payments to infected beneficiaries of MFT and ET, the Department had no involvement in identifying potential new beneficiaries, although there must have been some publicity of the new recurrent payments at that time, which may have resulted in new applicants to the Eileen Trust. When the 2011 announcement was made, extending MFET payments to those most seriously affected by hepatitis C, potential beneficiaries were identified through the same publicity campaign as described in the preceding paragraph 14.7.

14.12. The Caxton Foundation: The availability of discretionary support was also publicised as part of the 2011 announcement, and potential beneficiaries were encouraged to register their interest. Later, in 2014, we asked the SKF to make efforts to contact those to whom they had made a stage one payment, to try to increase awareness of the Caxton Foundation (see further below).

Changes over the Years.

14.13. I have been asked to describe how, if at all this process changed over the years.

14.14. I have commented on the issue of Medical Directors for the Skipton Fund above.

14.15. In relation to the Eileen Trust, this was set up to provide payments to non-haemophiliacs who had contracted HIV through NHS blood transfusions. This required very specific eligibility criteria with a need to ascertain/confirm whether the blood and/or tissue products transfused into the applicant could have been the source of infection. According to the ET Scheme of Payments 1992 [EILN0000016_001], the process included consideration by a panel,

should the Secretary of State wish to refer an application for decision, or should an applicant wish to appeal the Secretary of State's decision. I do not recollect how new applications were dealt with at the time I began to develop knowledge of the payment schemes (early 2009), but I do not recollect there being a Panel in existence.

14.16. I wrote to my devolved counterparts in July 2009 proposing that the Trust should send new applications directly to the Blood Service which served the claimant's area of residence [DHSC6873798]. As far as I can remember, this may have been because ET sponsor colleagues had dealt with a small number of applications during the previous few years and had come to the view that there was no benefit to the applicant or the Eileen Trust in the DH acting as intermediary between the Trust and the Blood Services, which had the information and expertise needed to assess eligibility / the evidence for transfusion, etc. I have requested some assistance in locating the file referred to in DHSC6873798, because this may assist me in providing more detail about the involvement I had or the changes made, but at the time of writing my statement it has not been possible to locate this further information. However, there is a reply to my email to my devolved counterparts in which Caroline Lewis agreed with my proposal [DHSC6873798].

14.17. I have also been reminded of an email to me dated 15 July 2015 [DHSC0041242_217]. In this my colleague drafted a reply to an enquiry from Mr Stevens about three new potential applicants. Mr Stevens had noticed the lack of established procedure in 2012/13. Ms Balabanoff's draft answer included this information: *"Historically, I understand that where a case was not clear cut, we had expert clinicians in DH who we asked to consider the application from an expert viewpoint and provide advice as to whether the applicant meets the criteria for payments. We no longer have such clinicians in the Department, and so each time there is an application we need to identify or procure a specialist/expert who can consider the cases for us. This can include a procurement exercise, if we cannot locate a clinician within the Department or its Executive Agencies [Arms-Length Bodies] who is able to undertake the assessment(s)."*

14.18. There is further reference, at 14.22 below, to the external medical expert whom we consulted in 2015.

Correspondence with Mr Stevens, April 2016

14.19. I do recall a disagreement between myself and Peter Stevens. Looking at the correspondence that the Inquiry has referred me to [AHOH0000091], dating from April 2016, the point of principle that Mr Stevens and I were discussing, was whether or not those who were infected with HIV as a result of a transplant or other qualifying event after October 1985, when HIV screening was introduced, would be eligible for payments from the Eileen Trust. My understanding of the scheme, as set out in the emails referred to, was that they would not.

14.20. Documents that were initially made available to me included an email from Mr Stevens dated 4 July 2015, in which he raised the case of three further applications and how they should be processed. He noted a lack of clarity in this regard, and also that at least one of the claims was based on a transfusion as late as 1998. The draft reply from a colleague (mentioned above at 14.17) raised the issue of whether there was a mid-1985 cut-off date [DHSC0041241_217].

14.21. The matter was not raised in the Annual Review meeting held on 8 October 2015 [WITN0823006] but further documents suggest that it continued to be an issue with some of the new applications received (although they were small in number).

14.22. It appears that the DH enlisted the help of Professor Gazzard to make an assessment of the cause of the HIV infections for the three new applicants. There is an email to Professor Gazzard dated 16 October 2015 setting out what was required for each claim; this made it plain that what was being assessed was whether or not the HIV infection was acquired through (as put forward) a blood transfusion; there was no mention of any cut-off dates [DHSC0041242_038] However the discussion of the final assessment with Professor Gazzard suggests that the 'cut-off date' approach was being applied: see [DHSC0041242_125, 4 March 2016] and the last of the three

cases being discussed. The likelihood of infection via transfusion in 1992 was "low" but "in any case" it was after the eligibility date for the Eileen Trust. It therefore appears that the approach of applying a 'cut-off' point was being applied, although this went hand in hand with an assessment, by an expert, of the probability of infection after the introduction of screening.

14.23. I have now been provided with further correspondence which shows that I asked my team to seek advice from our lawyers on this point, as indicated in an email from Monika Preuss to Yvonne Stupple dated 20 May 2016 [DHSC0006618_020]. This confirmed Mr Stevens' interpretation and I accepted that I had been mistaken in thinking the Scheme had a cut-off date. Two of the three applicants referred to in para 14.22 had previously been accepted as eligible for the scheme in March 2016. My colleague, Dr Preuss, pursued the third applicant's claim with NHSBT, who could find no records for the individual. NHSBT remained willing to pursue the matter further if, for example, the applicant's clinicians believed that the infection was transfusion-related and submitted a report. Dr Preuss wrote to the applicant on 16 June, informing them that their application had been unsuccessful but inviting them to submit further evidence such as a letter from their clinician, and the application would be reconsidered.

Q15. Contact with members of the beneficiary community

15.1. I have been asked about my contact with the beneficiaries of AHOs whilst at the Blood Policy Unit.

15.2. I and others at the Department of Health had considerable contact with members of the beneficiary community over the years. Contact included the meetings between Ministers and members of this community ([WITN1055150] and [HSOC0029810] are examples of this), Haemophilia Alliance meetings and meetings with charities such as the Haemophilia Society.

15.3. *Ad hoc* contact included occasional telephone calls with individual beneficiaries, sometimes instigated by them and sometimes by me. I cannot remember the details of those calls, but I think they generally related to plans

for forthcoming meetings with beneficiary groups, as well as discussions on the differing perspectives of those groups.

15.4. In around 2010, following the Archer Report, DH committed to regular meetings with the Haemophilia Alliance, which was an existing forum comprising representatives from the Haemophilia Society and haemophilia doctors, together with other professions involved in haemophilia care. Meetings were held at DH in London, with the DH providing funding to host the meetings as well as providing the secretariat. The first meeting was introduced by Dr Ailsa Wight from DH, and I attended most of the subsequent meetings to represent the DH Blood Policy Team, although Dr Ben Cole (Senior Policy Manager in my team, who acted as secretary for the meetings) stood in on one occasion when I was unavailable. Patient representatives from the DAs attended by phone, as sometimes did officials from the DAs. See for example [HCDO0000272_004], which is a record of the third meeting. It provided a forum for the beneficiary community to have reasonably regular meetings with us. Experts would also attend, as well as other colleagues from the DH beyond Blood Policy.

15.5. My recollection is that these meetings could be quite tricky because we were not always able to address issues raised by campaigners, which they wished to see addressed. For example, I have a general recollection of a discussion about NHS haemophilia treatment where, I believe, the campaigners wanted a certain approach to be nationwide. But we could not give instruction to the NHS in England, and decisions about healthcare in the DAs were their responsibility.

15.6. My attention has been drawn to page 26 paragraph 54, and page 33 paragraph 11 of witness statement WITN3988001 and page 54, line 18 of the transcript from oral evidence provided by witness WITN3988001 to the Inquiry at a hearing on 10 June 2021, which speaks about the discontent of one of the members of the beneficiary community and her feeling that issues were being "blocked" by myself and my colleague, Ben Cole. Again, I can only emphasize that my intent and the intent of the Department was not to "block"

issues. Likewise, when speaking at the meetings, it would never have been my intention to be condescending.

15.7. The witness statement is also critical of the late circulation of meeting minutes. I recollect an occasion when there was a delay in circulating the minutes because I had not been able to review them in a timely way. For that I apologise.

Q16. Knowledge and understanding of the needs of the beneficiaries of the AHOs

16.1. I have been asked about my understanding of the needs of beneficiaries of the AHOs whilst at the DH. I became much more aware of the needs of the beneficiary community as I became familiar with their situation (see further para 16.4).

16.2. I have been asked specifically about the sources of my understanding. From a policy perspective, my initial understanding began to develop in 2009, when I was asked to brief the Minister of Health on the recommendations made in the Archer report.

16.3. That was my first direct involvement in this area of policy although I can recollect earlier discussions between colleagues in DH about the document entitled "Funding long-term survival", submitted jointly by MFT and ET in late 2005, in which the charities made a case for a combined additional £7m annually in order to meet beneficiary needs. I do not remember seeing the document at the time, but remember discussions about the longer than expected survival of many of those infected with HIV, and the financial disadvantage they had to endure.

16.4. Post-Archer, my understanding of beneficiary needs was informed greatly by meetings and correspondence with the AHOs, clinicians and many beneficiaries themselves, both campaigners and also those affected who did not actively campaign.

16.5. However, there were very many sources of my understanding after this and particularly so from 2011 when I took over sponsorship of the AHOs.

Q17. Tensions between the beneficiary community and the AHOs

17.1. I have been asked about my awareness of any tensions between the beneficiary community and any of the AHOs. There were many tensions between the beneficiary community and MFT in particular, and I recollect that we received letters of complaint from MFT beneficiaries.

17.2. It must have made the work of the AHOs much more difficult as well as the grievances being an obvious source of unhappiness to the beneficiaries.

17.3. I think I tried to defuse tensions when the opportunity presented itself, e.g. in conversation with individual campaigners, when the subject arose, but I am not aware that DH took any specific action, save insofar as it made reforms to the schemes (including the funding available) following reports such as that from Lord Archer or in response to other pressures. Thus, we had hoped that when regular annual payments were introduced for those with HIV in 2010 it might help diminish tensions between MFT and its beneficiaries. I believe this may have happened to some extent, but I cannot comment further on this point.

The Skipton Fund

Q18. Involvement in the set-up of the Skipton Fund

18.1. I have asked if I had any involvement in setting up the Skipton Fund, but I had no involvement. The Skipton Fund was established in 2004 to support those infected with hepatitis C through National Health Service contaminated blood and blood products. As I have explained already above, my work did not involve the AHOs until much later.

Q19. Stage 1 and stage 2 payments (2004)

19.1. The Inquiry has asked me about the basis upon which the level of stage 1 and stage 2 payments were set. Again, I had no involvement in establishing these initial awards. But I have been referred to [MHRA0024725]. This is a briefing note that I prepared for a meeting between the Secretary of State (Alan Johnson MP), MS(PH) (Dawn Primarolo MP) and Lord Archer on 11 March 2009, to discuss the report of Lord Archer's independent inquiry.

19.2. A summary of the payments made by the Skipton Fund is set out at pages 10-11 of the briefing note. The briefing note explains that the scheme was set up in 2004 to make *ex-gratia* payments to persons who were treated in the United Kingdom under the NHS by way of the receipt of blood, tissue or a blood product and as a result of that treatment became infected with the hepatitis C virus.

19.3. Every person in the UK who was alive on the 29 August 2003 and whose hepatitis C infection was found to be attributable to NHS treatment with blood or blood products before September 1991 was eligible for the payments. The scheme meant that people infected with hepatitis C would receive initial lump sum payments of £20,000 (referred to as stage 1 payments) and people who developed more advanced stages of the illness, such as cirrhosis or liver cancer, would get a further £25,000 (referred to as stage 2 payments).

19.4. As explained at page 11 of the briefing, the level of stage 1 and 2 payments were based on proposals made by the Scottish Executive. The structure was decided after comparison with the level of payments made by the Macfarlane Trust Fund and the Eileen Trust and the recommendations made by the Lord Ross expert group in Scotland.

Q20. Publicity for the Skipton Fund

20.1. I am asked what steps the Department took to publicise the Skipton Fund. I do not know what publicity there was when the fund was set up because I had no involvement at this time.

20.2. However, I would assume that this question relates to the announcement by the Secretary of State for Health (Andrew Lansley MP) in January 2011, that there would be increased lump sum payments for those with the most serious consequences of hepatitis C infection, together with a widening of the eligibility criteria for Skipton Fund payments. We made concerted efforts to publicise these new payments (and also the existence of the new fund that would become the Caxton Foundation), using press notices, news items in NHS bulletins for medical and nursing professionals, the Skipton Fund itself, the

Hepatitis C Trust, NHS Choices, DH twitter feeds and website, and local information bulletins. I refer to this again in para 26.1.

20.3. See further the submission from Ben Cole, dated 26 April 2011 [WITN0823007], updating the Minister of State for Public Health (Anne Milton MP) and the Secretary of State. This stated that the new measures for existing Skipton Fund claimants (Stage 2 and pre-2003 catch-up claimants) had been *"publicised as widely as practicable, without paid-for advertising or public relations. The SKF, with help from DH officials, has also completed a ring-around of its existing stage 2 claimants who are eligible for the new payments but had not previously come forward. However, a significant number of those individuals could not be contacted because the SKF did not have up to date contact details for them*". It should be noted that because the Skipton Fund made one-off payments to its beneficiaries, it had no ongoing 'business need' to maintain contact with those beneficiaries.

Q21. Registration Deadline, 2011

21.1. The Inquiry has noted that following the review of the Skipton Fund in 2011, it was decided to extend the deadline for registrations in respect of patients who had died before the inception of the Skipton Fund.

21.2. I recall that when the Skipton Fund was established, the scheme did not cover widows or dependents of patients infected with hepatitis C, through blood or blood products, when those patients had died before the scheme was announced on 29 August 2003. This is documented in page 11 of the briefing note I have referred to above ([MHRA0024725], see Question 19). At page 12 of the briefing note, I highlighted this anomaly and set out that one of the ways it could be rectified would be to extend the Skipton Fund to make payments to the estate of patients who had died of hepatitis C before the scheme was announced. My recollection is that many of us in the Department felt this situation was unfair and wrong, and we recommended to Ministers that it be corrected.

21.3. The Government's response to the "Review of Support available to individuals infected with Hep C and/or HIV by NHS supplied blood transfusions or blood

products" [WITN4688072] was announced by the Secretary of State on 10 January 2011. The Secretary of State stated that before the end of March 2011, posthumous claims could be made on behalf of patients infected with hepatitis C who died before the Skipton Fund was established on 29 August 2003.

21.4. I believe that the deadline of the end of March 2011 was set for budgetary reasons and following a direction from DH Central Finance. This is reflected in some of the internal DH documents that have been located, in which updates on the progress of implementation of the policy announcements were provided. These refer to the 31 March deadline as aiming to incentivise claimants to come forward within the 2010/11 financial year, so as to reduce the risk of establishing an unfunded pressure in the 2011/12 financial year (see paragraph 9, at page 4 of [DHSC5658283 and WITN0823008]). DH Central Finance's advice was that the following year's budget contained little room for manoeuvre. The records indicate that the internal view was that the deadline was not a firm one, so would be extended – but plainly the hope was that early claims would be forthcoming. [WITN0823047] makes clear that it was always Ministers' intention to accept claims after this date. As in relation to so many issues, either the substantive decision or a matter of handling was driven by financial constraints or considerations.

21.5. I have been referred to a letter addressed to me, from Dr Charles R. M Hay (Chairman, United Kingdom Haemophilia Centres Doctors' organisation (UKHCDO)) dated 18 January 2011 [PRSE0004024], with the subject: *"Review of support available to individuals infected with Hepatitis C and/or HIV by NHS supplied Blood or blood products and their dependents"*. Dr Hay explained that he had been asked by the UKHCDO to approach the Department to request an extension of the deadline for the registration of dependents of patients who died before the inception of the Skipton Fund.

21.6. I do not now recall whether I replied to Dr Hay in writing, or by way of a telephone call, but I am certain that I would have replied and said that an extension of the deadline would be very likely to be granted. I may have had

to be circumspect in my reply, given that at that time (January 2011) DH's public position was that the 31 March deadline still applied.

21.7. I cannot recall what action was taken by myself or others in the Department in seeking further advice on possible changes to the Skipton Fund's eligibility evidence. I have seen the email exchange referred to in [DHSC5655747], which discusses how advice on eligibility evidence might be sought, but have not seen any later documentation that clarifies resulting actions.

The requirement for supporting documentation.

21.8. I am asked by the Inquiry if I was concerned about the points raised by Dr Hay in his email to Nick Fish (the Skipton Fund Scheme Administrator) and copied to me, dated 25 January 2011 [DHNI0000314_003]. In particular, the Inquiry refers to Dr Hay's concern that applicants would fail because of the requirements for supporting documentation, where notes may have been lost or destroyed or the patient may have died before the advent of HCV antibody or PCR testing.

21.9. I note that DHNI0000314_003 includes a response from Nick Fish, in which he stated:

> *"I share your concerns on some people not being able to furnish sufficient evidence for the purposes of the application. However, we hope that with a combination of I) information printed on the death certificate...II) records held at Haemophilia Centres III) records retained by the estate and IV) records which still exist at the hospital and/or GP surgery, most people will be able to receive a payment where it is due. For applicants which are declined there is always the appeals system whereby the medical knowledge and experience of the panel members may be sufficient to overturn certain unsuccessful applications".*

21.10. I understood the point that Dr Hay raised in his email. However, my view was that UKHCDO were very active in assisting applicants to the Skipton Fund, and the UKHCDO would do whatever they could to further assist pre-2003 applicants to the Skipton Fund. I refer again to [DHSC5655747], which includes an email sent by me on 28 January 2011, to my colleagues within

the Department and which relates to the emails between Dr Hay and Nick Fish This also discussed whether further expert input was needed, or further guidance, on handling these 'early' claims. I do not now recollect the outcome of this discussion and have not seen any further documents that could assist.

21.11. I am asked whether I considered the Skipton application system to be fair for applicants for whom medical records were no longer available or where the patient had died before the advent of hepatitis C testing. There has to be an evidential basis for giving out public money and I felt that the Skipton Fund would do everything they could to come to a fair judgment on each case. Each year, there had been new applications to the Skipton Fund, where there was little remaining documentation, but which were judged to be valid by the Appeals Panel on the balance of probabilities. In the absence of clear supporting evidence, the experts would make a judgment about whether it was more likely than not that someone might have been infected by a transfusion. The Skipton Fund's processes were strengthened by the appointment of the first Medical Director (Professor Howard Thomas) in 2012, and a second Medical Director, Professor Geoffrey Dusheiko, in 2015.

3. The Set-up of the Caxton Foundation

Q22. Awareness of problems with the Macfarlane Trust

22.1. I have been asked whether the Department of Health was aware, in 2011, of any problems with the Macfarlane Trust. As I remember, there had been some internal management difficulties resulting from the Chief Executive's (Mr Martin Harvey) long-term absence as a result of GRO-C, although I do not recall the detail, and I believe he was back in post by the time I took over AHO sponsorship. I also recall that there had been on-going dissatisfaction amongst some of the Trust's beneficiaries. I refer to these points again in my response to Q. 89.

Q23. Rationale for the Caxton Foundation

23.1. The Inquiry has asked about my understanding of why the Department of Health decided to provide monies to the Caxton Foundation for the benefit of

Skipton Fund beneficiaries, rather than providing financial relief directly themselves.

23.2. To recap, the purpose of the Caxton Foundation was to provide discretionary financial assistance and other benefits to meet "any charitable need" of individuals who had received blood, blood products or tissues from the National Health Service and in consequence had been infected with Hepatitis C (or been infected by someone who had received any of these); or the needs of (broadly) their dependants. Until Caxton was established, those affected solely by hepatitis C did not have access to needs-based funding. The thinking was to try and get parity between the Hepatitis C community and the HIV community who already had such charitable access. It would have created another anomaly if direct relief had been provided directly from the Department. Thus, we were trying to maintain parity in terms of the mechanisms for support across the beneficiary community.

23.3. I have been asked a number of further questions about this issue.

Replication of dissatisfaction

23.4. I have been asked if I (or anyone else in the Department of Health) were concerned about the beneficiary dissatisfaction with the Macfarlane Trust replicating itself with the Caxton Foundation. In answer: first, yes, we knew it was a risk, but we considered it important to align the hepatitis C community with the HIV community in this respect. Further, introducing any other arrangements that did not 'mirror' the MFT would have created another anomaly and introduced another cause for unhappiness, albeit a different one.

23.5. I have further been asked whether any consideration was given to providing access to additional financial support to Skipton Fund beneficiaries via a non-charitable vehicle, so as to avoid beneficiaries having to show 'charitable need' in order to access financial support.

23.6. However, this was what had been done by the announcement by the Secretary of State, in January 2011, of increased lump sum payments for those whose health was worst-affected by hepatitis C, as well as new annual

payments in line with those already made in respect of HIV – these were all new Skipton Fund payments. The Secretary of State also announced the establishment of a charitable vehicle for hepatitis C-affected individuals, which was to become the Caxton Foundation. All the elements of the announcement have to be linked together.

Q24. Consistency across the Caxton Foundation and the Macfarlane and Eileen Trusts

24.1. I have been asked why the Department of Health sought consistency between the Caxton Foundation and the Macfarlane and Eileen Trusts.

24.2. The Department tried to seek consistency or "read across" between the Caxton Foundation and the Macfarlane and Eileen Trusts in order to minimise dissatisfaction, or even, potentially, claims of discrimination. "Read across" was a Ministerial objective.

24.3. In relation to this, I have been referred to [HPCT0000210_015], which is a record of a meeting held on 18 February 2011 (not 2001 as the question suggests). As the Inquiry acknowledges, I did not attend, but the notes record my colleague Debby Webb stating that "to avoid the risk of creating new anomalies" it would be important for the functions of the new charity not to be too different from MFT and ET. Graham Kent (also DH) agreed that there should be consistency across the three trusts. For clarity, part of the background to the 2010/2011 work had been the argument that those suffering from HCV (and not co-infected with HIV) had access to more restricted financial support.

Q25. Appointment of User Trustees, Caxton Foundation

25.1. The Inquiry has referred me to CAXT0000095_016, which is the minute of a meeting held at the Department of Health on 28 June 2011, at which the Caxton Foundation Trust Deed was signed. I note from the minute that I was present at this meeting.

25.2. I have been asked by the Inquiry if I was concerned about Mr Evans' decision not to appoint a user Trustee. In short, my answer is that I was not. I believe

my understanding of this conversation at the time was that Mr Evans meant a beneficiary trustee, i.e. someone who would use the services of the Foundation. My recollection is that we had a number of discussions with Roger Evans and also, I believe, Peter Stevens, about the pros and cons of having a beneficiary as a trustee. We were sympathetic to the idea of a user trustee. But we also recognised the problem of potential conflicts of interest should a beneficiary also be appointed as a trustee, so we were content with his judgment to proceed without a user or beneficiary as a trustee. At a later date, the Caxton Foundation decided to appoint a trustee who had experience of living with hepatitis C, and this appointment was agreed.

Q26. Publicity for the Caxton Foundation

26.1. I have been asked what steps were taken to publicise the Caxton Foundation. I believe the establishment of a new charitable body was publicised alongside the other changes announced in January 2011. I have been shown a response from Nick Johnson in DH press office to my colleague Gerry Robb's questions about press coverage of the Secretary of State's announcement [DHSC5043634] which indicates that it received "modest national coverage and a really good prominent page spread in The Times". I have also looked at [HPCT0000210_015], the record of the meeting of 18 February 2011 (although as previously noted, I did not attend and the Inquiry may therefore have been intending to refer to another document when it says that I expressed views in that meeting). The meeting minutes refer to a communications paper that had been circulated showing the communications activities DH had undertaken thus far [DHSC513026]. These comprised a DH press release, a feature on the front page of the DH website and also on Directgov; features on the NHS Choices homepage, the Hepatitis C Trust homepage, the Skipton Fund website; features in professional bulletins (for Trust Medical Directors, GPs and Nurses); letters to MPs, an alert to the Hepatitis C Information Line, and links on local information sites [DHSC5131026]. My colleague, Debby Webb also said that a press release was planned for early March.

26.2. I have been specifically asked why it took until August 2014 for the DH to ask the Skipton Fund to contact those who had received a payment from the Skipton Fund, to inform them about the Caxton Foundation. I believe there had been efforts by the Caxton Foundation to reach further potential beneficiaries since its establishment. These had met with some success, but I recollect the Caxton Trustees were concerned that many of those affected did not yet know about the Foundation. As I remember, on various occasions we had discussed with Peter Stevens and Nick Fish whether the Skipton Fund could help, but the difficulty was that Skipton did not maintain contact with people to whom it had made a Stage 1 payment. There had been no need for it to do so when the payments were originally made, as the Stage 1 payment was a single lump sum. Skipton had managed to trace some of the Stage 1 recipients after the 2011 announcement but it was clear, by the time the Caxton Foundation published its Annual Report for 2013/14, that there were still many likely eligible people who were not aware of its existence. We therefore formally asked the SKF to update their contact details for people who had received a Stage 1 payment, and in doing so, inform them about the Caxton Foundation. This was a significant piece of work for the SKF, and resource-intensive. As I remember they had to recruit some additional temporary staff to help with the work.

Q27. Meeting with Jan Barlow, November 2012

27.1. The Inquiry has drawn my attention to [CAXT0000109_096], which is a short report from the interim CEO, titled 'Caxton Foundation Board Meeting 1 November 2012". The interim CEO notes they had met with me and my colleagues. It is said that our concerns centred on *"communication of information and the uncertainties around leadership and plans for new accommodation"*. The interim CEO noted that, *"these concerns are not severe and can be addressed with controlled provision of management information on a regular basis"*. Given the passage of time, unfortunately, I do not now recall having had those concerns at the time, and would need access to further documents to provide any more details.

4. Appointments of Trustees/Directors

Q28. The appointment process for the AHOs

28.1. The Inquiry has asked what I knew about the appointment process for the AHOs (presumably, the Trustees and Directors) during my time at the Department of Health.

28.2. I remember that it was not always easy to secure individuals for appointment as Trustees. They were voluntary positions. The position of Director was less difficult. It only arose in relation to MFET Ltd, and DH appointed Peter Stevens and Roger Evans as Directors, as both had considerable knowledge of the HIV charities. Whilst I was involved, Mr Stevens served as the Director of the Skipton Fund and as Chair of the Eileen Trust and a Founding Trustee of the Caxton Foundation; his experience across all these areas was invaluable.

Q29. The involvement of the Department of Health in appointments

29.1. I have been asked about what involvement I had, and the Department of Health had, in this process for each of the AHOs during my time at the Department, and whether my involvement changed over time.

29.2. From Oct 2011, my team took over responsibility for dealing with appointments to the AHOs. That may have involved inviting Ministers to confirm re-appointments where an existing appointee was willing to serve another term, or it may have involved inviting Ministers to approve new appointments. To the best of my recollection, I think the individual AHOs ran their own advertising and selection campaigns, and then notified us of their chosen candidates.

Q30. Selection Processes

30.1. The Inquiry has asked how the Department selected the candidates that it put forward as trustees of the AHOs (when this was part of its remit) and in particular what qualities the Department was looking for; also whether the positions were advertised, and if so where.

30.2. I note from a submission on appointments from Ted Goff in February 2009 [DHSC0041240_165] that DH had run a recruitment exercise for a new

medical Trustee for MFT. It is apparent that an interview panel was convened, but there is no information on the panel's composition.

Q31. DH Involvement in Selection of Trustees

31.1. I have been asked about the purpose of the Department of Health's role in the selection of trustees/directors of the Macfarlane Trust, the Eileen Trust and the Caxton Foundation, given their status as independent charities.

31.2. Each of the charities had a board of trustees. Director posts were relevant only to the two companies limited by guarantee, the Skipton Fund and MFET Ltd. With regard to the charities, as their founder, DH needed to appoint the initial Trustees. I was only party to these appointments for one charity, the Caxton Foundation. As it was our intention that there should be "read-across" between the new charity and the existing charities (Macfarlane and Eileen), we asked Peter Stevens and Roger Evans to act as founding trustees, together with Charles Gore, Chair of the Hepatitis C Trust, who could bring expert knowledge of issues facing the hepatitis C community. The founding trustees then made their own decisions regarding appointment of further trustees. As for the requirement for Ministers to approve appointments of trustees, I have no knowledge of the purpose of the continuation of that function, but did not find it unreasonable, given that the charities were established to operate a government-funded scheme. To my knowledge, those appointed to trustee posts by DH were not influenced by the Department and operated in line with what was required of them as trustees.

Q32. Caxton Foundation Trustees.

32.1. Schedule 2 of the Caxton Foundation Deed [CAXT0000095_006] required the Trustees to seek the Founder's consent to appointment of new Trustees. There was an option in the Deed, for the Founder (i.e. the Secretary of State or his/her representative) to refuse consent within eight weeks of the request being made.

32.2. To the best of my knowledge, this veto was never exercised. The more typical process can be seen at [DHSC6611838], which is a submission to PS (PH) from Mr Cole dated 30 August 2011 (copied to me) in which he recommended

that the Minister approve the appointment of six Trustees. He noted that there had been an open competition. The posts were advertised in the national media. The selection panel consisted of the Founding Trustees (who had been appointed by the Department at the start-up of the Trust), plus the Chair of the Haemophilia Society who acted as an independent assessor. The recommendation was for Ministerial approval.

32.3. I have been asked what the Department's view would have been, had there been a proposal to appoint a campaigner to the position of Trustee. This is a hypothetical question, so I cannot answer with confidence. Also, there might have been a variety of views in the DH. For my part, I knew that MFT had had some trustees who were also beneficiaries, and – perhaps to a greater or lesser degree – campaigners. So it had been done; the Inquiry may well have heard evidence as to the issues that it threw up. I would probably have been concerned to ensure that matters such as conflicts of interest (in policy-setting) as well as confidentiality were considered and addressed. I have already discussed above whether there was a distinction between lobbying by the AHOs and public campaigning, and there could have been issues about the boundaries between these, and the use of information in different capacities. But, as I said, the issue never arose.

Q33. Difficulties in the appointment of new trustees/directors at the AHOs

33.1. I have been asked whether there were difficulties in appointing new Trustees. My recollection is that it was not easy to find individuals who wanted to take on the role. That said, the Ministerial submission discussing the appointment of the new Caxton Foundation trustees (referred to above) shows the range of experience and expertise of those who applied for the role.

Q34. User trustees

34.1. I have been asked if the Department of Health had a view about user trustees. I have already referred to this issue at paragraph 25.5 above; please refer to this.

Funding of the AHOs

Q35. Process for the Provision of Funding to the AHOs

35.1. I have been asked about the process by which funding was provided to the AHOs. This is really a question that my financial colleagues would need to answer, especially as I do not have access to financial papers.

35.2. I have specifically been asked about the following:

35.3. *My understanding of why in about 2007 funding changed from a three yearly cycle to an annual cycle:* I am afraid I do not know, not least as this predates my involvement with AHO policy.

35.4. *The annual 'top-up' funding process:* I would need to defer to financial colleagues.

35.5. *Late information about annual allocations*. The Inquiry has commented that it has heard evidence that the Department of Health were very slow to inform the AHO's of their annual allocation. I have been referred to [MACF0000060_016], which is an email from Roger Evans to Dr Ailsa Wight, to which I am copied in and dated 7 January 2013. Mr Evans expressed that he and the Board were anxious to receive information from the Department about their financial allocation for 2013/2014, that they had not been provided with a *"financial principles document*" as promised, and that the information was essential prior to the January board meeting in order to develop the financial strategy.

35.6. I am afraid that this was reflective of the timing of processes in the Department in general. No part of the Department would know what its allocation was until Ministers had reached decisions on the funding available to all; the sums available were then apportioned. (There is a little information in [HPCT0000210_015] although this relates to a meeting in February 2011 before I took over the sponsorship role). Again, financial colleagues could explain the overall process better, but I do not think that this was an issue confined to the AHOs.

Q36. Changes to Financial Process

36.1. The memory that I now have, is that financial scrutiny (from Finance Division) increased from about 2010 onwards, as a consequence of the recession and spending constraints.

Q37. Section 64 Grants

37.1. The Inquiry has asked me about whether DH was making Section 64 grants when I was in post.

37.2. I have been referred to [DHSC0032299_116], which is an email from Robert Finch to Helen Christmas in relation to section 64 grants dated 5 November 2002. This and related emails were general communications about s64 grants, that would be widely circulated; I was not copied in because of any AHO involvement.

37.3. [DHSC0038526_024] is then an email chain from 2004 regarding section 64 grants for the AHOs and movement away from them. The general thrust of the emails was to express the view that the use of section 64 funding was not an appropriate way of providing the Macfarlane Trust and Eileen Trusts with their 'core' administrative costs. The Trusts also wanted to move away from Section 64 funding and that was also the view of Ministers. But I was not involved in correspondence on this issue either.

37.4. By the time I was involved more directly with AHO policy, I believe that the use of s64 grants to pay the administrative costs of the AHOs had ceased; indeed as I remember, the use of s64 grants had generally come to an end. Arrangements had also been made to share the budgeted operating costs across the AHOs as a whole.

Q38. Budget-setting for the AHOs

38.1. I have been asked how the Department set budgets for the AHOs.

38.2. Broadly speaking, I recollect the allocation for the HIV charities was usually based on the previous year's allocation. The Department of Health set the budgets by dividing the available money between the Trusts. It would be

divided on the basis of the proportion of beneficiaries that each trust had, that is, the proportion of primary beneficiaries i.e. those who had been directly infected. For the Macfarlane Trust this was 96% and the Eileen Trust 4%.

38.3. I recall that we discussed needs with the AHO charities and would suggest that a business case should be prepared if they wished to bid for additional discretionary funding. If more detail was needed, we would ask for this. Bids were then considered within the Department; financial colleagues would again be able to give greater clarity. But the overall pressures were very real. See for example [MACF0000025_046], the note of the MFET Ltd Annual Review Meeting on 5 March 2012. This records that the funding allocation for 2012/13 financial year was discussed and the DH confirmed that MFET Ltd allocation would be £7.5 million. Christopher Fitzgerald, the MFT Chair, noted that the 2012/13 allocation for discretionary funding was lower than in 2011/2012. The note continued:

"Rowena Jecock explained that there is downward pressure on all DH funding, and that Alliance House colleagues should expect that this would continue in future years, and plan accordingly".

38.4. I am asked to explain what impact the downward pressure on budgets, referred to in [MACF0000025_046] had on the funding allocations made to the AHOs. The ongoing downward pressure on Departmental budgets resulted in decreased or level funding to the AHOs in subsequent years. Someone from DH Central Finance team would be better placed than I to explain how decisions on funding allocations to the AHOs sat within the wider context of budgetary pressures within DH at that time.

Q39. <u>Operating balances for the three Charities</u>

39.1. I have been asked to explain the reasons why DH set operating balances for the three AHO charities, given that they were intended to be independent of government.

39.2. I recall that this was done as a result of the increased scrutiny on budgets by central DH finance team, resulting, as I have already indicated, from the

significant downward pressure on all government expenditure. My colleagues in finance at the Department had said to us that the charities should not be holding reserves, but rather that they should hold reasonable operating balances, which would enable them to cover any unexpected costs. Reserves were considered unnecessary for the charities as they were not dependent on external fundraising but had a steady funding flow from DH. Again, these accounting issues could be better explained by Finance Division colleagues. But I have discussed at paragraph 13.3 above, how independence in determining policy and payments to beneficiaries was not regarded as incompatible with a degree of accountability to DH regarding financial stewardship or accounting processes.

39.3. I had little direct input into the setting of budgets or operating balances as far as I remember, although I remember discussions with central finance colleagues in which Dr Wight and I argued the case for maintaining the annual allocation for the charities. I would also have agreed the proposed operating balance for each of the AHOs once my Finance Liaison Officer had made an assessment, and before it was communicated to the AHO in question. I recollect discussions between my Finance Liaison Officer and our Business Partner in the Central Finance Team, on the factors that should be considered when deciding on an appropriate level for each operating balance. We required the charities to provide us with evidence so that we could work out what a reasonable operating balance would be, and this involved looking at prior expenditure. The operating balances took account the degree of certainty of spend. So, we would not look at just the previous year but a number of years in order to get a feel for how expenditure fluctuated. I recall that because the Caxton Fund was new in 2011, we had no basis to determine their operating balance and so they got a higher operating balance than the Macfarlane Trust, which was much longer established – see below. We also asked the charities to invoice us at reasonable and regular intervals throughout the year, so that they would have funds to make the payments that they needed.

39.4. The Inquiry has referred me to some minutes of a Meeting between the Department of Health Blood Policy Team and the Caxton Foundation from 5 December 2011 [CAXT0000108]. Dr Wight, Julie Lucas and I attended from the Department. Peter Stevens, Roger Evans and Mary Leadbetter attended from the Caxton Foundation. The minute records that a sum of £100k (5%) had been agreed as an *"initial reserve"* and that this would be provided *"with a view to reviewing this early in the next financial year, once more information on discretionary payments [was] available"*. The minute illustrates how the setting of this amount was a matter of judgment, in the first year of operation. I note that the minute also records the concerns of some of the Trustees about cash flow and that *"being too heavily reliant on DH for money to fulfil its commitments blurred the line of independence"*. Dr Ailsa Wight is noted to have acknowledged these concerns, but she stated that it was "*early days*". Although the term "reserve" is used in the minute, a statement from the Caxton Foundation Annual Report for 2012 [CAXT0000034_010_010] indicates that, later in 2012, the Department had decided to provide an operating balance for Caxton in lieu of a reserve: *"In the period of this report, Caxton was negotiating with the DH an appropriate level of reserves…Since the period end, it has been agreed that Caxton will not hold a reserve. This will be kept under review."*

39.5. The Inquiry has also provided me with a copy of [MACF0000025_074], which is a note of a meeting between Martin Harvey of Alliance House, with myself, and Ben Cole from the Blood Policy Team, on 4 May 2012. The note provides an example of how we would approach working out the size of the operating balances. The note records that the Department was prepared to accept *"soft"* information to help estimate a reasonable level for the operating balance for each body, using examples from previous years (page 1). Various specific examples are then noted, such as, how often it had provided necessary to dip into the operating balance in the past, what the maximum amount that had ever been needed in the past was, whether there were other factors that might justify an upward or downward revision of the figure in current/future years (pages 1-2). [MACF0000051_006] is a series of emails between Naomi Balabanoff and Jan Barlow in February 2013, which explains the DH decision

to set the MFT operating balance at £60k, rather than the £220k initially requested by Roger Evans. Operating balances were intended to cover sudden and unforeseen expenditure. For MFT, the only unforeseen expenditure was for one-off grants or loans, amounting to up to £20k/month. Consequently, the operating balance was set at three times this amount to reflect the fact that funding was provided to MFT on a quarterly basis (for the first three quarters of the year, and then monthly). Ms Balabanoff also explained that MFT should submit their quarterly invoices to the Department 20 days ahead of making the payments for that quarter, in order to ensure that sufficient funds were available.

Q40. Periodic Payments.

40.1. I am asked why the Department only released the Caxton Foundation's allocation as it was spent during the year, rather than one annual payment.

40.2. In response I would say that, as far as I am aware, it was a matter of standard practice: the Department would not usually provide an entire years' expenditure to an organisation and expenditure would usually be released throughout the year upon receipt of periodic invoices. I have explained how we expected invoices for planned expenditure on a timely basis, so that funds were in the AHOs' account before payments needed to be made.

Q41. Source of AHO Funding

41.1. I have been asked to clarify whether the funding for AHOs have come from a different 'pot 'of money to the NHS allocation.

41.2. It is correct that the funding for the AHOs did not come out of the NHS allocation: it came from the DH revenue budget. See further the documents referenced in Q47. The funding was a part of the Department of Health's budget. A finance expert would be needed to give further details of how the Departmental budget was divided between the various calls on it.

Q42. Bids for Funding Increases

42.1. The Inquiry has noted that over the years, a number of bids were made for increased funding allocations.

42.2. The first example is one from the end of 2005, when a business case for a substantial increase in funding (to £7.5 million per annum) was made to the DH [MACF0000177_017]. However, that was not a matter I had any involvement in, being before I was involved with the AHOs in 2009.

42.3. MacFarlane Bid: I have then been referred to three documents which refer to a request made by the Macfarlane Trust to increase its allocation for the year 2014/2015 from £2.2 million to £3.2 million.

42.4. Thus [MACF0000026_088] is a draft letter addressed to me from Roger Evans (Chairman of the Macfarlane Trust) in which Mr. Evans asked for an increase in the Trust's allocation from 2014/15 for the 2015/16 financial year and future years. In his letter, Mr. Evans noted that the £2.2 million annual allocation from the DH left the Trust with an operational shortfall of approximately £800,000 per annum and that the Trust had been required to fund the shortfall through reserves that it still had available. Mr Evans noted that they could afford to do that for a further two financial years but that after that point (April 2017) if an increased allocation had not been received then they would have to *"significantly reduce"* the level of support given to the Trust's beneficiaries and that they would need to provide the beneficiaries with *"significant advance notice"* of the same. The draft letter also refers to the Trust's annual review meeting which was due to take place in the Department on 11 November 2014.

42.5. MACF0000026_058 is the Annual Financial Report of Macfarlane Trust for the year ending 31 March 2014. The passage at the bottom of page 3 is of particular note. It records that the Trust had *"partial success in 2013 regarding its negotiations with the DH over its financial allocation for 2014/15"*, in that the DH had agreed to a figure which was *"effectively, the same as the previous year"* but that *"bearing in mind the reductions being made elsewhere in public spending budgets, this was the best outcome [they] could have expected in the circumstances"*. The Report noted that the Board had agreed to continue supplementing the annual DH allocation from the reserve funds but that moving forward that would not be sustainable. The Report acknowledged that it could not be assumed that the DH would increase their budget but that the

Trust would *"nevertheless, continue to press strongly for an increase in annual funding"* (page 3).

42.6. MACF0000062_001 is a letter from Dr Wight to Roger Evans, responding to his *"business case for increased funding from 2014/15 onwards"*, dated 19 February 2014. Dr Wight relayed that Ministers had decided that it was not the right time for an uplift in allocation. Following the Westminster Hall debate of 29 October 2013, Ministers were continuing to consider how best to address a range of issues about the system of support available for those affected by contaminated blood. Dr Wight again contextualised the decision not to increase the trusts allocation in previous discussions about the continuing downward pressure on Government spending and referred to the *"need to carefully manage your beneficiaries' expectations"*. This was a very difficult message, but I believe one that would have been heard widely across Government at the time.

42.7. I believe that this answer from Dr Wight answers the questions about whether the submission was escalated to Ministers and also explains why the case for increased funding was not accepted. I also refer to my discussion of the issue of reserves; it is apparent that DH considered that, in the short term, the reserves should be reduced before additional funding was allocated.

42.8. Caxton Foundation: a request made by the Caxton Foundation to increase its allocation for the year 2014/15 ("Business Case for 2014/15") (AHOH0000001) which was turned down by the Department of Health in February 2014 (CAXT0000110_089). In its Business Case for 2014/15 the Caxton Foundation explained that it would *"like to introduce a form of regular payments to beneficiaries, based on their income levels, to enable everyone to have the means to live without the fear of not being able to meet basic living costs or getting into debt"*. The Caxton Foundation wanted to introduce a scheme based on 80% of median income for all primary beneficiaries and the bereaved. It estimated that to operate this scheme, the Caxton Foundation would require an additional allocation of £3.03 million in the first year and £4,805 million in subsequent years.

42.9. Dr Ailsa Wight's letter in response to the Caxton Trust, sets out the same response as that provided to the Macfarlane Trust for the 2014/15 financial year; namely, that Ministers had decided that it *"was not the right time for an uplift in allocation, whilst they continue to consider how best to address a range of issues about the system of support available for those affected by contaminated blood, many of which were highlighted during the Westminster Hall debate on the topic on 29 October 2013".* Likewise, Dr Wight again also referred to the *"continuing downward pressure on Government spending".*

42.10. MacFarlane Trust: Fourthly, I am referred to two further letters relating to a request made by MFT to increase their funding for the year 2015/16 financial year. MACF0000061_067 is a letter addressed to me from Roger Evans (Chairman, Macfarlane Trust) dated 5 November 2014, in which Mr Evans explained that the Trust's financial position remained as of 12 months ago i.e., as set out in MACF0000026_088 and detailed already in the relevant paragraph above.

42.11. The Inquiry has provided my response to this letter, dated 11 December 2014 (MACF0000061_066), which was copied to Dr Ailsa Wight. In the response, I referred to the difficult financial constraints facing the Department at that time. As I said in that letter the situation facing all parts of the health system was *"extremely tough"*. We recognised that the Board would need to make difficult decisions about whether to reduce or stop payments and that the Trust had been managing the shortfall between Trust expenditure and departmental funding by using the Trust's reserves and that this was not sustainable in the long-term but as with the correspondence from Ailsa Wight (referred to in the paragraphs above) the wider context was that of *"significant increasing pressure on the Department's central budgets".*

42.12. I have been asked how these submissions were received and in particular, first, which of these submissions for increased funding were escalated to the Minister. I have already noted the reference in Dr Wight's letter to Ministerial views at paragraph 42.6 above. Generally, I would comment that officials did not make decisions to approve or reject funding bids (although they might make recommendations) – Ministers did. I therefore believe that all these bids

are likely to have received Ministerial attention, with advice given on the business case (although I have not been shown submissions that would confirm this).

42.13. I recall that in October 2013 there had been a Westminster Hall debate, with a great deal of Parliamentary activity at that time. I recall that Ministers were thinking about how they wanted to improve the system, given what they had heard at the Westminster Hall debate. As a result, allocations were not going to be increased in the interim.

42.14. The Department did take account of the representations made by the relevant AHO. It was done through official examination of the business case. Decisions would then be taken by Ministers.

42.15. Although the AHOs had very limited success in increasing their allocation, I do not think that there was more that the AHOs could have done to persuade the Department to do so. The problem was that the budgets within the Department were very tight. There were many other areas which required priority funding and with which the AHOs had to compete.

Q43. Rejection of the Caxton Foundation business case, February 2014

43.1. The Inquiry has asked why the Caxton Foundation business case ([CAXT0000110_089], referred to above) was turned down in February 2014, given the Ministerial objective of 'read across' between the Caxton Foundation and in circumstances where the other charities had regular payment schemes. The answer is the same as in relation to questions 42b and 42c above. Ministers had heard the Westminster debates and were still giving thought to what might be a better system of support at that time.

Q44. Caxton Foundation Budget, 2014/15

44.1. I am asked by the Inquiry why the Department of Health refused to increase the budget of the Caxton Foundation in 2014/15, when beneficiary numbers jumped by over 50%. The Inquiry has referred me to the Caxton Foundation Annual Financial Report for the year ended 31 March 2015 [CAXT0000035_078], which refers to this increase – it happened

unexpectedly, from September 2014. The report notes that it was at the end of September 2013 that "*Caxton submitted a business case to the DH for additional funding for a regular payments scheme….* ", but it was declined. My answer is the same as to the previous questions; Ministers were still considering what would be the best system of support following the Westminster debate in October 2013.

44.2. The 2015 Annual Report also mentions the additional £25 million announced by the Prime Minister on 25 March 2015.

Q45. Views about underfunding of the Macfarlane Trust and Caxton Foundation

45.1. I have been asked when I first became aware of the view, held by witnesses from the Macfarlane Trust and Caxton Foundation, that both charities were underfunded. With regard to the Macfarlane Trust, I believe that this would have been some time in 2009, after the publication of the Archer Report. With regard to Caxton, I probably became aware in around 2013, and it became much more evident when they informed us about the significant increase in their beneficiary numbers.

Q46. My views on underfunding

46.1. I have been asked whether I personally agree that the charities were underfunded and if so, why. I agree that there was significant hardship amongst some of the beneficiary community. I know it was difficult for MFT and CF to prioritise the many requests for support that they received and it was right that they made business cases to us for increased funding. However, the financial allocation for the Trusts was constrained by allocation pressures within the Department, operating within the context of spending priorities set by the Government.

46.2 When annual payments were introduced for those infected with HIV (May 2009), the expectation in government was that the Trusts would be able to make higher payments to dependants [SOC0011282_002]. I believe this was the case. Indeed, in the MFT's 2011 Annual Report and Accounts, the Chairman's report acknowledged that *"the substantial increase in overall*

funding provided by the Department since 20 May 2009 for the support of the Trust's beneficiaries has also made it possible for the Trust to provide much more effective help for widows and dependants."

46.3 By the time the of the MFT's 2013 Annual Finance Report [MACF0000045_004], the Chairman's report noted the impact of the prolonged economic recession on its registrants, together with changes to the benefits and welfare system, and noted the allocation for the following year of £2.2m was effectively the same as the previous year. He acknowledged that this was probably the best the Trust could expect "*given the cuts in public spending*." In the Department, we were concerned that the MFT should try to manage their beneficiaries' expectations about what they – the Trusts – could provide, given the pressure on departmental budgets. I referred to this in my letter to Roger Evans of 11 December 2014 [MACF0000061_066]. This was also discussed at the MFT annual review meeting the following day [MACF0000061_057], where Dr Wight said that we were unable to give the MFT an indication of their budget for 2015/16 as departmental budgets had not yet been set. She suggested that MFT should "plan for different eventualities". I appreciate that this would not have been easy for the Trustees, who would have had to consider what types of support they could give based on the combination of an uncertain allocation and their diminishing reserve. .

46.4 I have already referred, in my answer to Q.44, to the reason why the Caxton Foundation funding was not increased following the significant increase in beneficiary numbers in 2014/15.

46.5 I have recently looked at the Caxton Foundation Annual Financial Report for the year ended 31 March 2015 [CAXT0000035_078], as set out above. This puts the matter fairly, in my view, when commenting on the APPG Inquiry's report:-

"The Alliance House organisations are well aware of the dissatisfaction of some beneficiaries with the fact that successive Governments' response over the years has been to set up five organisations… to provide non-discretionary

and discretionary support as opposed to providing any final settlement. Beneficiaries' dissatisfaction is compounded by the fact that the charities are not funded at a level which could meet many beneficiaries' expectations, and also have to be able to determine charitable need when making any form of discretionary payment."

Q47. The Macfarlane Trust Reserves

47.1. I have been asked about the impact that the level of reserves held by the Macfarlane Trust had on the decisions made by DH upon grant allocation; and in particular whether the Department considered that the Macfarlane Trust should be funding its annual grants programme from its reserves.

47.2. I recall that we in the Department did think that the Macfarlane Trust had built up a large reserve and that we wanted them to spend down their reserve. Their reserve had initially been £4m in around 2006, but this had reduced to around £1m by Dec 2011 [MACF0000061_104]. I believe that at this stage, DH Finance were limiting funds for non-NHS programmes, and we were concerned that MFT's funding might be reduced in light of their reserve. There were significant pressures on finance within the Department and across Government, given the wider economic situation of the fall-out from the financial crash. The position taken by DH Finance was that the Trust should start using the reserve before it was provided with its full allocation again.

47.3. The Inquiry has provided a copy of Meeting Notes from the Macfarlane Trusts records, of the Macfarlane Trust/ DH Annual Review Meeting, held at the Department on 8 December 2011 [MACF0000061_104]. I attended this meeting along with my colleagues, Ailsa Wight and Ben Cole. The issue of reserves was discussed at the meeting. Christopher Fitzgerald, the MFT Chair, advised that the Trust were working to reduce their reserves and suggested a two-year period to reduce the reserves from £1 million (although it had previously been as high as £2 million) down to about £100-£200k. The Notes record that this figure was in line with the Departments views but that we stressed that the reserves needed to be reduced much sooner than in 2 years, to which Christopher Fitzgerald responded that two years was a *"realistic timeframe"*.

47.4. The Notes record, that I *"informed [MFT] that funding for all charitable bodies was under considerable scrutiny and consideration"* and that *"for those charitable bodies fully funded by DH reserve levels need to be much lower than MFT's current level"* and that *"there simply could not be any justification for having high levels"* and so *"every effort should be made to bring down MFT's reserve level as soon as possible"* (page 2, The Notes). The Notes also record that I said that: *"the MFT should recognise that the reserves might have to be used for a time to fund the Trust's current commitments to Beneficiaries as financing was under tight review and DH Finance were limiting the pot of money to cover non-NHS programmes"*. The Notes record Dr Wight having suggested that the Trust submit a paper setting out why it was necessary to maintain the reserves and how the Trust intended to use them. Dr Wight is recorded as indicating that this *"might help to make it clear to Finance why the reserves should not be required in lieu of a discretionary allowance next year"* (page 2).

47.5. The *"Action"* point arising from this discussion, was that the Trust should produce a proposal, demonstrating clearly the means by which reserves would be reduced to £100-£200k (although it is noted I had said this should be closer to £100k). The Inquiry has provided a letter from myself following up on this, addressed to Martin Harvey and dated 18 May 2012 [MACF0000025_071]. The letter refers to a meeting on 27 January at which the Department met to discuss the Trust's draft proposal for paying down its reserves. It had been agreed that the Trust would provide a more detailed proposal that could be put to Ministers but as I noted in the letter, this was outstanding. Also of note in this letter, is that at a meeting on 4 May 2012, Mr Harvey had indicated that some of the Trustees were keen to begin funding a programme of capital payments from the reserve. I asked that they abide by our previous agreement and not to begin any new capital payments from the reserve.

47.6. The Inquiry has provided me with a series of emails from August to September 2012, which relate to discussions between Ailsa Wight, Ben Cole and myself (from the Department) and Roger Evans about the Macfarlane Trust's Business Case for spending its reserves [MACF0000060_047]. The Inquiry

has also provided me with the Macfarlane Trust's interim business case for spending its reserves, dated 26 July 2012. [MACF0000060_038].

47.7. I remember that I and colleagues were most concerned on receiving this interim business case that it did not provide a constructive basis on which to proceed. It did not set out specific proposals and did not demonstrate that £4m worth of charitable need existed, although we did not doubt that there was indeed a significant level of unmet need among MFT's beneficiary community. However, what can be seen from the email exchange is that colleagues at the Department were trying to work with Mr Evans to assist the Macfarlane Trust in preparing its business case, so that it was presented at its strongest before going to Ministers for approval and had the best possible chance of being approved by them. Both Dr Cole and Dr Wight offered to review drafts of the Business Case, to assist in approving it and meetings were also scheduled to assist in this endeavour.

47.8. I have been asked <u>why</u> the Department required MFT to provide a business case for the spending of its reserves, given that the MFT was an independent charity.

47.9. I have discussed issues relating both to a charity's accountability to its funder (DH) and also Finance's perspectives on reserves at 47.2 above.

Q48. <u>Offsetting Underspends</u>

48.1. I have been asked what the rationale was behind DH setting any Caxton Foundation underspend in one financial year against the allocation in the following financial year.

48.2. I believe this was because payments made by the Foundation were on the basis of financial need, and not a fixed allocation; for example, as in the Caxton Foundation allocation letter for 2016/17 [CAXT0000003_107] which says that the allocation "is up to £2.532m". If the Foundation did not spend the whole allocation in one year, this was regarded as if they had not identified a need to spend it all. There were other pressures within the Department, so the underspend would be set against the following year's allocation. That

approach released some pressure in the Department to allow for spending on other things.

Q49. Setting of Reserves for the Caxton Foundation by DH

49.1. The Inquiry has asked me the basis for the DH setting the level of reserves appropriate for the Caxton Foundation, given that it was an independent charity.

49.2. I have been provided with [DHSC5003907] which is a document dating from the set-up of the Caxton Foundation. Although a charity, it is evident that Finance took the view that it was "*highly likely that NAO [the National Audit Office] would look at Caxton as a new funding stream for DH".* They noted that the level of reserves had to be justified to NAO. 12.5% was regarded as difficult to justify and 5% was suggested. See also [WITN0823009], a record of a meeting with the Eileen Trust, in which there was a comment from a colleague from DH Central Finance that reserves held by charities funded by DH might now need to be consolidated into Departmental accounts. I am not aware that this happened, although I cannot be certain about this.

49.3. I have commented generally on the issue of financial accountability for the Trusts in this Statement. A financial expert would be better able to explain the accounting issues that affected both the Trusts that were fully funded charities, and the 'arms-length companies' such as the Skipton Fund and MFET Ltd.

Q50. Funding for the AHOs from the Devolved Administrations

50.1. I have been asked when funding for any of the AHOs was sought from the Devolved Administrations ("DAs"). My recollection is that the DAs contributed to payments in respect of hepatitis C, but not HIV, for which DH funded the payments UK-wide. I believe this was because the HIV payments had begun pre-devolution, and they had not been included in the devolution settlements. When the Secretary of State (Mr Lansley) announced the Jan 2011 reform package, which introduced increased lump sum payments and annual payments in respect of hepatitis C together with the introduction of new discretionary payments, he did so for England only. But he wrote to the DA

Health Ministers acknowledging the financial implications of his announcement for them [WITN0823010]. A submission from Dr Cole on 26 April 2011 [WITN0823011 and DHSC5009206] indicates that by that point, the DAs had decided to participate in the new financial arrangements.

50.2. I have also been asked about the level at which the DAs' contribution was set. I understand this question to relate to discretionary payments made through the Caxton Foundation. My recollection is that we initially worked out the level of the contribution on the basis of the "Barnett Formula". That then changed later to reflect the number of actual beneficiaries in each of the DAs. This is reflected in the email chain that has been provided by the Inquiry [DHNI0000499] which seeks views from the DAs about each of their contributions to the Caxton Foundation's allocation in 2015/2016.

Q51. Prime Minister David Cameron's Announcement, 25 March 2015

51.1. I have been asked about my understanding of the £25 million announced by the PM, David Cameron, on 25 March 2015. He announced that he would be allocating "*an extra £25 million for this year to help move us towards a better payment and support system for affected people.*" This was subsequently clarified as an additional £25 million in 2015/2016 (i.e. not 2014/15) to support any transitional arrangements to a better payments system.

51.2. Work on allocation of this money was briefly interrupted by the General Election of 2015, but I have been supplied with documents showing initial consideration of how the money was to be allocated from late May / early June 2015, after the new Government was in post. These include:

- Submission to the Secretary of State (Mr Jeremy Hunt) and the Parliamentary Under-Secretary of State for Public Health (PS(PH)), Ms Ellison (both having retained their posts). This updated Ministers on issues relating to Infected Blood and reminded them that a decision needed to be made on how to spend the additional £25 million; various options were set out [WITN0823012];

- A response from the Parliamentary Under-Secretary on 1 June 2015; [WITN0823013];
- A further Submission on options and costings of the same date [WITN0823014], now solely addressed to PS(PH), with a note stating that the Secretary of State had asked for her input, presumably (in effect) delegating this to her.

51.3 I have seen a draft submission dated 24 June 2015, prepared by my colleague, Naomi Balabanoff, who was leading on this issue [WITN0823015]. The submission recommended that PS(PH) lay a written ministerial statement (WMS) announcing both a consultation on payment scheme reform together with the government response to the Penrose Inquiry, which had recently reported. The result was a WMS on 20 July 2015[3] which included the following: "On 25 March the Prime Minister also announced that £25 million would be allocated to ease transition to a reformed system of support for affected individuals. While no decisions have yet been made on how this money will be spent, I must emphasise that the money will not be used for administrative costs, but will be used appropriately to support any transitional arrangements once we have consulted on how a new scheme might be structured."

51.4 I do not recall there being agreed plans for spending the £25m whilst I was still working on blood policy, although I have seen a submission indicating that in November 2015, consideration was given to using £2.5m to fund a one-off payment of £500 to all scheme beneficiaries [WITN0823016].

Q52. <u>Department of Health input into AHO Policy and Decision-making</u>

52.1. I have been asked whether I (or the DH) gave instruction or advice to the AHOs on policy. My recollection is that I did not give instructions or advice on policies relating to the use of charities' funds for beneficiaries; it was up to the individual trustees to determine policy. I have been referred to MACF0000024_045, a Macfarlane Trust document, in which I am recorded as having sent advice to MFT's Chief Executive about a potential beneficiary, that

[3] https://hansard.parliament.uk/Commons/2015-07-20/debates/1507207000019/InfectedBlood?highlight=penrose%20inquiry#contribution-1507207000166

MFT's trustees *"have the discretion to meet any charitable need that this lady might have, including any arising directly from her hepatitis C infection."* I expressed this view in response to a discussion with the MFT Chair, at which he requested that the Department consider an amendment to the Trust Deed in order for the trustees to assist this beneficiary in the way that they wished. I was pointing out that a change to the Deed was not required and that, in the Department's view, the trustees already had the flexibility they sought. I neither instructed nor advised the Trust on the decision they should make. It is possible that there may have been other occasions when I or others made comments on issues, especially if raised, but I believe they would have respected the role of the trustees. I have covered, separately, the input or views of DH upon issues relating to financial resources and accounting, e.g. the maintenance of reserves.

Q53. The Department of Health's views on 'charitable need'

53.1. I have been asked whether the DH had a view on what the term 'charitable need' meant. My recollection is that our view was that it was a wide term, going wider than alleviating financial distress to include educational need, psychological need etc. The charities took account of what their beneficiaries' needs were. We did, however, ask that they explain how they assessed charitable need, most notably when they wished to bid for an increased allocation.

Q54. Funds held by the AHOs until maturity

54.1. I have been asked if funds were held by the AHO for children until they reached maturity and whether the AHOs or DH received any advice on this. I do not recollect that funds were held for children, and cannot remember this issue arising. If they were, it would have been only the Eileen Trust and the Macfarlane Trust that did so, and they should hold further details.

Q55. Loans and advances from the MacFarlane Trust

55.1. I have been asked about the MFT's policies about providing loans and advances rather than grants. I know that historically, MFT did provide both secured and unsecured loans at the beginning, but I believe that this policy

was phased out. The APPG report (January 2015) stated [RLIT0000031]: "*Some MFT support used to be given in the form of a loan, but this is no longer the case and is unlikely to recur*" (Report, p42).

55.2. The most relevant note I have seen, in preparing this statement, is the discussion in [MACF0000061_081], the minute of the Annual Review meeting with MFT on 26 November 2012, where Mr Evans (RE) of MFT is noted as saying:

"RE explained that the Trustees are currently looking at the issue of loans, and how to deal with borrowers who struggle to repay. Some loans date from around 10 years ago, and are unsecured. RE assured DH that loans would not now be made on an unsecured basis."

55.3. This does not suggest a discussion of the principle of loans with DH at that meeting. I cannot say what, if any, discussions took place between MFT and DH about such loans when the MFT clearly did operate such a policy, before I took over the sponsorship role in 2011.

Q56. <u>The MFT and homosexual partners</u>

56.1. I have been asked about a meeting of the MacFarlane Trust dating from 20 January 2003 [MACF000009_0120], where an issue related to homosexual partners was discussed. This is substantially before my involvement as sponsor for the AHOs and I cannot assist the Inquiry with these questions.

Q57. <u>Policy on Assisted Conception, the Macfarlane Trust, 2005</u>

57.1. The IBI has noted that on 31 January 2005, Martin Harvey, Chief Executive of the Macfarlane Trust, wrote to Mr Connon (DH) about the issue of support for assisted conception [MACF0000014_049]. I have been asked for my observations.

57.2. Again, this is substantially before my involvement as sponsor for the AHOs and I cannot assist the Inquiry from my own knowledge.

Section 76: Section 3: Reform of the AHOs

Q58. Insurance cover: the views of the Association of British Insurers

58.1. I have been referred to a Ministerial Submission dated 24 February 2009 that I wrote to the MS(PH) following the Report from Lord Archer. I summarised the recommendations of Lord Archer's report and I set out a number of issues that the Department of Health needed to investigate in order to be able to come to a conclusion on the recommendations made by Lord Archer [DHSC0006755].

58.2. I wrote that the DH would seek the view of the Association of British Insurers (the ABI) on the recommendations regarding insurance. I have been specifically asked what their response was.

58.3. I am told by my advisors that copies of any correspondence with the ABI has not to date been located. However, their responses are summarised in the further Ministerial submissions. See, in particular:

- Submission dated 16 April 2009 [DHSC5024031] reporting on the response of the ABI (see p4, para 23) and suggesting that increased payments to haemophiliacs would cover this additional expense for this group, but not for those infected with HCV; further information as to be sought on this group;

- Submission for the Secretary of State (Mr Andy Burnham) dated 14 December 2009 [DHSC5190274], which gives fuller information about the ABI's input on those infected with HCV, and set out the Government's decisions (p5).

58.4. Ultimately, this issue was considered in depth by the Review of Support [PRSE0004024], which was established following the March Judicial Review and reported in January 2011. There was detailed consideration of the issue of insurance in Section 6 (p23) and a table provided by the ABI at Appendix 6 (p67). The Review concluded (p38) *that "Whilst it is recognised that some infected individuals might be uninsurable for some risks, a state-run insurance scheme is not considered to represent value for money. Individuals for whom*

insurance is available have the freedom to use the ex-gratia payments that they receive to help pay for the premiums".

Q59. Input into the Ministerial Response to the Archer Report

59.1. I have been asked about the input I had into the Ministerial Response to the Archer Report. I, together with colleagues in Health Protection Division, prepared briefings to assist Ministers to formulate their response to the Archer report. Where recommendations made by Lord Archer impacted on policy areas beyond my own, I sought advice and input from the relevant teams.

59.2. There were a large number of submissions prepared to advise ministers on how they might respond to Lord Archer's recommendations, and also to address questions from MS(PH)'s office. The Inquiry has referred me to some of them, although the list is not comprehensive.

59.3. Looking at the immediate response:

- Lord Archer's report was published on 23 February 2009. The Department did not have sight of the report prior to publication and we were not therefore in an immediate position to advise Ministers on what a potential government response might entail. I drafted the initial review of Lord Archer's report and its recommendations which was sent to MS(PH) on 24 February. [DHSC0041157_057]. On the topic of costings, I said: "*We need to consider and carefully cost the options for additional support, and consult DWP. However, the financial implications are enormous if we were to operate in line with the Irish system, as Archer recommends. (An initial estimate applying the average Irish payment to our 4 – 5000 cases would be £3 - 3.5 billion. We need more work to properly qualify these recommendations).*"

- It is apparent that this generated substantial numbers of questions from the Minister or her Private Office [DHSC0011469];

- These led to a further submission dated 26 February 2009, seeking to answer the Minister's questions as far as possible in the time available. [DHSC0011467];

- I also emailed a number of colleagues on 24 February 2009 to advise them that their input was likely to be needed on preparing the Government's response to the recommendations, given that they impacted quite widely on other policy areas [DHNI0000175];

- Arising out of this, the Secretary of State (Mr Alan Johnson) and the Minister of State for Public Health (Ms Dawn Primarolo) met Lord Archer on 11 March 2009. On 10 March, I provided briefing for the meeting [copy of submission including annexes at [MHRA0024725].

- I was copied into a note of the meeting from the Secretary of State's private secretary (Penelope Irving), commissioning further work [DHSC5564474]. Ministers asked officials to look at the eligibility criteria "*for those who receive money under the various schemes including options to rationalise the schemes",* amongst other things. However, it was plain that there was no Ministerial enthusiasm for considering the Irish scheme as a model.

59.4. On 19 March, I drafted a submission, addressed to the Secretary of State and the Minister of State for Public Health, setting out possible responses to Archer recommendations, following this meeting with Lord Archer on 11 March; see [DHSC0041157_046]. At that point we were still awaiting a response from the Association of British Insurers (see previous question).

59.5. This is not a comprehensive survey of the Ministerial submissions prepared, although further details can be provided if helpful. But it shows how the process of submissions worked. As I remember, I drafted the Government's response to the recommendations, which was announced on 20 May 2009.[4]

[4] I have been further referred to two documents [DHSC0041307_014] and [DHSC0041307_017]. However, DHSC0041307_014 is a submission dated 17 March 2010 from my college D Webb to MS(PH), addressing the options for bringing forward a review of the Skipton Fund and the possibility of providing personalised health budgets for haemophilia patients. DHSC0041307_017 is a further submission from me dated 26 March 2010, relating to the handling of an announcement that the review of the Skipton Fund was to be brought forward. I do not think that they materially assist, relating as they do to later events.

Q60. Lord Archer's Recommendations on Parity with Ireland.

60.1. I have been asked what part I played in the Government's decision not to implement the recommendation made by Lord Archer that there should be parity of support with that paid in the Republic of Ireland. I have been further asked what the factual differences relied on by the DH between the two countries were.

60.2. I was involved in discussions with policy, legal and finance colleagues to consider the implications and costs associated with a scheme similar to that in Ireland, and advised Ministers accordingly.

60.3. In order to answer this question, I have been referred by the Inquiry to [DHSC0006649] amongst other documents. However, that is a submission dated 11 August 2020, which refers to the re-taking of the decision following the March Judicial Review (judgment April 2010). Given the Inquiry's Questions 61 and 62 below, I have assumed that Q60 is intended to refer to the first Government decision, of May 2009. This is discussed below.

60.4. I have already referred to events up to 19 March 2009, including initial submission with remarks on costings, and the briefing of 10 March 2009 which made some brief reference to the factual position in Ireland at p6 [MHRA0024725].

60.5. After that, the key submissions included:

- A further submission from me dated 31 March 2009, containing further information about possible uplifts to the financial support available [DHSC0041157_035];
- Response from the Minister's Private Office on 6 April 2009 [DHSC5567339]; the Minister stated that it did not address her concerns and asked for further work to be done;

- On 17 April 2009, a further submission from my Director, Liz Woodeson, which addressed the response to Lord Archer's recommendations [DHSC0041307_021].

- A note from the MS (PH) to the Secretary of State on 23 April 2009 [WITN4688069]. The Minister wrote that she wanted to respond as positively *"as far possible, whilst recognising that some of the recommendations are simply unaffordable, particularly at the present time".*

- I note that there was a parliamentary debate in the House of Lords on 23 April 2009. Baroness Thornton replied for the government, but did not address the issue of costing parity with Ireland, stating that the recommendations were being considered.

- There was a short note sent to MS(PH) dated 13 May 2009 from Debby Webb (copied to me) [DHSC0041307_029], on the publication arrangements for the Government's response to the Archer report. This stated briefly, in a section on the likely criticisms of the response, that *"Whilst average payments for those with HIV will rise to £12,800, this falls short of countries, such as the Republic of Ireland, where liability has been admitted."* [DHSC0041307_029]. There was a similar comment in the note from Judith Moore to the Minister dated 18 May, discussing whether the Minister should give interviews when the Government's response was published [DHSC0041307_025].

- The government response of 20 May 2009 [HSOC0011282_002]. This stated that the Government was responding to the recommendations for further support *"in as positive a way as possible at the current time, being in mind the constraints on public funds"* (p8).

- Also relevant are the comments made by the Minister (Ms Gillian Merron) in the Westminster Hall debate of July 2009 [DHSC5610922]; these attained prominence in the *March* judicial review.

60.6. Further details are continued in:

- My colleague Ms Webb's evidence for the *March* Judicial Review (i.e. *the Queen (on the application of Andrew March) v the Secretary of State for Health* [2010] EWHC 765 (Admin), which followed shortly; see in particular paragraphs 42 – 46 discussing the situation in Ireland and 58 -66 [DHSC0015684];

- The comments in Ms Webb's email dated at DHSC0003623_062, p3; and

- The judgment in the *March* case [DHSC0003819_011], which contains the judicial assessment of the decision-making.

- I also note from a letter from the Minister, Ms Milton, in late October 2010 (i.e. by the time that the second decision was being taken) that information about costings was placed in the House of Commons library by that date [see DHSC0006607_008].

Q61. Input into the *March* Judicial Review

61.1. I have been asked about my input, if any, into the Government's response to the judicial review of its response to the Archer Report. Work on the Government's response to the judicial review of its response to the Archer report was led by my colleague, Deborah Webb. I do not recollect being directly involved, although I was aware of the work being undertaken and was copied into at least some of the correspondence about it.

61.2. The documents to which I have been referred (DHSC0003623_004[5] and DHSC0003623_028[6]) confirm this recollection, as does the email chain discussing the Ministerial statement in the Westminster debate at [DHSC0006615_121].

61.3. However, [DHSC0003623_062], which is the Ministerial Submission that I wrote to PS (PH) on 7 October 2010, indicates I was involved in the substantive policy-making on further issues related to support for the infected community. That submission addressed the subject of a review of the Skipton Fund in England. It was not at that time intended to cover payments for HIV

[5] Submission from Ms Webb dated 26 May 2010 to MS (PH) about responding to the judgment in *March*, copied to me.

[6] Email exchange between colleagues concerning reactions and response to the judgment, 20 October 2010.

infection, as they had been increased to a minimum annual payment of £12,800 in May 2009, i.e. as part of the initial response to Lord Archer's report.

61.4. This distinction is also evident from the email exchange at [DHSC0006615_132], which is an exchange dated 17 March 2010 about updating the DH website with information that potentially overlapped with the substance of the *March* claim; I asked for advice on whether this was appropriate. This again confirms my recollection that I continued to be involved in substantive policy-making, rather than in the handling of the judicial review, although I was kept abreast of developments.

Q62. Retaking of the Government's decision following the judgment in *March*.

62.1. I have been asked about my input into the re-taking of the decision about parity with the Republic of Ireland following the quashing of the decision by the court. As my answer to Q61 indicates, this work was led by my colleague, Debby Webb. I was however aware of the steps being taken to enable the Minister to re-make the decision.

62.2. This was following the General Election of May 2010 which led to changes in Ministerial portfolios. The Inquiry will be aware that the General Election took place on 6 May 2010 resulted in the return of a coalition government and new appointees: the new Secretary of State for Health was Mr Andrew Lansley and Ms Anne Milton was appointed as the Parliamentary Under-Secretary of State for Public Health (PS(PH)).

62.3. Submissions (to which I was copied in) which followed include:

- On 26 May 2010, Ms Webb sent a submission regarding a decision not to appeal the *March* judgment; this was agreed on 2 June 2010 [DHSC0003623_004];
- On 8 July 2010 a submission was written by Ms Webb to PS(PH) [DHSC0006616_114], regarding the recommended decision to be retaken;
- On 11 August 2010, she sent a further submission [DHSC0006649];
- DHSC0006616_114 (annex A)

- ARCH0001105 (annex B)
- DHSC0006616_112 (annex C)
- On 16 September 2010, a submission was written by Mr Cole [DHSC0003623_109] , which stated:

> "*We continue to recommend that you reject 6(h) for the reasons given in previous submissions, and that based on legal advice, this decision is announced in September. We further recommend that a review of wider issues is undertaken internally, supported by appropriate external experts, and that the areas for review are also announced in September. This review could be completed by December.*"

62.4. I sent a further submission to PS (PH) on this topic on 7 October 2010 (see [DHSC0003623_062] at para 61.3). I noted that the Minister was due to make a Written Ministerial Statement (WMS) announcing the response to the *March* judgment and the decision to conduct a short review. I attached a copy of the proposed Terms of Reference, which were based on the main issues raised by campaigners in meeting with the Minister and in their written representations, and discussed issues such as the interrelationship with the Devolved Administrations.

62.5. Ultimately, the decision that was taken by the Minister and laid as a WMS on 14 October 2010 [DHSC0006626] was in accordance with this submission. It was immediately followed by a Parliamentary debate in the Commons on the same day [ARCH0001103] in which a motion that would have committed the Government to parity with Ireland was defeated by 285 votes to 44.

Q63. Mr Lansley's Announcement of 10 January 2011

63.1. The Inquiry has asked what input I had into the Secretary of State (Andrew Lansley)'s announcement on 10 January 2011 that Skipton Fund Stage 2 beneficiaries were to receive an increase in their lump sum payments from £25,000 to £50,000 and that there would be annual payments of £12,800 for Skipton stage 2 sufferers.

63.2. Mr Lansley's announcement on 10 January 2011 [ARCH0001478] was a product of the internal review whose work – subject to Ministerial approval –

was canvassed in the submissions which I have referred to at Q62 above. As I remember, I led the review work in conjunction with Dr Wight.

63.3. I have been referred by the IBI to [DHSC0003814_049]; this is a submission from Mr Cole dated 16 September 2010 to the Secretary of State and PS(PH), setting out information on the potential costs of some of the options that the review would be considering and setting out the Terms of Reference of the review, for agreement. More significant is the report of the Review itself, which was published in January 2011 and can be seen at [PRSE0004024].

63.4. Recommendation 11.2(i) related to the flat-rate annual payment for all living Skipton Fund Stage 2 payment recipients (p36). This was part of the measures to reduce anomalies with HIV payments.

63.5. Recommendation 11.2(iv) (p37) was that the Stage 2 Skipton payment should be increased from £25,000 to £50,000. (See further paragraphs 21 and 27 of the submission referred to below, on the rationale for this increase).

63.6. The rationale for these recommendations was set out in the Review's report. The process of the Review is summarised in Section 3 (p9). This was an internal DH review (with the external input listed in the Report). I have also been supplied with a submission that I wrote on 7 December 2010 [see DHSC0003814_090; DHSC0003814_091 (Annex A); DHSC0003814_092 (Annex B); DHSC0003814_093 (Annex C); DHNI0000371 (Annex D), when the Report had been received in draft form. I informed the PS (PH) and the Secretary of State of anticipated recommendations and the options that might be pursued, and how these might be advanced. The submission shows that the intention was to seek the PS (PH)'s preferred recommendations to present to the Secretary of State. Once agreed internally, Ministers would write to the PM and HM Treasury. Treasury approval was essential because as, as I noted at paragraph 10, "*There is no current resource to meet the costs set out above*" (which, depending on decisions, amounted to an upfront cost of £100 – 172m, plus £9 - £13m over the Spending Review period: see p4). Suggestions were put forward on how to manage these increases.

63.7. The announcement made by Mr Lansley was the outcome of this Review. Other reforms were made, in addition to the two highlighted by the IBI above; for example, it was this review that led to the establishment of the Caxton Foundation to provide discretionary support to those with HCV and their dependants, to bring their position in line with the discretionary support available to those with HIV.

Q64. Parliamentary Progress of the Contaminated Blood (Support for Infected and Bereaved Persons) Bill

64.1. I have been asked to provide a narrative explanation of the introduction and passage through parliament of the Contaminated Blood (Support for Infected and Bereaved Persons) Bill.

64.2. In November 2009 Lord Morris introduced a Bill in the House of Lords to make various provisions for those infected through their NHS treatment with blood or blood products.

64.3. It was my understanding that Lord Morris was not satisfied with the Government's response (May 2009) to the Archer report and introduced this Bill as a result. I have been supplied with a copy of the briefing that I provided to MS (PH) (by then, Ms Gillian Merron, who succeeded Ms Primarolo) on 25 November 2009 [DHSC0041240_016] – Annex A [DHSC0041240_017, Annex B [DHSC0015670, Annex C [DHSC0041240_019] and Annex D [DHSC0041240_020]. This outlined the nature of the Bill, which was to be introduced in the House of Lords, and repeated what the Government had announced on 20 May 2009, said to be "*as positive as possible in the current circumstances*" (which was a reference to the current financial pressures). I noted that the second reading in the House of Lords was provisionally scheduled for 11 December. I recommended that the Minister write to the House's Legislation Committee recommending that the Government expressed reservations about the Bill in the House of Lords and oppose it should it reach the House of Commons. Please see the briefing for further details.

64.4. From the Submission referred to below, it can be seen that the Bill passed through the Lords and was introduced to the Commons on 21 January 2010; but was objected to on the three occasions it was presented for a Commons second reading. It fell when the Parliament was dissolved ahead of the General Election of 6 May 2010.

64.5. My colleague Ms Webb sent an updating submission to PS(PH), now Ms Milton, on 4 June 2010 [DHSC5032774], Annex A [DHSC0041240_017, Annex B [DHSC0015670, Annex C [DHSC5032777] and Annex D [DHSC5032778] copied to me. She noted the history of the Bill and that it was unchanged since its last introduction. The recommendation, about writing to the Parliamentary Business and Legislation Committee was unchanged. A draft letter was attached. The submission noted that a new decision, following the *March* judgment, had not yet been made. Please see the submission for details.

64.6. Mr Cole wrote again on 11 October 2010 [DHSC6542576]. He noted that the Minister had written to the Parliamentary Business and Legislation Committee on 17 June 2010 but had not received a reply. It was recommended that a further letter be sent. Mr Cole noted that the second reading of the Bill was due in the Lords on 22 October 2010.

64.7. There is a response from the Rt Hon Sir George Young to the Minister dated 20 October 2010 [WITN0823017] confirming that the Committee would express strong reservations on the bill and seek to oppose it should it reach the Commons.

64.8. On 22 October, the Bill was duly debated in the House of Lords. I believe that the Bill was successful in passing through the Lords to the Commons again. As far as I remember, it was then overtaken by events, as before it could go through the necessary Commons stages, the Secretary of State announced significant reforms to the payment schemes in January 2011.[7]

Q65. Consultation on Reformed Schemes, 2015 – January 2016

[7] https://bills.parliament.uk/bills/651/stages

65.1. I have been asked about my input into the DH's consultation on the reform of the schemes run by the Alliance House Organisations that culminated a consultation paper published in January 2016 [WITN3904006].

65.2. I was closely involved in preparing the January 2016 consultation on reform of financial and other support for those infected and their families.

65.3. I should make it clear that the consultation document was only the beginning. The outcome of the consultation was announced on 13 July 2016 [WITN3953052], but the work of reforming the AHO schemes continued, and led, in England, to the creation of a single support scheme administered by the NHSBA.

65.4. However, I retired in January 2017, when work on the reform process was ongoing. I should also repeat (see Q3) that by the time I retired, I was no longer in charge of Blood Policy, having been asked to make a lateral move to oversee the Branch's environmental protection work following the retirement of a colleague. Although I do not recall the exact date, I believe this occurred during the spring or early summer of 2016. I continued to assist the Blood Team, when required, until my retirement, but was much less actively involved in that area of policy. Consequently, those who carried it through will be in a better place to discuss the nature of and rationale for any changes made, if this is what the Inquiry is asking about.

Q66. <u>Meeting, 17 April 2015</u>

66.1. The IBI has noted that I attended a UK Health Departments Infected Blood Payments Scheme Reform meeting on 17 April 2015 [WITN4688017] and have been asked about the devolved Health Departments' attitude to parity amongst the financial support schemes.

66.2. At this meeting, the devolved Health Departments stated their desire for parity between the administrations in respect of any reformed scheme. The Scottish position was, however, the most complex. The note reads: *"Scotland is committed to reviewing the payment schemes. While some affected patients in Scotland would like the new scheme to be a Scottish scheme, the Cabinet*

Secretary (Shona Robinson) has recognised that a UK wide scheme will avoid duplication of administration, reducing service delivery costs. Scotland is going to appoint an independent chair for the review (likely from the 3rd sector)".

66.3. I have been asked whether DH was working towards this stated desire for parity between the administrations in respect of any reformed scheme by the time I retired (January 2017).

66.4. At the time of my retirement, I was no longer in charge of blood policy, having moved in spring/early summer 2016 (see please Q65 above); but I helped the team with various matters. This did include some liaison with officials from the DAs, with whom I had a long-established and good working relationship. As far as I can remember, by the time I retired, Wales, Northern Ireland were still working towards parity, but the Scottish Government had already reviewed payments, following the report of the Penrose Inquiry, and had introduced its own scheme or was planning to do so. But again, colleagues more directly involved (including those in Scotland) would be in a better position to assist.

Q67. <u>The Infected Blood Reference Group</u>

67.1. I have been asked what, if any, input did I have into the Infected Blood Reference Group.

67.2. For the purpose of this statement, I have refreshed my memory about this group. The Terms of Reference of the Group are at [DHSC0046884_012]. The document opened as follows:

> *"**Purpose***
>
> *The Infected Blood Reference Group is an advisory Panel of relevant subject matter experts and other key interested individuals. The purpose of the Infected Blood Reference Group is to provide expert advice, insight and input to support and advise the Transition Board on developing the decisions following the outcomes of the Infected Blood: Reform of Financial and other Support consultation. It will ensure officials are transparent and help them to understand the impact of decisions that will inform progress of the implementation of a reformed payment support scheme leading to robust outcomes."*

67.3. The membership was set out; the Chair was Chris Pond, Chairman of The Caxton Foundation. DH membership was limited to Dr Ailsa Wight, Deputy Director, Emergency Preparedness and Health Protection Policy Directorate (although other DH figures were listed as observers). Later minutes of meetings show that DH attendees included Mr Kypros Menicou, in particular. However, I am not listed as an attendee in any minutes that have been located to date.

67.4. The first meeting of the Group was held on 17 May 2016 [DHSC0046884_014], with Dr Wight and Mr Menicou attending for the Department. Chris Pond, chairing the meeting, informed the group that "the purpose of the Reference Group is to act a critical friend to the Blood Reforms Transition Board."

67.5. Based on these documents, I can see that I had no direct involvement in the work of this Group (although it is possible that its conclusions or advice would have reached me indirectly, as part of any other work with which I was continuing to assist the Blood Team).

Q68. Transfer of Personal Information to the New Schemes

68.1. I have been asked what view the DH took during my tenure about whether the details of beneficiaries could be passed from the AHOs to the proposed new schemes. As far as I remember, we consulted the existing AHOs about the basis upon which they held beneficiary data and took advice from DH colleagues responsible for data protection issues. I think we considered whether the AHOs should contact their beneficiaries to seek permission to share their personal information with the proposed new schemes, but there were concerns that if consent was not given (or it was considered that it could not be properly given, for legal reasons), beneficiaries could lose their payments.

68.2. This is referred to in the email that the IBI has referred me to [DHNI0000632], which is an email dated 3 November 2016 from a Scottish colleague referring to the advice received by him and his colleagues. It was suggested that beneficiary consent should not be relied upon (as it could not be given

freely). Rather, the processing should be seen as necessary for the exercise of a government function. There was reference to the need for a data sharing agreement with the existing schemes.

68.3. I do not remember whether this was resolved before I left DH and I have not been supplied with any documents that would assist.

Section 77: Section 4: The Blood Services

Q69: My Role in respect of Recombinants and vCJD

69.1. I have been asked to outline my roles and responsibilities whilst working for the DH with regard to decisions and actions regarding vCJD and recombinant Factor VIII.

69.2. My responsibilities as Head of the CJD team included ensuring the Department had expert advice for the assessment of vCJD secondary transmission risk from, and risk management measures for, blood and blood components. This included plasma used for therapeutic purposes. Clotting factors synthesised via recombinant technology did not come within my remit, although I became aware that recombinant FVIII had been provided by the NHS since 1998 for patients under 16 years of age. I believe the decision to extend provision of recombinant Factor VIII to adult patients had also been made before I took up my post, although I understand that full implementation took some time. I have no recollection of participating in any work associated with implementation of that decision. Clotting factor products were covered by medicines regulation, and while MHRA would have dealt with regulatory matters, DH Medicines Division and/or the Blood Policy team would probably have dealt with other policy matters. In early 2009 I took over as Head of Blood Safety and Supply. In this role, I became directly involved in workstreams relevant to supply of clotting factors, both recombinant and plasma-derived. None were vCJD-specific, but I describe them here to assist the Inquiry.

69.3. Very early in my role as Head of Blood Safety and Supply (February 2009), I was asked to advise DH finance colleagues on a proposal for a 3% reduction

in the FY 2009/10 financial allocation to the NHS for procurement of recombinant clotting factors [DHSC5559954]. I advised against reducing the allocation because the data I had obtained from the NHS Purchasing and Supplies Agency already indicated a significant gap between the allocation provided for 2008 and the estimated actual spend on products in that year. My main concern was that haemophilia patients had already been badly affected over the years from infections acquired via plasma-derived products, and a further widening of the funding gap might cause some commissioners to decide against funding recombinant products. I also drew my finance colleagues' attention to on-going parliamentary interest in blood safety policy, with Lord Archer's report expected shortly, Lord Penrose's Inquiry in Scotland underway, and "a forthcoming announcement from the HPA which would impact on people with haemophilia". I believe I was referring to the announcement of the first finding of vCJD infection in a person with haemophilia.

69.4. Second, I recall a series of meetings (which I believe I chaired) with colleagues from DH Commercial Medicines Unit, together with representatives from UKHCDO, to agree requirements for a new tender for clotting factor procurement. As I recall, tenders were issued on a periodic basis to enable the NHS to procure the best available products (both recombinant and plasma-derived) from a range of manufacturers at competitive prices. I have not seen papers to confirm when this took place although it is possible that this was part of the project referenced in my submission to MS(PH) of 31 March 2009 [WITN0823018].

69.5. The following pieces of work refer to BPL Ltd, and therefore relate solely to plasma-derived clotting factors.

69.6. Third, in 2010, I worked with colleagues from DH's commercial team to present a case to ministers to transfer BPL out of NHSBT into an existing DH-owned company, PRUK Ltd (Plasma Resources UK Ltd). [DHSC5040397] This was in line with the proposal set out in "Liberating the NHS: Report of the Arm's Length Bodies Review", published in July 2010. [WITN0823019]

69.7. The Inquiry has heard about BPL's manufacture of clotting factors from human plasma, particularly from the 1970s to the early 1990s. BPL continued to manufacture clotting factor products using surplus plasma collected by the blood service until 1999. It was then required to switch to using only plasma sourced from the U.S. This was because of concern about the potential risk of transmission of vCJD via human plasma from UK donors. In 2002, to secure plasma supplies for BPL, DH purchased a U.S. plasma supply company (DCI Biologicals Inc). BPL remained part of the National Blood Authority (from 2005, NHSBT) although there was no longer a link between it and the domestic blood service. In 2010 ministers agreed to the transfer of BPL out of NHSBT into PRUK Ltd, which continued to be owned by the Department.

69.8. Fourth, in 2013, I contributed to further work (Project Naga) to assess the case for selling all or part of PRUK [DHSC5744835]. I chaired a working group to consider any issues that might arise in relation to security of supply of BPL's fractionated plasma products for the NHS. The outcome of Project Naga was that Ministers approved the case for sale and PRUK was subsequently part privatised.

Q70: <u>The working Relationship between the DH and Blood Services</u>

70.1. **(a)** I have been asked to explain the lines of communication between DH and the Blood Services, including how information was shared and the working relationship between the organisations.

70.2. I took over responsibility for sponsorship of NHSBT from Mr Connon in late 2008/early 2009, so my comments are restricted to the period between then and 2012, when sponsorship responsibility transferred to another team in DH.

70.3. Following devolution, DH Ministers only had oversight of the Blood Service in England. Ministers in the devolved administrations had responsibility for the blood services in their own administrations. This was slightly complicated by the fact that the National Blood Authority, later NHSBT, which ran blood collection and processing services in England, also provided blood collection services for north Wales at that time. However, as far as I remember,

NBA/NHSBT was accountable to the Welsh government for the blood services it provided in Wales, and by the time I retired, the Welsh government had established a fully Welsh Blood Service.

70.4. During my period of responsibility for sponsorship, NHSBT was, and I believe remains, a Special Health Authority. There were good working relationships between the UK Blood Services, and good working relationships between the officials responsible for blood policy in the four nations. There were structured mechanisms in place to enable the UK blood services to share information. I believe witnesses from the blood services have already covered these in detail.

70.5. Information was shared between DH and NHSBT through both formal and informal mechanisms. Formal mechanisms included attendance by DH at monthly or bi-monthly NHSBT Board meetings, and annual Accountability Review meetings held by DH and chaired by the Director General for Public Health. In addition, DH colleagues and I worked closely with NHSBT colleagues on many topics, and both NHSBT and other UK Blood Service colleagues were crucial members of government advisory committee structures.

70.6. **(b)** I have further been asked to explain the principles and policy objectives which underpinned the relationship between the Department and NHSBT. NHSBT was one of the Department's arms-length bodies, responsible for the collection and supply of blood components, organ donation and transplantation services, tissue donation and also a number of specialist services. It had a large degree of autonomy. In simple terms, the Department was responsible for agreement with NHSBT of its strategic objectives on an annual basis, and for holding it to account for effective delivery of its executive functions within its financial allocation. NHSBT was required to provide assurance to the Department via appropriate and timely management information, and I and other DH colleagues then met with NHSBT to discuss any issues that arose. A fundamental principle of the relationship between DH and NHSBT was for DH to satisfy itself about NHSBT's ability to manage risks to its business, including its assessment of risk, and having appropriate plans and mechanisms in place to manage any risks that materialised. With regard

to the blood donation arm of NHSBT's business, this was to enable officials to provide assurance to Ministers about the integrity of the national blood collection and delivery system.

70.7. The Inquiry has drawn my attention to a minute that I sent on 26 July 2004 to Professor Lindsey Davies, then Chair of MSBT, the Departmental advisory committee on the microbiological safety of blood and tissues [DHSC0006903]. She had received a request from the Director of the National Blood Service to extend the remit of the CJD incidents Panel to provide ethical advice to the NBS on vCJD risk mitigation measures. My advice was that this was inappropriate, and that it was for the Blood Service to establish their own ethical advisory mechanism. This was more than four years before I took over sponsorship for the Blood Service. The document does perhaps hint at the Blood Service being less autonomous at that time than in later years, in persistently seeking help from the Department on a matter that should have been straightforward for NBS to deal with, but I do not consider it sheds any light on the principles underpinning the relationship between the two organisations.

70.8. As far as policy objectives are concerned, I have not seen relevant papers that might inform my answer, but as far as the Blood Service was concerned they would have included policies to support provision of a quality blood collection service for donors, a dependable supply of high quality blood components to the NHS, policies to support the appropriate use of those products by the NHS and policies to minimise risks to patients from blood/blood products for transfusion, including of course, infection risks.

70.9. **(c)** The internal structure at DH for managing the relationship with the Blood services, including the role of DH officials, was through the sponsorship team who were the primary point of contact between DH and NHSBT. The sponsorship team was responsible for oversight of all matters relating to NHSBT, including accountability arrangements. Individual policy teams would liaise with NHSBT on their particular areas of responsibility, as would DH finance and business teams, but all were expected to keep the sponsorship team sighted on key issues.

70.10. **(d)** I do not recollect any areas of significant overlap of responsibility between DH and NHSBT. If any such concern was raised, either by me or by NHSBT, I believe we would have agreed an appropriate division of responsibility, taking account of DH's wider health policy function and NHSBT's executive and advisory function.

70.11. **(e)** I have been asked about the process for receiving information by DH from the Blood Services and how this was communicated to Ministers, including standard information for briefing on a first day in office. This was handled by the sponsorship team. I would assess information in the round, including that received from NHSBT, in conjunction with my team and senior colleagues. Decisions on whether to communicate information to Ministers were dependent upon policy relevance, whether there were significant operational issues or likely parliamentary and/or public interest. For example, in 2012, Ministers were briefed on NHSBT's introduction of screening for West Nile Virus in blood donations given by people recently returned from risk areas. Also in 2012, a briefing was provided about a flood that temporarily closed an important NHSBT processing site near Bristol.

70.12. Officials, not NHSBT, prepared standard information provided to Ministers upon taking office. It would generally follow a format common to all arms-length bodies, comprising a short explanation of NHSBT's functions, its relationship to DH, its key officers (Chair and Chief Exec) and a note of any key current issues and/or Ministerial decisions likely to be needed in the coming months.

70.13. **(f)** Ministers were routinely kept up to date via briefing notes or submissions from officials. There were also occasional meetings between ministers and the NHSBT Chair and Chief Executive.

Q.71: <u>The working relationship between the Department of Health and individual clinicians</u>.

71.1. I have been asked to describe the working relationship between the Department of Health and individual clinicians, focusing on how frequently I was approached by individual clinicians on issues relating to blood and blood products.

71.2. DH worked closely with many clinicians from many sectors. I can only comment on the types of relationship with clinicians that I had personally, or of which I was aware. In the majority of cases this was to seek their expert advice or views on a matter, and to try to ensure as far as possible that policy development took account of clinical knowledge and practice. I found that the clinicians with whom I worked were, for the most part, incredibly generous with their time and expertise.

71.3. As for contact from individual clinicians, for the most part this would have been clinicians seeking advice from DH or its advisory committees. The CJD Incidents Panel secretariat would probably have dealt with most of these contacts, as clinicians involved in CJD incidents would report them to the Panel and seek advice on incident management. A proportion of these would have related to blood and blood products, but I do not know how many. I remember being contacted personally by individual clinicians on occasion, but cannot remember any of these contacts being specifically in relation to blood or blood products.

Section 5: vCJD

Q72: Information on v CJD Risks

72.1. **(a)** The Inquiry has asked who was responsible, and what was the procedure, within the Department of Health, first, for ensuring that the Department was kept informed of the growing awareness (internationally and/or domestically) about the risks of vCJD arising from blood and blood products and the various national and international responses to such risks.

72.2. The Department was kept informed of growing awareness of risks associated with blood and blood products through a number of routes: the National CJD Surveillance Unit (later the National CJD Research & Surveillance Unit, NCJDRSU) which co-ordinated the international surveillance network, together with the UK Blood Services, our expert advisory committees and the Health Protection Agency (HPA).

72.3. **(b)** The responsibility for briefing Ministers about the risk of vCJD from blood and blood products, together with the international responses, fell within the remit of the Branch responsible for infectious disease policy. Initially this was the specific responsibility of the CJD team until around mid-2004, as indicated in the previous paragraph. From then on, the responsibility remained within the same Branch but colleagues from different teams would contribute to different aspects of the work. During the entire period, we worked closely with other colleagues in DH, notably the Health Protection analytical team, to provide ministers with an accurate and comprehensive picture as knowledge developed.

72.4. **(c)** Assessments of risk were regularly reviewed and updated as new information emerged. Dr Wight and I, together with other CJD policy colleagues, regularly met with the DH analytical team to discuss our work plan. Discussions took account of information and advice received e.g. from the NCJDRSU, the Health Protection Agency, our advisory committees and the Blood Services via NHSBT and/or JPAC (the oversight committee for the UK Blood Services advisory structure). I and my team were responsible for ensuring that Ministers were kept informed of changes in the understanding of relative risk.

72.5. Timing of notification depended upon the circumstances. For example, when the first case of possible transfusion-associated transmission was reported to DH in December 2003, I notified Ministers immediately, ahead of the risk assessment being reviewed. On other occasions, Ministers were alerted when a revised risk assessment meant that changes to management measures were being considered. This happened in 2005 [DHSC5136495] & [WITN0823020] when the MSBTO Chair, Professor Lindsey Davies, informed ministers that the Committee considered there were grounds for taking action in relation to healthy donors, based on an updated risk assessment from DH analysts. A letter followed this to Ministers from the CJD Incidents Panel Chair, Mr David Pryer, to say that a Panel subgroup advised immediate cessation of use of blood from people known to have donated to a recipient who later developed vCJD. Then on 6 May 2005 I sent a briefing to CMO and Ministers about a planned joint meeting between MSBTO and the CJDIP, and

the expectation that they would give advice on further measures to protect the blood supply, and then again on 20 June to provide forewarning that the advice was likely to entail notification to a small number of healthy blood donors that they would be considered "at risk of vCJD for public health purposes". This was the first time that donors rather than transfusion recipients would be notified of their risk status, based on the new risk assessment.

72.6. (d) I have been asked whether civil servants were forthright with Ministers about the known risks of vCJD associated with blood and blood products.

72.7. During the period in which I headed the CJD policy team I was forthright with Ministers about such risks, and believe other civil servants were similarly forthright.

Q73: The Role of Ministers, Civil Servants and the CMO

77.1. The Inquiry has asked what kinds of decisions, relating either to the risks arising from blood and blood products or the response to such risks, would be taken personally by (a) Ministers or (b) the Chief Medical Officer or (c) civil servants.

77.2. **(a)** Policy decisions would be taken by Ministers; that is, Ministers set policy and make key decisions on policy development and matters that would attract parliamentary and/or public interest. Ministers did not make decisions on matters of policy implementation, as these were the concern of civil servants, although they may have expressed their views. Ministers also made decisions on financial allocations, although I do not remember this being relevant while I was leading the CJD Team.

77.3. Examples of Ministerial decisions on vCJD include whether to accept expert advice on measures to reduce the risk of secondary transmission of vCJD, and agreement (or not) to plans for parliamentary and public communication.

77.4. At the time that I was responsible for the CJD policy team, Professor Sir Liam Donaldson and his deputy Chief Medical Officer, Dr Pat Troop, were very concerned about vCJD. We were expected to keep them informed on all aspects including scientific advice sought and received, risk assessments and risk management options, advice to ministers, and plans for communication

with medical professionals and the public. Sir Liam had his own website as CMO, and occasionally sought material from the policy team to inform updates on the website. [WITN0823021].

77.5. Sir Liam advised Ministers directly, but I was not party to this. As far as I recall the types of decisions made personally by Sir Liam included the issue of the approval of patient management notification matters. For example: the establishment of a database of "contactable patients" (that is patients who had been identified as potentially being exposed to CJD as a result of healthcare treatment, and who may need to be contacted at a future time; see the 12th meeting of CJDIP, May 2004, [DHSC0020746_005]), and the approval of the concept of a public information campaign to give patients choice about being told whether they had been exposed to an increased risk of vCJD (same reference). Sir Liam took an active role in public communication on vCJD, contributing to press releases and press conferences, and issuing advice to the medical profession for example, advice on donor deferral [WITN0823022].

77.6. **(b)** In some instances, the CMO asked DH expert committees to consider matters and advise the Department. For example, in light of the first possible case of transfusion-associated transmission in December 2003, he asked MSBT to consider whether further precautionary measures were needed [WITN0823023]. If the CMO considered there were gaps in DH's repertoire of expert advice, he requested the establishment of new advisory groups. For example, it was at his request in 2002 that the CJD Therapy Advisory Group was established to maintain an overview of potential therapies, advising the 4 UK Health Departments. I believe this was prompted by the emergence of possible treatments for vCJD; for example a trial of quinacrine had been requested of the MRC by Sir Liam in late 2001, and pentosan polysulphate was emerging as another potential therapeutic candidate at that time [DHSC0008826].

77.7. **(c)** Decisions made by civil servants covered all aspects of government business. Civil servants decided when to notify Ministers about particular issues, what information and advice to provide, and whether to make recommendations. This might have included identifying appropriate data and information sources, commissioning research, analysis, or legal advice and

seeking stakeholder views, all of which could inform policy options that could be put to Ministers. Civil servants also made decisions on the detailed planning of actions required to implement policy decisions made by Ministers, including what factors need to be considered and who should be consulted. In some instances, decisions were fully within the control of civil servants, but very often they were not. In these cases, decision-making had to be informed by consultation and with advice from others. Examples referenced in this statement are decisions about how patients were best informed of their elevated CJD risk status, and who should communicate that information.

77.8. I do not recollect any specific discussions that would indicate that the approach to decision-making on vCJD differed from that in other areas of departmental policy.

Q74: Party-Political Positions

74.1. The Inquiry has asked for information on any ways in which party-political positions such as any manifesto pledges or public ministerial statements influenced the position taken by Ministers, or had an effect on the decision-making process or actions taken by the Department of Health with regard to the safety of blood and blood products, the risks of transmission of vCJD and the response to such risks.

74.2. I do not remember that party political decisions or statements by Ministers had an effect on the decision-making process or actions taken by DH with regard to safety of blood and blood products, the risks of transmission of vCJD or the response to such risks.

74.3. I do recall that during the period of coalition government (2010-2015), officials were required to alert Ministers to any differences in the position held by their coalition partners on particular issues.

Q75: Development of Awareness of vCJD Risks

75.1. I have been asked about I first became aware of the key events of the vCJD crises, including when I first became aware of vCJD and how it was

transmitted and my understanding (and how it developed) of the relative risks of vCJD infection from the use of domestically and commercially supplied blood products; I have in fact considered the risk from blood and blood components below.

75.2. I first became aware of vCJD via the news media in the mid-late 1990s, as did most of the population, and in a non-professional capacity, followed the developing understanding of the link with BSE over the next few years. It was not until I took over the CJD policy team at the start of 2002 that I began to develop more detailed knowledge of the potential routes of transmission, and the assessment of relative risk associated with blood. I have been directed to a number of documents in this regard, which I shall consider in chronological order.

75.3. [DHSC0006331_004] is a memorandum which I prepared for the CMO, informing him of SEAC's discussions at a meeting on 25 February 2004. SEAC was the overarching government committee responsible for advising government departments, including DH, on CJD and other transmissible encephalopathies. SEAC had received a presentation from Dr Pat Hewitt from NBS on the identification of the first case of possible transfusion-associated transmission, reported to Parliament on 17th December 2003. The committee had expressed no surprise at this report, given the available data from transmission studies in animals.

75.4. [DHSC0006977_163] is a briefing note drafted by me and addressed to Helena Feinstein, Private Secretary to SofS. The date was 21 June 2004, and I provided advice on briefing the European Commission about a second case of possible transfusion-associated transmission, recently identified in Scotland. The most significant points were that the patient had died of causes unrelated to vCJD, but evidence of vCJD infection had been found in spleen and a lymph node at post-mortem, although not in brain tissue; and that this was the first time that infection had been detected in a person who was heterozygous at codon 129 of the gene that encodes the prion protein. This was significant because, as SEAC noted subsequently, this demonstrated the susceptibility of this genetic sub-group to infection. (All 124 cases of vCJD in

which genotype had been established at that point were methionine homozygous at this codon (MM), whereas this patient was MV.)

75.5. [DHSC0006977_068] is a briefing note dated 2 July 2004, which I sent to a colleague at FCO (Jon Orr) in order to notify Frances Delaney in the European Commission of SEAC's assessment of the same case. SEAC had advised that this second case re-enforced the potential risk from human blood, although it provided no information that would help quantify the level of infectivity in blood.

75.6. [NHBT0041229_003] is an email, dated 21 March 2005, from Dr Hewitt to me and to Dr Kate Soldan at HPA providing early warning of a new possible case of vCJD, but this time in a blood donor rather than a transfusion recipient. The donor was known to have donated blood within the last 2 years. The Blood Services were following up the fate of the donations but would take no further action unless/until the patient was classified as a probable case of vCJD. Dr Hewitt subsequently confirmed that the case had been reclassified as "probable vCJD".

75.7. [DHSC0038543_137] is a memorandum from me dated 30 January 2006, and agreed by CMO, notifying ministers of a third possible case of transfusion-associated transmission of vCJD. By this time, there was strong evidence in support of the risk of secondary transmission via transfusion. DH continued to update and review all its vCJD risk assessments in conjunction with the advisory committees as new evidence emerged.

75.8. In 2009, further evidence emerged to support vCJD transmission via domestically-sourced plasma product (clotting factor). Evidence of abnormal prion protein was found at post-mortem in the spleen of a haemophilia patient known to have received Factor VIII to which a donor who subsequently died of vCJD had contributed. The implicated plasma donation had been made in 1996. As a precautionary vCJD risk reduction measure, plasma for manufacture of plasma products had been imported from countries assessed as having a lower risk of vCJD than the UK since 1999.

Qs76 – 78: *These questions have been withdrawn by the Inquiry*

Q79: Actions Taken by the Government

79.1. The The Inquiry has asked me to provide an outline of any proposals, whether accepted or not, that were made in an effort to protect the blood supply from the risk of vCJD, including the development of screening or diagnostic tests, donor selection and exclusion policies, the importation of product from the USA or elsewhere and surveillance. I was initially asked to include filtration policy, quarantine of batches, product recall and recombinant blood products in my answer, but the Inquiry has since withdrawn those elements of its request.

79.2. *Surveillance* I refer firstly to surveillance, which informed and underpinned decisions on all measures. Throughout the period that I was involved in vCJD and blood safety, active surveillance continued, led by the National CJD Research and Surveillance Unit in Edinburgh. In 1997 a joint programme of work had begun between the NCJDRSU (then NCJDSU) and the UK Blood Services to examine links between vCJD cases and any form of blood transfusion. This was the Transfusion Medicine Epidemiology Review (TMER), and it enabled the identification, in December 2003, of the association between blood transfusion and vCJD transmission [DHSC5330296]. It was also the mechanism through which subsequent instances of transfusion-associated transmission and the fate of donations from donors who later developed vCJD were identified and tracked. I refer to this again in my answer to Q82.

79.3. *Donor selection, importation and other measures* Over the years that I was involved in vCJD policy and blood safety, DH considered a wide range of proposals to reduce the risk of secondary transmission of vCJD through blood and blood products. Certain measures had already been implemented by the start of 2002, the time my involvement began. These were:

a) Withdrawal of all blood components, blood products or tissues obtained from any individual who later develops vCJD, to prevent their use. Introduced in 1997.

b) Provision of recombinant (synthetic) clotting factor for the treatment of haemophilia in under 16s. Introduced in 1998.

c) Sourcing of plasma for the manufacture of fractionated plasma products from non-UK sources from 1999.

d) Leucodepletion of all blood components for transfusion. This entailed reducing the number of white blood cells in donated blood. Implementation was completed in 1999. (Studies to assess the distribution of infectivity in blood using animal models had shown that the majority of the infection was associated with white blood cells and the plasma component)

79.4. Decisions on implementation of further risk reduction measures were informed by expert advice from the Department's blood safety advisory committee (MSBT, later MSBTO). Identification of a first case of presumed transfusion-transmitted vCJD in late 2003 prompted further action. MSBT met on 22 January 2004 to consider. As a result of their advice, Ministers agreed to a further donor selection measure, that people who had themselves received a transfusion of blood components since January 1980 should be excluded from donating blood. In July of 2004, following further advice from MSBT, this measure was extended to two other groups who had received transfusions of blood components since 1980: previously transfused platelet donors and donors who were unsure whether they had previously been transfused.

79.5. In 2004, following further advice from MSBT, virally-inactivated single unit fresh frozen plasma (FFP) began to be imported from countries with low BSE risk for transfusion to those born after 1 Jan 1996 (i.e. not exposed to BSE through diet). In July 2005, as an extension to these arrangements, the National Blood Service began to import FFP for use in children up to the age of 16, and also virally-inactivated cryoprecipitate for the same patient group.

79.6. It was SaBTO, under the chairmanship of Professor John Forsythe, that began the first really wide-ranging and strategic look at vCJD risk from blood and blood components, beginning in early 2008, [NCRU0000196_018] although by that time the above precautionary measures had been implemented. SaBTO's remit did not include advising on plasma derivatives, which are

products manufactured from pooled plasma donations in plasma fractionation centres (such as albumin, clotting factors and immunoglobulins). Plasma derivatives are regulated under medicines regulations and since 1999, as a vCJD risk-reduction measure, all plasma derivatives used in the UK were manufactured using donations from countries assessed to have a low risk of vCJD.

79.7. Whilst considering individual interventions that might further reduce the level of risk from specific components (red cells, platelets, plasma and products such as cryoprecipitate), SaBTO also considered measures that were applicable to all components, namely further reducing inappropriate use of blood components within the NHS, screening tests and selection of donors not exposed to BSE through diet, ie resident outside the UK during the risk period.

79.8. Considerable effort was made to assess proposed vCJD risk reduction measures against other potential risks that they might introduce or elevate, so that recommendations on additional measures were proportionate. This included assessing impact on the blood supply. Cost effectiveness was also taken into account.

79.9. During 2008 and 2009, SaBTO considered the following proposals for vCJD risk reduction in blood components:

79.10. a) Red cell components: reduction of the volume of plasma in red cell components by choice of processing method for whole blood; collection of double dose red cells for patients requiring multiple transfusions (double dose collection enables more red cells to be collected from a single donor, thereby reducing the number of donors to whom a transfusion recipient is exposed); importation of red cells from a low risk country.

79.11. b) Platelet components: reduction of the volume of plasma in platelet units by suspending them in platelet additive solutions (PAS); increasing the percentage of platelet donations collected by apheresis. Apheresis is a method of collecting platelets so that one donor can provide enough platelets for a single transfusion, whereas platelets collected from whole blood require platelets from four donors to be pooled in order to provide a single transfusion.

The use of apheresis platelets therefore reduces the number of donors to whom a platelet recipient is exposed.

79.12. c) Plasma components: extension of the importation of fresh frozen plasma from countries with a low vCJD risk for all patients; alternatives to the use of cryoprecipitate.

79.13. As I remember, following various feasibility studies, SaBTO recommended the following be implemented: the Blood Services should work as far as possible towards collecting 100% platelets by apheresis (and achieve a minimum of 80%), and importation of fresh frozen plasma should be extended for all patients. This latter measure was not implemented because the model used to estimate the risk of vCJD transmission was subsequently re-assessed in light of the fact that the observed number of cases was increasingly divergent from that predicted, and the measure was not considered cost-effective. Other relevant work undertaken by the committee, that I recall, included a review of the process already developed for evaluation of screening tests for donated blood, should such tests become available (see paras 79.14 and 79.15); consideration of use of fibrinogen as an alternative to cryopreciptate; advice on the suitability and safety of prion filtration for red cells; and, following a request from the Blood Services, advice on the use of donations that could be sourced from people born after 1 January 1996 when they became eligible to donate from 2013 onwards.

79.14. *Screening test* Preparatory work in the Department for the introduction of a vCJD screening test had been underway since 2003, beginning with the establishment of a vCJD Subgroup of the Committee on Microbiological Safety of Blood and Tissues (MSBT) [WITN0823024]. In subsequent years, a great deal more work was undertaken by the UK Blood Services and other agencies, with advice and help from expert committees. It should be noted that a diagnostic test for vCJD is not the same as a screening test, and the former would not be suitable for protection of the blood supply. I therefore restrict my comments to work undertaken in anticipation of a screening test coming to market.

79.15. A number of issues had already been raised about the development and introduction of such a test or tests. Briefly, these included: the impact of donor screening on donor numbers, the impact of false positive and false negative results, both for the individual donor and for transfusion recipients, how tests would be evaluated, what type of samples would be required for evaluation of screening tests in addition to blood, and the ethical issues associated with collection of such samples. The Subgroup advised that the best way to regulate vCJD screening tests, should they be developed, was under Annex II List A of the forthcoming In Vitro Diagnostics (IVD) Medical Devices Directive, which would come into force in December 2003. This was the list for tests for which the risk of a false result to the patient, user or third party was perceived to be the highest. Work by the Subgroup had determined that unless a test had very high specificity, most "positive" results would be false. Another area of concern was that fear of having their donation tested might significantly influence current donors to discontinue, thereby potentially reducing the supply of blood components for transfusion. The regulatory issues were set out on 22 February 2007 [DHSC0007165]. This was legal advice from a departmental lawyer, Libby Gunn, to my colleague Janet Gibson in anticipation of the introduction of a screening test for pre-clinical vCJD coming on to the market within the following 18 months. Ms Gunn's opinion was that if vCJD screening of donations were to be implemented, donors would have to be informed of the potential for an inaccurate positive result, and all donors would have to be informed of a positive test result That would lead both to an unnecessary blood shortage and the need to tell large numbers of donors why their blood could not be used, causing considerable distress, as well as resulting in knock-on effects for the NHS in managing their future care (they would need to be considered "at risk of vCJD for public health purposes"). For these reasons, the Subgroup advised that no screening test should be introduced unless a reliable confirmatory test was also available. On 26 June 2006 I updated the CMO and MS(PH) on this and on other developments for pre-clinical diagnosis of vCJD and protection of the blood supply [WITN0823025], indicating that several companies were making progress with development of a screening test. At that time, our best estimate was that a test would be on the market in late 2006 or early 2007. We were

wrong. Despite the efforts of a number of research teams and commercial companies, the difficulties in developing a test proved too great, and no test came to market during the time that I was involved in blood safety policy. The UK was, however, successful in its efforts to have vCJD screening tests included in Annex II List A of the IVD Directive. I believe this happened in around 2009.

Q80: This question has been withdrawn by the Inquiry

Q81: Assessment of Steps Taken

81.1. **(a)** I have been asked whether, in my view, the risk of secondary transmission via blood and blood products was adequately mitigated in the UK in line with what was known about the potential risks of vCJD at that time.

81.2. My answer to this is "yes", it was adequately mitigated. The DH Health Protection Analytical Team undertook a comprehensive programme of work on risk assessment, and this fed into our relevant expert advisory committees to advise on risk and risk management: the Advisory Committee on Dangerous Pathogens (ACDP); MSBT (later MSBTO, then SaBTO); and the CJD Incidents Panel, from 2000 until about 2011. There was also a cross-Government Advisory Committee on TSEs (SEAC). Risk assessments of the implications for secondary transmission were rapidly undertaken for each new case that emerged, and advice on risk management options communicated to the Chief Medical Officer and ministers, including the devolved administrations by way of their officials, with whom DH officials worked closely.

81.3. **(b)** I have been further asked whether any decisions/actions could and/or should have been made earlier by DH and how this might have affected the number of individuals considered to be at risk of developing vCJD.

81.4. I have been referred to the minutes of the second meeting of SaBTO from April 2008 [NCRU0000196_018], at which a number of members are recorded as saying that current practices could be improved for informing patients of the risks associated with transfusion and gaining their written consent.

81.5. Given the UK history of transfusion-transmitted infection, it is perhaps surprising that there had not already been more of a focus on informing patients of the risks associated with transfusion and obtaining specific consent where practicable, although I believe that advice had already been published on this for hospitals in Scotland. It is important to note that there had been and continued to be significant effort to help the NHS improve its transfusion practice by many dedicated professionals, and these had resulted in some important improvements. Other witnesses have covered these many initiatives in their evidence [WITN6982001 & WITN7001001]. When I took over the blood policy team later in 2008, there was ongoing work with the CMO's National Blood Transfusion Committee and the Blood Services to develop further advice on transfusion practice for the NHS, as part of the "Better Blood Transfusion" initiative which had been running for some years.

81.6. SaBTO decided to undertake a specific piece of work on informed consent for transfusion, arising from the discussion at their April 2008 meeting. The work stream was led by Catherine Howell, a SaBTO member and senior nurse from NHSBT, and involved a public consultation on the subject which was, I believe, the first time this had been done [WITN0823026] and SaBTO's advice on informed consent was published in 2011.

81.7. In my view, seeking and documenting informed consent for transfusion should surely be best practice. However, even if implemented decades earlier, I consider it highly unlikely that this would have affected the number of individuals considered to be at risk of developing vCJD.

Q82: Notification Exercise, September 2004

82.1. I have been asked whether I had any input into the notification exercise announced by the Secretary of State for Health, Mr John Reid, in September 2004 to notify patients who may have received blood products contaminated with vCJD, and what, if any, advice did the Department take on the legal and ethical arguments for and against such notification.

82.2. During the period in which I had responsibility for the CJD team, two notification exercises took place, the first in December 2003 and the second in September 2004, although planning for the latter began several months

earlier. The Inquiry has subsequently asked me to respond to the question with regards to both notification exercises, and in light of document HCDO0000869_007, the minutes of the 15th meeting of the CJD Incidents Panel, dated 11 May 2005. I refer to this further at para 82.21.

82.3. I shall address the notification exercises in turn. The first began in late December 2003, following the identification of the first possible case of transfusion-associated transmission of vCJD. A recipient of a blood transfusion in 1996 died from vCJD in Autumn 2003. The transfused blood was found to have been given by a donor who showed no signs of vCJD at the time of donation, but who died of the disease in 1999, The detection of this case was made possible by the joint NCJDRSU/Blood Services epidemiological study to which I referred in para 79.2. On 9 December 2003, I was notified by Professor Will from the NCJDRSU. Having made senior colleagues aware (Gerard Hetherington and David Harper), I minuted CMO to inform him [WITN0823027].

82.4. Separately, I and Departmental colleagues were at that time planning an imminent submission to Ministers, at the CMO's request, seeking approval to publish the CJD Incidents Panel (CJDIP) Framework for the management of CJD incidents, including those involving blood. On 9 June the CMO had written to Dr Troop (by then HPA Chief Executive) requesting that HPA establish a small team of experts to support local health teams managing CJD incidents in developing strategies to communicate to and counsel patients [WITN0823028]. I note from the draft minutes of the CJDIP's meeting on 23 October 2003 [WITN0823029], which I had been unable to attend, that HPA reported that they had arranged a meeting for 4th November to discuss this with stakeholders and that *"it was envisaged that the group would include expertise both in counselling patients and clinical aspects*". In response, the minutes note that "*Panel members were agreed on the importance of providing consistent advice; one way of achieving this might be the inclusion of some Panel members in the group*…" An email from Ailsa Wight to CMO's office, dated 5 December 2003 [WITN0823030] noted that this action was not complete and that HPA had been asked to expedite it by the end of the year.

82.5. Reverting to the notification from Professor Will, I attended an oral briefing with Ministers on 11 December. I cannot now remember who else attended that meeting, but I followed up with a submission noting that the UK CMOs were holding a teleconference with experts the following day, and an expert group had been convened for the 15 December to assess the evidence and recommend any further precautions to protect the blood supply [WITN0823031]. A decision was made at some point in the next few days to notify other recipients of blood from donors who had subsequently developed vCJD, but I have not seen documents which detail that. The notification exercise would require the 14 surviving recipients of implicated blood components to be informed of their risk status, and told of the public health precautions that they would be required to take.

82.6. The HPA liaised with the DH in preparation for the notification exercise, and I note a handwritten comment that I made on an email from the HPA CJD Team to regional HPA leads dated 17 December, copied to me and attaching draft letters for the notification exercise. These included letters for GPs to send to patients. My note said I was "*unhappy with these drafts – too public health oriented and not sensitive to individual patient needs*". [WITN0823032]. HPA then sent me revised drafts to consider

82.7. Following Ministers' statements to Parliament on 17 December [DHSC5016321], announcing this first case of possible transfusion-associated transmission, and the consequential public health actions, HPA colleagues kept me and other DH colleagues informed of both their plans for and progress with the notification. For example, an email from Helen Janacek on 18 December discusses how HPA would help individual GPs in decisions on when and how to notify patients for whom local support arrangements could not be implemented until the New Year, and also how to inform patients who could not be contacted by phone [WITN0823033]. A second example is the daily status report from HPA for 29 December 2003, which notes that 4 of the 12 patients in England had been notified and the remaining 8 plus 2 patients in Wales, and also said that psychiatric advice had been provided to a GP whose patient had an underlying mental health condition.

82.8. The second notification exercise related to patients potentially exposed to vCJD who were recipients of plasma-products. I do not believe I had any involvement in this exercise, as my responsibilities were changing as a result of divisional restructuring. As I remember, the Health Protection Agency (HPA) liaised directly with my Branch Head, Dr Wight.

82.9. DH had asked the HPA to undertake the preparatory work and lead the exercise, as referenced in para 82.10 below. The precursor to the exercise was that in his 17 December 2003 statement, the Secretary of State had acknowledged that recipients of plasma products might be at risk, and that the CJD Incidents Panel would advise on a case-by-case basis which recipients would need to be contacted as more information became available.

82.10. On 15 January 2004, David Harper (Chief Scientist and Director of Health Protection, International Health and Scientific Development) provided the Secretary of State with a submission titled, *"vCJD and Blood Donation: Update on Patient Notification*", updating him on the position in relation to the December 2003 notification of patients who received potentially contaminated blood and plasma derivatives. The submission noted that the HPA was working on behalf of the CJD Incidents Panel to carry out risk assessments on a case-by-case basis and that "as a result of the highly precautionary approach taken by the Panel, the contactable group may well include all the haemophilia patients regularly treated with plasma-derived clotting factors" (paragraph 7). The submission noted that mechanisms for tracing and contacting recipients considered by the Panel to be at risk were being developed by the HPA and that the HPA would "enhance the support to those healthcare workers responsible for contacting this group of patients, so that their particular needs are met" [DHSC0032258_032]. I note that an identical submission was also sent by David Harper to the CMO on the same date [DHSC0032258_032].

82.11. It was during the time that this notification exercise was being planned that business restructuring was taking place in infectious disease policy, including CJD, and consequently my role was in transition. I can see that I was contacted by Dr Nicky Connor, consultant epidemiologist from the HPA on 18th May about HPA's progress and plans for the notification exercise

[DHSC0032258_062]. I asked Dr Connor to write to Dr Wight, which indicates that I had not been closely involved in discussions between our two organisations. Dr Connor also referred to a meeting with Dr Harper, to which I had not been party. Dr Connor's memorandum to Dr Wight [DHSC0032258_062], headed *"Variant CJD and plasma products: informing patients"*.

82.12. On 21st July 2004, Dr Wight provided a submission which sought agreement to a proposed plan of action for notifying patients who have received plasma products potentially contaminated with vCJD [DHSC5024957]. The submission noted that the preliminary risk assessment carried out by the HPA on behalf of the CJD Incidents Panel had now been completed and that people with haemophilia and patients with primary immunodeficiency had been identified as key groups affected by the risk assessment outcomes (paragraphs 2-3 and 7-8). Paragraph 9 of the submission summarised the outcome of the risk assessment as follows:

"People with haemophilia and other bleeding disorders are a particular group (around 6000) with high usage of plasma products. There is a particular subgroup of these people who will have received specific UK sourced plasma products (factor VIII, factor IX or anti thrombin) between 1980 and 2001 (around 4000). It is now known that some of those UK sourced products are implicated as possibly infected with vCJD. The expert view is that for the sub-group of people with haemophilia and other bleeding disorders who have received these products…there is a high likelihood that if done [assessments] would show a clear majority of this group to be at risk. Individuals in this group received frequent, repeated doses of product which the risk assessment identified as "high risk"".

82.13. The submission [DHSC5024957] noted that since the Secretary of State's statement in December 2003, experts, including representatives of the CJDIP, the HPA, the haemophilia and primary immunodeficiency doctors, Blood Products Limited (BPL), and the National Blood Service (NBS) have been consulted in the light of the completed risk assessments on the plasma products (paragraph 11). In relation to "*people with haemophilia and other bleeding disorders, a consensus of relevant patient and doctor groups*" was that "*all patients with clotting disorders should be informed as soon as possible that they are at increased risk of vCJD if they received UK sourced factor VIII,*

factor IX or anti-thrombin between 1980 and 2001" (paragraph 12). Recommended action, as part of the DH policy on vCJD to take a precautionary approach and in view of the "*clear lobbying and support from patients with haemophilia and other bleeding disorders and doctors' groups*", was that officials believed an "umbrella" approach to the notification exercise was most appropriate (paragraph 14). An "umbrella" approach meant informing "*all people with haemophilia and other bleeding disorders in the specific sub-group who received the UK sourced factor VII, factor IX or ant thrombin between 1980 and 2001, irrespective of whether the batch of product has been implicated or not be classified as 'at risk'*" (paragraph 14). The need for a "staged process of *communications with patients"* was emphasised, which included clinicians responsible for patients being contacted first, so that they were in a position to provide information to their patients (paragraph 18-19).

82.14. The July submission was followed by a further submission on 10th August 2004 from my Acting Divisional Director, Gerard Hetherington, which referred to the need to change the timing of the notification exercise [DHSC5144240]. The original plan had been for the HPA to send out letters to clinicians and other healthcare professionals on 11 August with notification of patients aimed for 24 August. Two of the patient groups, the Haemophilia Society and the Primary Immuno-deficiency Association, which had been consulted as part of the preparatory work had written to the Secretary of State requesting that the exercise be postponed until the beginning of September. The recommendation in the submission was that this request was agreed.

82.15. I note that on 9th September 2004 I emailed Gillian Turner and Frances Hall from the CJD Support Network and the Human BSE Foundation to let them know of the patient notification exercise being announced that same day and advising that they would be receiving information from the HPA to help them when dealing with any concerns from patients who were being contacted. As I recall, I was asked to do this because I had an established working relationship with both support organisations. My only involvement in this particular exercise related to contact with countries that had received imports of implicated plasma products. I worked with the DH international division and

FCO to co-ordinate the dissemination of information prepared by Bio-Products Laboratory and the HPA to those countries to which these implicated batches had been exported. Please refer to my answer to Q84 below.

82.16. **(b)** *Legal and Ethical Advice*. The Inquiry has asked whether the Department took any advice on the legal and ethical arguments for and against such notification. The CJD Incidents Panel had members with legal and ethical expertise together with patient communication expertise, and I believe that the CJD incidents Panel had considered such matters and advised the Department accordingly. I have been referred to HCDO0000869_007, which is the minute of the 15th meeting of the Panel, held on 11 May 2005. I am not aware that the Department took additional advice on ethical or legal matters.

82.17. **(c)** *Psychological Advice*. Regarding advice on the psychological impact that notification could have on patients, particularly those already infected with Hepatitis and HIV, again I cannot recall that the Department took advice. However, I believe that the UKHCDO, together with the doctors treating patients with primary immunodeficiency, and the relevant patient support groups may have provided such advice to the HPA, given their previous experience in communications on HIV and hepatitis C with this patient group.

82.18. I have been provided with some of the minutes of the CJD Incidents Panel and I can see that the impact of notification on patients, including the psychological impact was considered during the meetings in May and September 2004. The minutes from the meeting of 10th May 2004 [DHSC0020746_005] note that some Panel members had expressed concern about future patient notifications and the need to audit the impact on patients (pages 8 -9 of the minutes). The minutes also refer to the *"preliminary results"* of a postal survey of GP's involved in the 2003 notification exercise, which had been conducted by Mr GRO-A. Mr GRO-A noted that *"the majority of GP's who had replied so far (12 out of 15) considered that their patients had coped fairly well and were positive about the information provided by the HPA. Two GP's, however, expressed serious concerns about the way the incident had been managed and the pressure they were placed under"* (pages 8-9). Dr Painter reported that, *"in his role with the HPA, he was developing a document which clarified the respective roles of the CCDC and other members of the local team*

involved in patient notification. This would aim to provide a firm foundation for the effective management of CJD patient notifications, including sources of support and information" (pages 8-9). The minute also notes that, *"although CMO had accepted the Panel's recommendation for a public information campaign to give individuals choice about being told that they had been exposed to an increased risk of vCJD, this was not feasible without the creation of the 'research' database of exposed individuals. However, CMO desired further public debate about its establishment"* (pages 8-9).

82.19. The minutes of the meeting of the CJD Incidents Panel in the subsequent meeting on 6 September 2004 [DHSC0038672_051] refer to the continuation of the discussion with the full report being presented by Mr GRO-A (page 10). The Minutes notes that:

> "*Panel members discussed the importance of access for patients to both accurate information and appropriately trained health service staff who could enable them to explore and come to terms with the implications of the information, including its emotional impact. It was suggested that having a dedicated CJD counsellor funded by the DH and attached to a body such as the CJD Support Network might be one way of meeting this need, complementing the HPA toolkits and cadre of experts. The possibility was raised of undertaking a survey of the patients and families involved so as to improve the process of future notifications. Ms Turner agrees to obtain feedback from patients and their families in touch with the CJD Support Network and share this with the Panel" (page 10).* The results of this survey are presented in para 82.21.

82.20. I remember subsequently contacting Professor Gill at the HPA, asking him to confirm that access to an expert counsellor was being provided to all patients who were notified.

82.21. I refer now to [HCDO0000869_007], the minute of the CJD Incidents Panel meeting of 11 May 2005, to which the Inquiry has drawn my attention. I was present at this meeting as an observer for the Department. The Panel received a report of a small survey of 12 patients and relatives who had contacted the CJD Support Network helpline following the 2003 notification. The key messages were that patients had received the messages well where they had been informed by a GP they knew and with whom they had a good

relationship. Difficulties had arisen where patients had been informed by someone they did not know; where the informant had little knowledge of CJD; and where the patient had to seek information/support elsewhere.

82.22. At this same meeting, the Panel discussed a request from the CMO for advice (jointly with MSBTO) on actions that should be taken in relation to individuals who had donated blood to patients who subsequently developed vCJD. An assessment of risk by the Department's analysts (known as the "reverse risk assessment") indicated that there was a distinct possibility that infections in blood recipients may have been acquired from infected donors rather than via consumption of BSE-infected meat products. The Panel's view, subject to agreement by MSBTO, was that donors in this category should be notified and told that they are "potentially at risk of vCJD for public health purposes". It was acknowledged that although this would cause anxiety for the donors, they would likely readily accept that other patients should not be put at risk through donation of their blood, tissue or organs. Although I have not seen the relevant documents, I remember that the Health Departments subsequently agreed that such donors should be notified, and a further notification exercise took place later in the Summer of 2005. On this occasion, the Blood Services led on the notification exercise.

82.23. I would say that relation to each of the notification exercises, the DH, together with the other organisations involved in the process sought to learn lessons and improve on earlier notification exercises, including by endeavouring to be sensitive to the patients and to how the process of notification might affect them emotionally and psychologically, bearing in mind (as is noted by the Inquiry's question) that some patients had already been infected with Hepatitis and HIV.

82.24. Thus [WITN0823034] is a review document authored by Dr. Patricia Hewitt from NHSBT, and others. Although it relates primarily to the 2005 notification exercise of blood donors by the UK Blood Services it contains a summary of the learning processes from the previous notification exercises at pages 12-13. At page 13 it notes that:

"The majority of individuals identified as "at risk" of vCJD due to treatment with plasma products during the notification in September 2004 were

patients with bleeding disorders, very many of whom were undergoing care at a haemophilia centre. Haemophilia centre clinicians, by whom they were known, informed them. Staff in these centres had earlier been involved in communicating information, when this became known, about previously unknown infective risks (HIV and HCV) associated with use of plasma products. Such information introduces great uncertainty for the patients' future health. This previous experience was invaluable, in addition to that gained with the earlier CJD notifications, in planning the notification of these patients. Furthermore, there was the advantage of being able to work through clinicians who were well informed about both the individual patients and the issues relating to the notification information…"

Q83: Notification Exercise (continued)

83.1. In relation to the patient notification exercise, I have been asked to set out:

a) The dealings that I had with UKHCDO (UK Haemophilia Centres Doctors Organization);

b) The dealings that I had with blood products licensing authorities;

c) The dealings that I had with the CMO;

d) The dealing that I had with the Foreign and Commonwealth Office (FCO).

83.2. a) With regard to the UKHCDO, I had no dealings with them in relation to the 2004 notification exercise.

b) With regard to the blood products licensing authorities, there is correspondence to me from Carol Penning at MHRA [DHSC5348108] requesting information about the plasma products relevant to the notification exercise, in order to prepare for a forthcoming EMEA (European Medicines Evaluation Agency meeting). I am afraid that beyond what I have seen in the documents (and it may be that there are further documents that I have not seen), I do not have any specific recollection that I can provide to assist the Inquiry.

c) With regard to the 2003 notification exercise, my dealings with the CMO are set out in paras 82.3-82.5. I may also have attended briefing meetings with him but have seen no documents to confirm this. With regard to the 2004 notification exercise, I believe my only direct contact from the CMO is

described in an email dated 21 September 2004 from myself to an official in the French Government, which indicates that the CMO had requested that I send the recipient a copy of the press release announcing further precautionary measures being taken in the UK in relation to the vCJD and plasma products [WITN0823035]. I have been shown two further documents in relation to the 2004 exercise, in which I am copied in to requests from CMO's office. One is an email to me from a colleague in my Branch, dated 26 Aug 2004, seeking comments on the drafts of the patient notification media handling plan, written ministerial statement and a letter to Paul Burstow MP ahead of sending to the CMO [DHSC0041032_028]. The other is an email to Dr David Harper, dated 15 September 2004, regarding the CJD Incidents Panel's annual report [DHSC0004603_045], which was forwarded to me to suggest some particular wording. In neither case have I been directly asked by CMO's office to contribute, but I think colleagues approached me because of my familiarity with the issues.

83.3. With respect to (d), the FCO, there are several documents that I can refer to in relation to my dealings with the FCO and I do so below.

83.4. *Liaison with the Foreign and Commonwealth Office*. Following from the 2003 notification, a further blood donor was identified who had subsequently developed vCJD. One recipient of that donor's blood was a German national, and I ensured that our FCO contact in Berlin was made aware and asked her to liaise with the German Health Ministry [WITN0823036].

83.5. With regard to the 2004 notification, this had implications for several countries that had received certain batches of plasma product from BPL that had been identified as containing a donation from someone who subsequently developed vCJD. Colleagues and I at the Department of Health were involved in ensuring that the Health Ministries in other countries were informed about the notification exercise by providing the relevant information via diplomatic channels through the FCO. In practice this involved contacting *"FCO posts"*, which as I understand the term, meant Embassies (in non-Commonwealth countries) and High Commissions (in Commonwealth countries).

83.6. On 22 September 2004, I sent an email to Claudia Garland at the FCO, attaching a *"telegram to posts"*, to be sent to the British embassies in Brazil, Turkey, Belgium, Brunei, Singapore, India, Jordan, Morocco, Oman, Holland, Israel and France, and asking the embassies to immediately notify the relevant Health Ministries in the twelve countries, as well as informing them that additional country specific information would be supplied shortly thereafter. Claudia Garland responded the following day, confirming that the telegram had been sent and indicating that she had flagged both herself and myself as contacts should any queries arise. The telegram was titled, *"vCJD further precautionary measures announced, information for posts"*. It sets out that:

> *"Selected groups of patients in the UK are this week being notified about the results of a risk assessment exercise for blood plasma products.*
>
> *The notification exercise, which relates to the possible transmission of variant Creutzfeldt-Jakob disease (vCJD) through plasma products, was announced by Health Secretary, John Reid on 9 September. Plasma products are made from pools of thousands of plasma donations, which would greatly reduce the risk of vCJD being transmitted via this route. Nevertheless, the UK is being highly precautionary, and taking public health measures to minimise any risk of further onward transmission via this route…*
>
> *The following countries have received imports of certain batches of plasma products from the UK, which have been found to have contained a plasma donation from a donor who subsequently developed vCJD:*
>
> *Brazil, Turkey, Belgium, Brunei, Singapore, India, Jordan, Morocco, Oman, Holland, Israel and France.*
>
> *For each of your countries, the UK manufacturer, BPL, will have contacted the consignee in your country, provided details of the product batches affected, and asked that the information be shared with the relevant regulatory authority in that country. Should Health Ministries request any further information about the products specifically, they should discuss with their regulatory authorities in the first instance. No product withdrawal is required; all products are well beyond their shelf-life".*

83.7. The *"telegram to posts on vCJD"* had been drafted by Brian Mulrennan (European Union Business Management and Communications, International Division, Department of Health) and edited by Dr Noel Gill (Noel was Head of CJD at HPA), as well as myself, before it was sent to Claudia Garland at the FCO [DHSC0004126_032] [DHSC0004126_034]. After the initial *"telegram to*

posts on vCJD" was sent, the promised further information was gathered, which included country-specific information. Noel Gill was responsible for drafting the country-specific information. It looks like he drafted this and that I might have commented on it before it was sent [WITN0823037].

83.8. On 24th September 2004, the twelve countries were provided with further information about the notification exercise and the implications for those countries. The correspondence sent to the Health Ministries (via the Embassies and High Commissions and the FCO) included:

a) a letter to the Health Ministries,

b) the recommendations of the CJD Incidents Panel,

c) a document setting out the implementation of public health precautions in the UK,

d) a summary of the patient notification exercise,

e) a country-specific note,

f) the BPL notification letter.

83.9. Further to the dissemination of this information, the Health Protection Agency (HPA) assisted with questions from individual countries about the public health management aspects of the exercise, whilst technical questions about specific product batches were directed to BPL. There is relevant email correspondence to clarify this [WITN0823038&WITN0823039].

83.10. In addition to transmitting this information to the twelve countries through the FCO, WHO-EURO were also informed, as was the EU Commission under the European Union Early Warning Scheme (EWRS) [WITN0823038]. I provide a brief explanation about the WHO-EURO and the EWRS in my answer to question 84 below. I can see that I sent an email to my colleague, Julie Pettman, requesting that she send a document to the EWRS on 24 September 2004. The contents of that document are included in [DHSC0004126_005]. It set out the background about the implicated plasma products, the risk assessment that had been carried out by the CJDIP, that patients in the UK who were "at risk" were being notified and that countries who had received

imports of certain batches of plasma products from the UK had been contacted by product manufacturers as well as provided with further information from the Department of Health and the Health Protection Agency (HPA).

The Inquiry will wish to note that further notification exercises took place in later years, for example, in March 2006 the Department was notified by Dr Connor at HPA of two vCJD patients whose donated plasma had been used to manufacture albumin (in one case) and Factor VIII (in the other) [DHSC5406211. Dr Connor then provided an update in June [DHSC5418213] and the HPA/UKHCDO-led notification exercise began in November [DHSC5440073].

Q84: Liaison with Other Countries on vCJD

84.1. I have been asked to outline the discussions and negotiations between the Department of Health and Governments in different countries relating to vCJD, with a focus on the issue of sharing information to assist identification, etc, of vCJD.

84.2. International contact and information sharing on vCJD occurred at several levels. Policy decisions/actions were discussed at inter-government level, and communication on public health actions of interest to other countries was undertaken between national health protection agencies. There was also an international vCJD surveillance network, to which I have referred previously. Within the EU, there existed a specific mechanism for reporting early warnings of significant health concerns, and this was operated through ECDC (European Centre for Disease Control). This was the EWRS (Early Warning Reporting System). As I remember, it was initially the DH's responsibility to report to the EWRS but at some point this changed and it became the HPA's responsibility to report through the EWRS on behalf of the UK. DH also shared information with WHO on behalf of the UK. I think this would have been undertaken through DH International Division.

84.3. With respect to intergovernmental discussions, DH had contacts at official level through "FCO posts". An example is the 2004 notification exercise referred to in answer to Question 82 above. Other later examples show how

the notification exercise evolved as we became aware of other countries that were impacted. For example, in August 2005 we became aware that Morocco had to be notified, as the earlier advice that we had received that they had only used plasma for diagnostic reasons and not therapeutic reasons [DHSC5380030] was incorrect. I therefore ensured that the documents were sent to them through our FCO post as soon as possible [DHSC5382138]. Another example is in September 2005, when the Health Protection Agency asked for additional information to be provided to Brazil and for Egypt to be notified as they had become aware of batches of plasma that had been provided to both countries that had not been included in the earlier notification exercise. I was then responsible for ensuring that the correct information was provided through our FCO posts [DHSC6004790].

84.4. I recall that for the 2004 notification exercise, the UK manufacturer, BPL, was responsible for contacting their distributors in each country that had received exports, to provide technical information about the batches. I am not sure who would have liaised with the regulatory authorities in each country. It may have been their counterparts in the UK – the MHRA (Medicines and Healthcare products Regulatory Agency).

84.5. The sharing of scientific data/information was mainly between the surveillance units of each country, and expert advisory committees. For example, SEAC would liaise with their counterparts in other countries (such as Switzerland and the US) in order to be kept up to date with any experimental research into CJD and their surveillance programmes [DHSC0006331_007&WITN0823040].

84.6. Part of the role of the SEAC was to review the epidemiological information on vCJD, more specifically looking at the definite and probable vCJD cases in the UK. Where the information showed that cases in other countries had previous residence in the UK, the National CJD Surveillance Unit would therefore be in contact with the relevant national investigators and Departments of Health of the respective countries to obtain further information of those patients [DHSC0006468_007].

84.7. Similarly, there were occasions whereby within the statistics of the UK cases who were at risk of exposure, there was a patient that underwent treatment in the UK who was a national of another country and had subsequently returned to their country. The approach adopted by the Department was for contact to be made via the NCJDSU with the country in question's surveillance system in order for notification and surveillance to take place [WITN0823041].

84.8. We would also receive requests from government officials of other countries to share information, especially when the officials were visiting the UK and wished to arrange a meeting with that objective. We would lead on arranging the meeting and also consider including other departments (such as MHRA) to participate in the discussion [WITN0823042].

Q85: This question has been withdrawn by the Inquiry

Q86 - 87: Knowledge of and Relationship with the vCJD Trust

86.1. I have been asked to describe the working relationship between the vCJD Trust and the Department of Health, and, specifically, whether I was ever made aware of any difficulties, and their consequences. I have also been asked to set out my own involvement in the Trust.

86.2. I have answered these two questions together.

86.3. As far as I remember, I had little involvement with the vCJD Trust, although sponsorship resided within my team for a period of time when I was head of the CJD policy team. Prior to my involvement with the vCJD Trust, another team in the department (PH5), led by Eileen Lawrence, had more of a working relationship with the vCJD Trust. It was Eileen's team which had the responsibility of setting up the compensation scheme with the Trust; this was the focus of the Trust when it was set up in March 2002 [DHSC5014372 &DHSC0004565_059].

86.4. At the time, I was responsible for dealing with other CJD policy issues, as I was part of the CJD Policy team at the DOH (PH6 team). It was only after the compensation scheme had been established that it was decided that, as the compensation scheme had been set up, the responsibility of dealing with any

business in relation to the scheme would be transferred to the CJD Policy Team, PH6. This occurred in early 2002 [WITN0823043].

86.5. There was an overlap between my team and Eileen's team from about April 2002 in dealing with the vCJD Trust to allow a period of handover between myself and Eileen with the Trust and their administrators, Charles Russell Solicitors [DHSC0046926_006], [WITN0823044 &WITN0823043].

86.6. I have been asked whether I was aware of any difficulties in relation to the Trust. I cannot recall any difficulties, but I have been shown four documents dating between October and December 2004, which indicate that the Trust was having considerable difficulty with the discretionary component of the scheme, and that the costs of administering the scheme were disproportionate because of the scheme's complexity.

86.7. I was not copied into any of these documents, which, if I was sponsor at that time, I would certainly have expected. Consequently, I speculate that sponsorship of the vCJD Trust may have transferred to Jonathan Stopes-Roe's branch within our Division. This may have happened following the departmental restructuring that took place earlier in 2004. However, I have seen no documents to confirm that. If that was the case, it seems likely that sponsorship responsibility would have passed back to Ailsa Wight's branch again in October 2011, together with the AHOs, when Mr Stopes-Roe retired.

86.8. I do recall that the Department received an annual report and accounts from the Trust. I note that at some point, the administration of the Trust appears to have passed from Charles Russell Solicitors to Field Fisher and also note that in 2012, my colleague Naomi Balabanoff sought the Secretary of State's agreement for a proposed change to the Trust Deed, requested by the Trustees, to enable the "basic sum" that was paid out to each patient to be increased by 2% per annum, and to note the appointment of a new trustee [DHSC5014372]. I believe the proposed change to the Trust Deed was agreed. I also note that in October 2014 [WITN0823045] another of my colleagues, Mark Noterman, attended a meeting of the Trustees at which they raised the question of whether the Trust remained a good use of public money, and proposed to prepare an options appraisal on the way forward. I believe this

proposal may have been because the Trust had only had to make one new payment in the preceding few years, and considered it appropriate to reduce as far as practicable the administrative costs associated with managing the Trust. Indeed, [WITN0823046] sets out the Department's legal view on the Trust's proposals, specifically that the Trustees did not have the power to delegate their functions, even amongst themselves. As I remember, Dr Wight wrote to the Trustees in accordance with the draft prepared by GLD, noting this but supporting the aim to reduce administrative costs.

86.9. I do not recall being aware of any difficulties between the vCJD Trust and the Department of Health.

Section 5: **Record keeping and Other Issues**

Q.88 Copy of the Eileen Trust Deed.

88.1. I have been told that the Inquiry has heard evidence from Mr Peter Stevens [WITN3070003] that during my tenure that DH did not hold a copy of the Eileen Trust founding document.

88.2. Mr Stevens was correct to say that I had asked for a copy of this document. The DH hard copy files for the Eileen Trust contained a copy of the Scottish scheme document, but I had not been able to find one for England, Wales and Northern Ireland. I do not remember exactly when I first realised the document was missing, but it would have been after I took over the AHO sponsorship business. I would likely have consulted my predecessor about the whereabouts of the document, although I do not specifically remember a conversation. My assumption was that the document had been misfiled. I continued to look for it as and when my team recalled hard copy files from the archive. I am sure it was some considerable time later when I eventually requested a copy from Mr Stevens, presumably when it became necessary to refer to it for a particular matter.

Section 6: Other Issues.

Q.89 Running of the AHOs

89.1. The Inquiry has asked for my views on whether I thought the AHOs were well run.

89.2. Given the very difficult circumstances under which the charitable bodies were operating, I considered that they were generally well run. The Eileen Trust in particular, had established a very good relationship with its beneficiaries, and was able to provide a personalised service. This was possible because of the Trust's low number of beneficiaries. Smooth running of the Trust was also aided by the fact that, as I understood matters from conversations with Mr Stevens, there was not a strong campaigning element amongst its beneficiaries.

89.3. This was not the case with the MacFarlane Trust, or later, the Caxton Foundation, both of which had to manage considerable levels of discontent among their beneficiary populations. Caxton had a difficult period during the first year or two after its establishment. I do not recollect the details but believe administrative problems may have contributed. I also remember that there was a period towards the end of Mr Harvey's time as CE of MFT where his ill health resulted in some internal difficulties in Trust day-to-day management. As I recall, the situation improved when Ms Barlow was appointed as CE of the MFT. Later, following Mr Evans appointment as Chair of MFT, it became clear that relationships between him, some of his Board and Ms Barlow had become difficult. Dr Wight and I were concerned that this was having a detrimental effect on the running of the Trust and this added weight to my view that system change was overdue.

89.4. I should say that although I did not meet or know most of the Trustees of the three charitable Trusts, there was every indication that they were highly dedicated people, who worked to provide the best services that they could for their beneficiaries.

89.5. With regard to the Skipton Fund, I considered Mr Fish to be a good administrator. He was always well prepared for meetings, and regularly supplied us with anonymised data on applications to/payments made by the Fund. As soon as Dr Wight and I were alerted to complaints from the hepatitis

C community about the Skipton Fund's decision-making process in 2013, we ensured that Skipton appointed an expert medical Director, Professor Howard Thomas, to assess applications to the Fund. Later, in 2015, a second expert medical Director, Professor Geoff Dusheiko was also appointed in order to further assist the Fund in assessing the increasing number of applications where evidence was lacking or less clear-cut.

Q90: Further Information

90.1. I have been asked if I can provide any other information and or views relevant to the Terms of Reference. I have not remembered anything that I think important to add with regards to the Inquiry's work.

Statement of Truth

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

Signed. GRO-C .....

Dated.....27 May 2022.....