Witness Name: John Canavan Statement No.: WITN7115001

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### INFECTED BLOOD INQUIRY

### FIRST WRITTEN STATEMENT OF JOHN CANAVAN

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### Section 0: Preface

I, John Canavan, will say as follows: -

0.1.	My name is John Canavan. I	was born on <b>GRO-c</b> 1947. My address is <b>GRO-C</b>	
	GRO-C	South Lanarkshire GRO-C	

- 0.2. I am providing this statement in response to a Rule 9 request from the Inquiry, dated 24 June 2022. I was a civil servant in the Department of Health and its predecessors from August 1966 until November 2002.
- 0.3. From January 1989 to March 1994, I worked in policy areas of direct relevance to the Inquiry's request. In this period, I was involved in the HIV haemophilia litigation and, on the DH side, the publicity campaigns to persuade the Government to settle. I helped set up the arrangements for making an ex-gratia payment of £20,000 to each infected haemophiliac and the payments made after the out of Court settlement of the litigation. I also helped devise a scheme for making payments to blood transfusion recipients who were infected with HIV. I was also the Administrative Secretary to the Advisory Committee on the Virological Safety of Blood. I give further detail of these matters below.

### **Opening Comments**

### Reflections

0.4. I welcome the Inquiry and sincerely hope that it can deliver answers to the entirely understandable questions raised by those infected and their loved ones. Since I received the Inquiry's request for a statement, I have worked hard to familiarise myself with the very large volume of material with which I have been provided. I am willing to help the Inquiry as much as my memory will allow, supplemented with what is apparent to me from the documents.

### The process of providing this statement

- 0.5. I had been retired for almost 20 years when I received the Inquiry's request for a statement. The events that I am asked about took place 28 years ago or more. The Inquiry provided me with five full lever arch files of documents. My advisers provided me with a supplementary bundle of documents that also runs to five full lever arch files. While I have had legal assistance in tackling these materials, it has nevertheless been a very significant task to read and assimilate the material to which the Inquiry and my advisers have directed me. Reading the material has brought back some memories, but I am very conscious that, inevitably, my recollection would have been much better closer in time to the events than it is now. For this reason, I am heavily reliant on the documents that have been made available to me.
- 0.6. I am also conscious that, despite the large volume, the material provided to me is only a selection of what I would have seen over the years. I say this because there are areas of my work in blood policy which the Inquiry has not asked me about (plasma supply; BPL / CBLA; the creation of the NBA; CJD; payments to those infected with HIV by transfusion (and the Eileen Trust), to name a selection). If further material relevant to the Inquiry's request is brought to my attention, then I may need to revise my statement.
- 0.7. Whilst my work in blood policy often involved matters of a scientific or medical nature, I did not have any scientific or medical qualifications or expertise. I should emphasise that I was a civil servant on the administrative side of the Department, with involvement in policy.

### **Section 1: Introduction**

### Q1: Biographical details

1.1. I have set out my name, date of birth and address above. I do not have any professional qualifications relevant to the Inquiry's Terms of Reference.

### Q2: Employment history

1.2. I joined the Ministry of Pensions and National Insurance in August 1966, which within a very short time became the Ministry of Social Security. In 1968, the Ministry of Social Security merged with the Ministry of Health to become the Department of Health and Social Security (DHSS). I spent most of my career working in the DHSS (which became the Department of Health, in 1988) until I retired from the Civil Service in November 2002. I held a number of different positions within the Department during my career. The following is a chronology of the various positions that I held. The dates are approximations and are based on the documents.

### August 1966 to late 1988

- 1.3. In brief summary, I held the following roles:
  - a) August 1966 to September 1971. I worked in National Insurance Offices in Liverpool and later in Glasgow. I supervised clerical staff processing benefit claims and later decided benefit entitlement in less straightforward cases.
  - b) October 1971 to September 1972. I relocated to London and started work in the Medicines Division of the DHSS. I supervised clerical staff doing preliminary checks on applications for licences to market medicines that had been marketed in the UK before the introduction of a full licensing system.
  - c) October 1972 to October 1978. I moved on promotion to the branch responsible for the pharmaceutical price regulation scheme.

- d) November 1978 to late 1979 / early 1980. I worked in the branch that negotiated the pay and conditions for professions auxiliary to medicine, such as physiotherapists, occupational therapists etc.
- e) Late 1979 / early 1980 to 1983. I moved on promotion to the Department's management services branch where I carried out organisation and method studies, with a view to improving systems and processes for administering social security benefits.
- f) 1983 to 1988. I was promoted and took over as Section Head for policy in relation to high street optical services.

### January 1989 to December 1991: Principal, HS1 (later named EHF1)

1.4. In January 1989, I took over from Dr Roger Moore as Principal in Health Services 1A (HS1A) [DHSC0003311\_012]. The role of Principal was equivalent in terms of seniority to what later became Grade 7 within the civil service hierarchy. HS1 branch was an administrative branch of the DHSS with responsibility for:

"Hospital scientific and technical services; hospital pharmaceutical services; blood transfusion services including NBTS; laboratory services; toxicology and chemical health hazards; radiological protection; hospital health records, hospital complaints, Community Health Councils, health advisory service, medico-legal questions." (see Civil Service Yearbook for 1989).

1.5. As HS1A Principal, I was the head of the HS1 section that was concerned with policy in relation to blood supply and blood safety, including blood transfusion services. The "A" was simply an alphabetical denomination for my branch of HS1. The responsibilities of HS1A were listed in an undated note [WITN7115002] (other documents suggest the note is dated from around September 1989 [DHSC0004479\_050] and [WITN7115003]). These included: the National Blood Transfusion Service (NBTS); blood supply; the Central Blood Laboratories Service (CBLA); "Haemophilia/ Macfarlane Trust"; and "AIDS litigation". The note listed the names of six members of my support staff. At various times my support staff included the HEOs Mike Arthur, David

Burrage, Pam Reenay and John Rutherford. Elaine Webb was an EO in the section for some of my time working there. Elaine Webb was succeeded by Monica Gibson.

- 1.6. Under "Professional Support" the note listed three Senior Medical Officers, namely Dr Andrzej Rejman; Dr Peter Bourdillon; and Dr Robert Hangartner. Brian Godfrey was also listed. At that time, the Department operated a parallel structure; each subject area had both a medical and an administrative division. The administrative structure reported upward to the Permanent Secretary and the medical structure reported upward to the Chief Medical Officer. This structure remained in place until early 1995.
- 1.7. In the relevant medical branch, namely Med SEB, I worked most closely with Dr Rejman. Dr Rejman was a haematologist and therefore the Senior Medical Officer (SMO) in the medical branch with expertise in the policy areas with which I was concerned. Dr Rejman reported to Dr Hilary Pickles, a Principal Medical Officer (PMO).
- 1.8. I reported to the Assistant Secretary (Grade 5), initially Malcolm Harris and later Charles Dobson. Charles Dobson was an operational researcher by profession. He was quietly spoken but very bright and a quick worker. He had no grounding in the clinical matters that he was dealing with, but was bright enough to understand them and was well attuned to identifying what issues mattered.
- 1.9. HS1 was one of several branches that made up the Health Services Division. The Health Services Division was headed by an Under Secretary (Grade 3), initially John Cashman and later Dora Pease, and sat within the overall umbrella of the Health and Personal Social Services (HPSS) Group. The Under Secretary reported upward to the head of the HPSS Group, a Deputy Secretary (Grade 2), Strachan Heppell. His role meant he was concerned more with strategic and politically sensitive issues (some of which would have been

delegated down from the Permanent Secretary) and tended not to get involved in the fine detail. Strachan Heppell in turn reported upward to the Permanent Secretary, initially Christopher France and later Graham Hart.

1.10. HS1 changed its name to EHF1 (Environmental Health and Food Safety Division) in around February 1990. Its responsibilities remained the same.

### January 1992 to June 1992: Principal, HC(A)4

- 1.11. In January 1992, after a Departmental reorganisation, EHF1 became Health Care (A) 4 branch (HC(A)4). My responsibilities within it remained the same. I did not move office. The branch was described as concerned with, amongst other things, "blood supplies and HIV litigation" (see Civil Service Yearbook for 1992, August edition). My designation in the documents was HC(A)4B (the "B" being no more than an alphabetical designation for my section of the branch). I reported to the new branch head, Roger Scofield (Grade 5), which was really, so far as I can recall, the key change between my role in HS1 and HC(A)4.
- 1.12. HC(A)4 sat within Health Care (A) Division and alongside the equivalent medical branch (HC(M), which included Dr Rejman), in the parallel structure. The Division was headed by a Grade 3, Clive Wilson. I rarely dealt with him. He reported upward to Strachan Heppell, who headed what was by then called the Health and Social Services Group. Strachan Heppell continued to report upward to the Permanent Secretary.

### June 1992 to March 1994: Grade 7, CA-OPU2

1.13. In June 1992, HC(A)4 became the Corporate Affairs Operational Policy Unit (CA-OPU), which was part of the Directorate of Corporate Affairs, which in turn sat within the overall umbrella of the NHS Management Executive (NHSME). I was a Grade 7. My designation in the documents was CA-OPU2. The branch's responsibilities included, amongst others, "Blood Services" (see Civil Service Yearbook for 1994). CA-OPU was headed by Roger Scofield. He reported to

the Director of Corporate Affairs (Grade 2), John Shaw. He in turn reported upward to the Chief Executive of the NHS Management Committee, Duncan Nichol.

- 1.14. Medical colleagues working on the same issues were members of Health Care (Medical) Unit 1 (HC(M)1), which included Dr Rejman. In this period, I was involved in the reforms that led to the establishment of the National Blood Authority (NBA), which was set up on 1 April 1993.
- 1.15. I left CA-OPU on 29 March 1994 [**DHSC0006212\_041**]. My successor was Tom Kelly.

### April 1994 to September 1995: seconded to NHS Ombudsman

1.16. I went on secondment to the NHS Ombudsman. I was there for around 18 months, or so. I managed a small team that investigated complaints about peoples' dealings with the NHS (not on clinical matters).

### October 1995 to 1999: HP3B

- 1.17. I joined Health Promotion Division 3 (HP3) upon my return to DH in around October 1995. The branch's responsibilities included, "Notifiable and other communicable diseases (including HIV and AIDS); vaccination and immunisation; blood borne viruses." It was headed by a Grade 5, Almas Mithani (see Civil Service Yearbook for 1996).
- 1.18. Initially, I took on the role of administrative secretary to a Working Group reviewing blood borne virus prevention in renal dialysis units. This had been set up by the Public Health Laboratory Service (PHLS) at the DH's request. PHLS provided the medical secretary for the Working Group.

1.19. Afterwards, I took over as section head within HP3 with responsibility for policy on the prevention of hepatitis in the public, e.g., by drawing attention to risk factors such as needle sharing, and considering the cost benefits of vaccination against hepatitis B. We also had policy responsibility for the policy on whether HIV infected health care workers could work. We issued general guidance to hospitals and served as the administrative secretariat for an expert group that advised on guidance and made decisions on individual cases.

### Early 2000 to 2001: SC2

1.20. In early 2000, I worked in branch SC2, which sat within the Social Care Group. I headed a small section within SC2 dealing with the voluntary sector and the payment of grants for projects relevant to health and social care.

### 2001 to November 2002: optical services

1.21. My final period at DH was spent back dealing with high street optical services. I took early retirement in November 2002.

#### Q3: Committee memberships

- 1.22. I was a member of and/or observed or attended at the following groups or committees, in the following roles:
  - Administrative Secretary, Advisory Committee on the Virological Safety of Blood (ACVSB).
  - b) Secretariat, Advisory Group on Hepatitis (AGH).
  - c) Observer, Central Blood Laboratories Authority (CBLA) Committee.
  - d) Administrative Secretary, Public Health Laboratory Service (PHLS)
     Working Group on blood borne viruses in renal units.
  - e) Administrative Secretary to the UK Advisory Panel for Healthcare Workers infected with Bloodborne Viruses.

### **Q4: Advisory Committee on Hepatitis**

- 1.23. I do not recall any involvement with a committee that went by this name. I assume that the reference should be to the Advisory Group on Hepatitis (AGH). I cannot now recall the nature of my involvement with the AGH; what I say below is apparent from the documents.
- 1.24. The Terms of Reference of Related Groups was incorporated within the document setting out the ACVSB's Terms of Reference. The ACVSB's Terms of Reference and the Terms of Reference of Related Groups were put before the Committee as ACVSB1/1 (the papers that went before the Committee followed this numbering convention) [WITN4486049]¹. In relation to the AGH, ACVSB1/1 stated:

### "8. Advisory Group on Hepatitis

This group "provides medical advice to the Chief Medical Officers of the Health Departments on all aspects of communicable hepatitis" and has the appropriate expertise for detailed consideration of the technical aspects of screening donors and plasma for various forms of hepatitis, leaving the advisory committee on the virological safety of blood to consider the wider policy issues."

1.25. I have been shown a submission dated 18 August 1997 from Mr Robb (HP3B) to the Chief Medical Officer (CMO), then Sir Kenneth Calman, and the Deputy CMO (DCMO), Dr Jeremy Metters, and copied to me [DHSC0006281\_127]. The submission said that the AGH was set up in 1980. It sought agreement to review the AGH's membership and Terms of Reference.

"We suggest that the terms of reference are more focused to cover the Group's important function of advising on the prevention and control of viral hepatitis, particularly in relation to immunisation and the protection of patients from infected health care workers, and to take account of the AGH's relationship with other advisory committees (eg. the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation, the Joint Committee on Vaccination and Immunisation

<sup>&</sup>lt;sup>1</sup> [PRSE0001189] and [PRSE0004113] appear to have been mixed up on IBI's database such that each contains the second page of the other. [WITN4486049] appears to contain correct copies of both documents.

and the UK Advisory Panel for Health Care Workers infected with Bloodborne Viruses)."

- 1.26. I have been shown a small selection of AGH minutes. The 12 March 1991 minutes recorded Dr Rejman as one of the DH attendees [DHSC0003967 049]. He provided a report on behalf of the ACVSB. I offered apologies for not being able to attend. The 14 October 1996 minutes noted that I attended in my capacity as Administrative Secretary to the PHLS Working Group tasked with preparing guidelines on blood borne viruses in renal [DHSC0006410\_035]. By the date of the 24 February 1997 meeting, I was listed as part of the AGH's Secretariat [DHSC0006410\_017]. I see from the submission that the Secretariat was provided by HP3.
- 1.27. I have also been shown an email from Charles Lister to Anita James, dated 8 December 1999 [WITN5426145]. Charles Lister said that he had spoken to me as the "person currently responsible for the Hepatitis C Advisory Group". I assume that this was a reference to my role on the AGH Secretariat.
- 1.28. On 21 January 2000, I received an email from Anita James, DH solicitor, in relation to non-party discovery in the Hepatitis C virus (HCV) litigation [WITN5426164]. The claimant's solicitors, Deas Mallen Souter, wanted the minutes of the Advisory Group on Hepatitis between 1988 and 1991. On 24 January 2000, I confirmed that I had requested the files from the store in Nelson (Lancashire) [WITN5426166]. I said, "They may contain little if anything about hep C in blood supply, as this came within the ACVSB remit from 1989."

#### Q5: Private interests

1.29. I do not have (nor have I had) any private or business interests which are relevant to the Inquiry's Terms of Reference.

### **Q6: Involvement in other inquiries**

1.30. I was involved in the HIV haemophilia litigation, which I explain further below. As mentioned above, I had brief, passing involvement in the non-party discovery in the HCV litigation. Otherwise, I have neither provided evidence to nor have I been involved in any other inquiries, investigations, criminal or civil litigation in relation to HIV and/or hepatitis B virus (HBV) and/or HCV infections and/or variant Creutzfeldt-Jakob disease (vCJD) in blood and/or blood products.

# Section 2: Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee")

2.1. The Inquiry asks me a series of questions about the ACVSB. In terms of its remit, functions and activities, the Terms of Reference stated [WITN4486049]:

"To advise the Health Departments of the UK on measures to ensure the virological safety of blood, whilst maintaining adequate supplies of appropriate quality for both immediate use and for plasma processing".

"Note remit is UK-wide. Our concern is matters of major policy, not the detailed implementation of policy. The intention is that any proposed changes in requirements or practices of one of the main groups (transfusion service, fractionators, regulators) that has major implications for the others are brought to this group first for discussion. Whilst our specific remit is with blood donors, our advice will also be made available to those within the Department who have policy responsibility for tissue and organ donors."

2.2. The Chairman's brief for the first Committee meeting on 4 April 1989 attached a Background Note [**DHSC0002494\_023**]. My name appears on the document, so it may have been authored by me. It said,

"Concern to maintain the safety of the blood supply has been heightened by greater public and clinical awareness of the potential for viral contamination and the developments in product liability legislation. Decisions on testing for particular viruses involve a range of disciplines. Clinical and scientific expertise must be balanced by expertise representing the practicality and cost/benefit of testing. Other interested parties in this field such as the Committee for the Safety of Medicines, the Central Blood Laboratories Authority and the Blood Transfusion Services do not have the remit nor the expertise to take this broader approach. Hence the need for this new Advisory Committee on which all the interests are represented but which can also take an overview."

2.3. The Inquiry refers me to a document titled "Overview of Problems for this Committee", which was circulated as part of the papers for the first Committee meeting (ACVSB1/2) [WITN4486049]<sup>2</sup>. This was a proposed work plan. It

<sup>&</sup>lt;sup>2</sup> The Inquiry's reference is to [PRSE0004113] but a better version is at [WITN4486049].

Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") itemised the five main issues, at that stage, for the Committee (and included testing for Non A Non B (NANB) hepatitis).

- 2.4. As the Principal in HS1A, I was the Administrative Secretary to the Committee. Dr Rejman was the Medical Secretary. The Secretariat's job was to ensure the efficient functioning of the Committee. My role (supported by my staff in HS1A) involved arranging for the Committee to meet appropriately and reasonably frequently; ensuring that any papers were obtained and distributed to Members in good time; assisting with drafting the Chair's brief, the agenda and minutes (all in consultation with, and with the advice of, Dr Rejman); reporting decisions to the right people in the Department; and monitoring any follow up actions. This was the first advisory committee with which I had been involved. I was frequently copied into Departmental correspondence in relation to the Committee (of which I give more detail below), but was usually the most junior copyee.
- 2.5. Dr Rejman was a Medical Officer, so he inevitably took the lead on medical or scientific matters in so far as the Secretariat was concerned. For example, providing updates on clinical developments, summarising the contents of papers or preparing papers for the Committee to consider. For some of the meetings, a junior colleague from HS1A would attend (either Mike Arthur, Pam Reenay or Elaine Webb) and, if present, they would take the minutes.
- 2.6. Dr Rejman and I had a very good and close working relationship. He was new to civil service but his professional expertise as a haematologist was particularly relevant to issues considered by the ACVSB. He was also a very helpful colleague. He was not resistant to taking on work; indeed, he was a very hard worker. He gained the respect of my whole section. They valued his input.
- 2.7. There was a heavy medical bias to the issues considered by the Committee. Its members were some of the most eminent practitioners in this field in the

Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee")

country. The Committee gave independent advice on whether it was appropriate, and at what stage it was appropriate, to introduce testing. As a non-medical, Principal grade civil servant I would not have been in a position to second guess the expert advice given by the Committee.

- 2.8. The Committee was chaired initially by Dr Ed Harris (for the first three meetings) and later by Dr Metters. They were both DCMOs. This was significant. It meant that although the ACVSB was an advisory committee, it had a very senior official as its chair. Dr Harris or Dr Metters were well placed to direct that a submission on a particular issue discussed in the Committee should be put promptly to the CMO or ministers. If either of them was in any doubt about an issue, then they could have gone straight to ministers for a decision. This was not the case of a committee made up entirely of outsiders with me as the Administrative Secretary then disseminating the advice. The Committee was wired into the Department through its chair.
- 2.9. Dr Metters was hugely experienced, a heavyweight character and a very good chairman. There were various disciplines around the table and Dr Metters allowed them to put in their opinions and advice. He was good at drawing the threads together. He was also politically astute and alive to the possible repercussions of the Committee's advice and decisions. I have very little recollection now of Dr Harris.

### Introductory matters concerning the ACVSB: Q7 to Q13

Q7: Dr Harris' minute, January 1989

2.10. The Inquiry refers me to a draft minute from Dr Harris [DHSC0006876\_152] and enclosed submission [PRSE0003956]. The draft minute was in fact attached to a covering minute dated 3 January 1989 from Dr Hilary Pickles (Principal Medical Officer, Med SEB) to the Private Secretary to the CMO, Sir Donald Acheson (copied to me) [DHSC0002429\_076].

Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee")

- 2.11. Dr Pickles' minute said that a submission on the ACVSB had gone to the then Parliamentary Under Secretary of State for Health, Edwina Currie MP, on 6 December 1988. Edwina Currie had agreed it before she left DH (in December 1988), but the letters had not been sent. Dr Pickles' minute also noted that the CMO had reservations about the proposed committee's remit and membership. Dr Pickles suggested that the change of minister meant that the submission should go up again and attached the draft minute for Dr Harris to send on his return.
- 2.12. Sir Donald Acheson's Private Secretary replied on 10 January 1989 to say that he was content for the submission to go to ministers on the basis of what was then the proposed remit and expressed his preference for Dr Tuddenham as a member [DHSC0003597 071].
- 2.13. On 12 January 1989, Dr Harris sent a revised version of Dr Pickles' minute (I am told the attached final submission has not been found) to the Private Secretary to the Parliamentary Under Secretary of State for Health, who was by then Roger Freeman MP (and copied to me) [WITN0758014]. The minute said:
  - "1. I attach a submission which seeks PS(H)'s agreement to the establishment of a new advisory committee. Mrs Currie had agreed to this group in December but delays occurred because of changes thought necessary in the proposed membership. These changes have now been incorporated into the new submission."

[...]

- "3. We are anxious to proceed without any further delay because expert advice on this complex subject is urgently required."
- 2.14. The Inquiry asks me to explain the changes that were considered necessary to the proposed membership and what decisions had been delayed pending the establishment of the Committee. The proposed composition of the Committee had been drawn up before I was in post, but as far as I can see from the documents Dr Tuddenham was preferred by the CMO of the names put forward. For the same reason, I do not know what decisions had been delayed,

- Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") although I was aware of the proposed work plan, which also had been drawn up before my time in post. This gave some indication about what were the matters that required early attention.
- 2.15. The Chairman's brief said that the EC Directive, HTLV1 and CJD were "the issues which seem to require early attention" [DHSC0002494\_023]. These were the substantive Agenda items for the first meeting [WITN4486049]. The Overview of Problems document, referred to at paragraph 2.3 above, noted that testing for NANB hepatitis was "also of some urgency" and "could be a major item for the next [second] meeting". The minutes said that the CMO had asked for CJD to receive early consideration [NHBT0000041 003].
- 2.16. I observe that the final version of Dr Harris' minute also removed the reference to decisions having been delayed and simply said that it was urgent. As to the period of delay, it seems it was from mid-December 1988 to mid-January 1989. It may, at least in part, have been attributable to a change in minister.

### Q8: Membership of the ACVSB

- 2.17. The Inquiry asks me to explain how the membership of the ACVSB was determined and who made the decision to appoint an individual. The Inquiry refers me to my minute to Dr Harris on 21 February 1989, which confirmed approval for the new ACVSB from all UK Health Ministers [DHSC0003597\_056]. I invited Dr Harris to write to the proposed membership, an example of which is Dr Harris' letter dated 8 March 1989 to the NBTS' National Director, Dr Harold Gunson, asking him to serve on the committee [WITN4486049].
- 2.18. The list of proposed committee members would have been drawn up before my time in post. I do not know by whom or the criteria used. Dr Moore may have been involved in looking at appropriate membership on an administrative level, but decisions on membership would have been driven by the medical staff in

Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") the department (including the AIDS Unit). They would have known who was who in relation to what we wanted. Dr Harris would have had views. Dr Harold Gunson may well have been asked for names. My minute noted that the Scottish National Blood Transfusion Service (SNBTS) had made its own nomination.

2.19. I have been shown a list of Members, which I believe represented the membership as at the first meeting [PRSE0001865]. Drs Rotblat, Purves and Pickles from DH were listed as observers.

### Q9: My role within the ACVSB

2.20. I am asked to outline the remit, functions and activities of the ACVSB and to describe my role within the ACVSB. I refer to the explanation set out at paragraph 2.1 onwards above.

### Q10: Chairman's brief for the first meeting

- 2.21. The Inquiry refers me to the Chairman's brief for Committee meetings on: 4 April 1989 [DHSC0002494\_023] (and cover minute [DHSC0003597\_017]); 22 May 1989 [DHSC0003583\_043]; 3 July 1989 [NHBT0000061\_031]; and 17 June 1992 [DHSC0006980\_042]. I am asked whether I routinely prepared the Chairman's brief and to describe how I went about the process.
- 2.22. The Chairman's brief was prepared in discussion with Dr Rejman. The contents of the brief would be determined by the work program and whatever topics the Chairman or the Members wanted to discuss. My role was to pull together the issues and materials that the Committee wished to have before it and provide that in summary form to the Chairman. We always had a pre-meeting with Dr Metters when he was the Chairman. Dr Metters liked to go through the brief with the Secretariat so that we could amplify what had been written in the brief or to incorporate updates on papers or apologies that had come in since the brief was drafted.

2.23. The Inquiry asks why the brief for 4 April 1989 said, "We would not wish to have the Committee discuss the merits of the proposed programme at this stage." This comment in the brief was made in the context of a discussion of the "Overview of Problems" document, to which I referred at paragraph 2.3 above. This had been circulated to Members in advance. The comment was not a suggestion that the Chairman should seek to stifle debate about what issues the Committee should discuss. Rather, that stage in the meeting would be used to set out the programme. The brief suggested that the chair mentioned that Members "will have the opportunity to suggest items for future meetings". This was about running the Committee efficiently.

### Q11: Paper on EC Directive on Blood Products

- 2.24. The Inquiry refers me to a minute that I sent Mr Cox (MB1) on 20 March 1989 [DHSC0002429\_036]. The minute said that I was preparing a paper on the EC Directive on Blood Products for the Committee. It enclosed a draft paper [WITN7115004]. The final version was appended to the Committee's papers as ACVSB1/3 [NHBT0000041\_005].
- 2.25. The Inquiry asks whether I routinely prepared papers for the Committee and to describe the process. To the best of my recollection, I think that the EC Directive paper was the only one that I prepared for the Committee. The documents I have seen do not suggest otherwise.
- 2.26. The draft paper was brief (one page only) and summarised the objective of the Directive and the next steps in terms of its implementation. The Directive was intended to harmonise the licensing arrangements for blood products across the EC. I surmise that I was asked to draft the paper because it was on a regulatory (rather than a medical or scientific) topic. The purpose of the paper was to provide context to the Committee. After that first meeting, the lead on

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this topic passed to the Medicines Control Agency (MCA), who were responsible for licensing in the UK.

### Q12: Minutes of first meeting of ACVSB, 4 April 1989

2.27. The Inquiry has referred me to the minutes of the first meeting at the Department of Health [NHBT0000041\_003]. Dr Metters introduced the Terms of Reference and explained,

"the Committee had been set up to give advice to the UK Health Ministers. A number of different interests were represented and it was hoped to avoid conflicting views to Government from other committees. ACVSB's views would initially be referred to the CMOs. The Committee would be concerned with the major policy issues and the implementation of the policy would be for others."

- 2.28. The Inquiry asks me a series of questions about the Committee's role in advising Ministers. While the Inquiry's questions are of a general nature (not specific to the any one issue), I answer them with the HCV screening documents in mind.
  - a) First, the Inquiry asks the extent to which, in my opinion, the DH's decisions were informed and/or influenced by the recommendations of the ACVSB. The ACVSB was set up by DH for the express purpose of advising the Health Departments. The Committee was made up of leaders in their field. My view is that DH ministers and senior officials placed considerable weight on the ACVSB's advice.
  - b) Secondly, I am asked whether considerations of cost or financial resources formed part of the role of the ACVSB when exploring major policy issues. The ACVSB had to be alive to real world cost or financial resource implications, but it was not a decisive factor in their recommendations. Cost and resources were ultimately matters for Ministers to decide on, advised by officials (and for this purpose the Economic Advisers' Office would usually be called on to produce an economic analysis). I should add, the Committee's discussion often

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referenced cost/benefit issues, but "costs" did not necessarily mean purely financial ones. For example, the "cost" of a new test might be a potential negative impact on donor numbers and thus the security of the blood supply, which the ACVSB Terms of Reference explicitly required them to take into account. I comment on financial considerations further at paragraph 2.83 below, in response to the Inquiry's question about how much consideration the Committee gave to the economic viability of any recommendations.

- c) Thirdly, I am asked who was responsible, and what was the criteria for, bringing a matter that was being considered by the ACVSB to the attention of a Minister. I explained at paragraph 2.8 above that the Chair was uniquely well placed to act as a link between the Committee and Ministers. Dr Metters was very much on top of ACVSB business both as its Chair and as a Departmental official. He was mindful of the need to keep Ministers informed. In general, judgements about when to go to Ministers are a part of a civil servant's role. There were no set criteria. In relation to the ACVSB, however, my recollection, borne out by the documents, is that Dr Metters gave a steer on when we needed to put submissions to the CMO or Ministers (whether that was to provide an update on the Committee's latest advice or seek a decision). There are examples of this in my statement.
- d) Finally, the Inquiry asks about the individuals and/or bodies who would be responsible for the implementation of policy. This is a difficult question to answer because in the ACVSB years (broadly, 1989 to 1994) various reforms took place to the Department's structure, which may have shifted some responsibilities around but my own relation to blood remained unchanged. The RTCs of course had a significant role to play in relation to the introduction of new tests. In relation to the implementation of HCV screening, I give further detail in the chronological account below.

### Q13: Summary of actions points

- 2.29. The Inquiry refers me to a summary of action points that was prepared following the second ACVSB meeting on 22 May 1989 [DHSC0002494\_048] and to Dr Rejman's oral evidence, in which he said that this summary would have been prepared by me or my deputy [INQY1000204, page 80 of the transcript]. This was likely Mike Arthur in the earlier period and Pam Reenay later.
- 2.30. The Inquiry asks me who drafted the summary, whether it was typical to prepare a summary and who was responsible for addressing the action points. I cannot refute the possibility that I prepared these action points, but I cannot now recall. I do not think that it was my normal practice to produce such a summary. The meeting minutes would usually identify any follow up action required arising from the discussion (see, e.g., the minutes of the fourth meeting), and how it should be followed up. The individual responsible would be determined by what it was that had to be done and was usually identified in the minutes.

### **ACVSB decision-making: HCV screening**

2.31. The Inquiry asks me a series of detailed questions about the ACVSB's decision making on HCV screening. I have sought to address the issues raised by the Inquiry in broadly chronological order.

### Q14: Chairman's brief for the second meeting of the ACVSB, 22 May 1989

2.32. The minutes of the first meeting recorded that Hepatitis would be on the agenda for the second meeting on 22 May 1989. Members were invited to submit papers. On 18 May 1989, I minuted Dr Harris about a briefing meeting between Dr Harris, Dr Pickles, Dr Rejman and me [DHSC0003583\_042]. I enclosed the Chairman's brief [DHSC0003583\_043].

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- 2.33. The Inquiry draws my attention to the oral evidence of Dr Rejman, in which he said that the Chairman's brief was a joint effort but "Mr Canavan would be in the lead, so to speak" [INQY1000204, page 69 of the transcript]. To the best of my recollection, I think I would have been primarily responsible for drafting the briefing. I think Dr Rejman is probably right to say that I was in the lead in so far as administrative arrangements for the meeting were concerned (and this is apparent from the context of Dr Rejman's answer), but I would not have given any steer to the Chairman on medical matters.
- 2.34. The Chairman's briefing referred to papers on NANB hepatitis from Professor Zuckerman (ACVSB 2/6) [CBLA0002432]; Dr Rejman (ACVSB 2/7) [NHBT0000061\_022]; Dr Lane (ACVSB 2/8) [NHBT0000187\_069]; and Dr Mortimer (ACVSB 2/9, which may well have been [WITN7115005]; [NHBT0000014 053]; and [WITN7115006].
- 2.35. The Inquiry refers me to Dr Rejman's paper on NANB hepatitis (ACVSB 2/7) (the first page of which refers to a submission by Dr Mortimer, which appears to be an error in the Inquiry's version of the document). The paper reported on Chiron's success in May 1988 in cloning of the NANB hepatitis virus and the potential development of a specific test for NANB hepatitis. Dr Rejman's paper concluded.

### "5. Recommendations to be considered

At present there does not appear to be any urgent need to introduce routine surrogate testing for NANB hepatitis among voluntary blood donors in the UK in respect of public health. The position should be reconsidered by this Committee when the results of the UKBTS NANB study are available. This should give an indication of the effect of donor testing for surrogate markers of NANB hepatitis on donor panels, the costs involved and an indication of its value in the UK, where NANB hepatitis incidence is lower than in the US. The availability of the Chiron test will help with interpretation of the data obtained. The Chiron test may also make surrogate testing obsolete, provided that the UKBTS and other studies confirm the promising results so far, reported, and assuming that the cost benefit analysis is satisfactory."

2.36. The Chairman's briefing said,

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"Following the general discussions you will wish to focus the Committee's attention on the recommendations in paragraph 5 of ACVSB2/7. You may wish to point out that while CBLA has legitimate concerns about marketing its products, the Committee should consider the issues only in relation to protecting public health. The question is whether the Committee agrees there is no pressing need to introduce routine surrogate testing for Non A and Non B hepatitis for health reasons but that the position should be reconsidered when the results of the BTS study are available."

- 2.37. The Inquiry asks, first, whether the wording of the briefing was intended to navigate how the Chairman should address the issue of routine surrogate testing with the Committee. As I have said, Dr Metters was a hugely experienced and formidable figure. There would have been no intention on our part in drafting the brief to attempt to "steer" Dr Metters in how he approached a particular issue with the Committee. He was very capable of making up his own mind on how to conduct the discussions.
- 2.38. The Inquiry asks, secondly, "Whether, as may be suggested by the wording 'whether the Committee agrees there is no pressing need', the DH had already formed the view that routine surrogate testing for NANB hepatitis should not be introduced". The extract from the briefing quoted to me by the Inquiry omitted to refer to the point made in the briefing that the Committee should consider issues only in relation to public health.
- 2.39. The briefing was intended simply to reflect what was in Dr Rejman's underlying paper. It indicated to Dr Metters that the subject needed to be covered. It was not the case that the DH had already formed a view. The briefing was intended to flag the recommendation in the paper; the question was whether the Committee agreed.
- 2.40. The Inquiry asks, finally, what informed the view that there was "no pressing need" to introduce routine surrogate testing. I do not think I can add anything to the reasons given in Dr Rejman's paper (ACVSB 2/7).

### Q15: Minutes of the second meeting of the ACVSB

2.41. The minutes of the second meeting on 22 May 1989 recorded that,

"17. Members advised that although colleagues in the US considered only one virus caused NANB, there may be two or more. The Chiron test was estimated to pick up approximately 50% only and there was a need for caution. There had been enormous progress and once the sequence was published it would be possible to test without recourse to Chiron.

[...]

- 20. It was agreed NANB testing should not be introduced into the NBTS prior to the results of the UKBTS NANB trial; anti HBc testing was not without problems. The Chairman considered that PHLS may need to be involved in the follow-up.
- 21. The Department would keep the issue of testing under review. The use of Chiron or surrogate testing would be influenced by Chiron data once released; MRC might be asked to consider. Members regarded the matter to be a priority." [NHBT0005019]
- 2.42. The Inquiry asks me to expand on the context of paragraph 20 of the minutes. I am asked to include in my response why anti HBC testing was viewed as "not without problems", to confirm whether there was a dissenting view at the time, and to explain how and when the Department kept the issue under review.
  - a) As best as I can recall, the screening tests were unreliable (high rate of false positives and false negatives) and there was a lack of confirmatory tests to confirm the results. I have been shown the minutes of the ACVSB's fourth meeting on 6 November 1989, which said,
    - "24. During the discussion that followed, members voiced their concerns that the [Chiron] test did not appear to be suitable for testing UK pooled plasma (which tested negative compared with US positive, that test results varied from kit to kit and that diluting a positive sample (by 1:10, in Scotland's experience) resulted in a negative result." [NHBT0005043].

This is helpful in explaining why the Committee was concerned about the reliability of anti-HBc testing.

b) I have also been shown a slightly earlier minute dated 9 October 1989 from Dr Metters to Graham Hart (then Director of Operations, NHS

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Management Board), copied to me [NHBT0000188\_074]. The minute concerned a letter dated 2 October 1989 from Dr Gunson to Graham Hart [NHBT0000188\_056] about the cost of HCV screening (not copied to me at the time). Dr Metters' minute said,

- "3. The main points that concerned ACVSB at their last meeting [3 July 1989] were that the Chiron test cannot be independently validated, and as a result we have no idea of the false positive or negative rate. Some recent reports suggest that patients with chronic hepatitis test negative to Chiron, despite the fact they may be transmitting the virus, and that they were previously Chiron positive. Hardly a reassuring finding if confirmed. From Dr Gunson's letter the specificity still seems to be a problem, and if so it could well deter the Committee from recommending the general introduction of Chiron."
- C) The minute carried a handwritten comment dated 13 October from Graham Hart that asked Charles Dobson, my superior, to "keep an eye on this and check on progress in November". The minute indicates the seniority of the DH personnel involved in actual decisions in relation to this. There was a strength of view being expressed by Dr Metters. When these issues arose and Dr Metters was concerned about it, he took it straight up the hierarchy. I do not recall any particularly strong dissenting views within the Committee, although equally I cannot recall the attitudes of individual members. The issue of NANB hepatitis was a regular item on the agenda for the ACVSB meetings and would advise the DH when appropriate.
- 2.43. Returning to the second meeting on 22 May 1989, the actions arising following the meeting (referred to previously in paragraph 2.29 above) included amongst others, keeping the subject under close review,
  - "8. NBTS to reconsider its policy of accepting donors providing they have not suffered from jaundice or hepatitis in the past twelve months. Need for anti-HBc testing to be addressed.
  - 9. Members to submit comments on UKBTS/NIBSC Guidelines direct to Dr Gunson, copying to Dr Rejman.
  - 10. Dr Follett's paper on anti-core to be consulted. Efficiency of test to be considered.

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- 11. Update members on results of Dr Gunson's questionnaire on behalf of Council of Europe on extent of surrogate testing for NANB Hepatitis. Update members on other findings of NBTS study, including correlation of Chiron test.
- 12 Consider prospective study of post-transfusion non-A non-B either among blood recipients or in stored sera for haemophiliacs (refer Dr Tuddenham). Consider contacting MRC.
- 13. Consider separate requirements for ALT testing. Pure science or public health?
- 14. Consider reminding clinicians of need for post-transfusion hepatitis reporting.
- 15. Keep subject under close review."

### Q16: Note on 11 September 1989 following the third ACVSB meeting

- 2.44. The third ACVSB meeting took place on 3 July 1989. The minutes noted that Dr Metters would take over from Dr Harris as Chairman on 31 July 1989 [NHBT0000072\_025]. Dr Mortimer has attended a recent conference (the papers suggest that this was Ortho's symposium in Paris on 30 June 1989). He reported that "he considered the findings represented a persuasive case that the Chiron test results were reliable". Dr Harris asked for a compilation of all the data to be given to the Committee for consideration at the next meeting. Members were asked to forward contributions on NANB hepatitis to Dr Rejman.
- 2.45. On 3 August 1989, Dr Rejman minuted Dr Gerard Jones (MED ISD), copied to me and Drs Metters and Pickles [NHBT0000061\_035]. Dr Rejman had spoken to the Scottish Home and Health Department (SHHD) to confirm that the ACVSB had decided "at present" not to introduce routine screening. The minute further said,
  - "6. I spoke to Dr Gunson who confirmed that at present there was a pilot study of the Chiron test on the ten thousand samples in North London. These results would be available during the next month or so and would be reported to the next meeting of the ACVSB on 17 October. He would also report on a review of the European experience of Chiron testing which was to be discussed in Rome in mid September.
  - 7. Dr Gunson had discussed the Chiron test with Ortho and had explained to them that the decision on routine Chiron testing would be made by the ACVSB. He had also stressed his anxiety that the Chiron test took three and a half hours which was not very practical when blood components

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(such as platelets) might need to be used on the same day as they had been donated. In addition there was no confirmatory test available and reliance had to be placed on repeated positivity. This might lead to the loss of a lot of falsely positive donors, if the situation is anything similar to HIV in the early days of testing. (HIV testing takes just over two hours and the extra hour and a half is very significant).

- 8. I mentioned to Dr Gunson that I had heard via PD that PHLS (Dr Mortimer) were soon to publish results of their experience of Chiron testing of presumed NANB samples. PD had been given to understand that PHLS would be making a recommendation for use of this test in this publication. Dr Gunson suggested that this would be very unhelpful to DH, and he hoped that Dr Mortimer who is a member of ACVSB would be sensible."
- 2.46. On 1 September 1989, Dr Gunson wrote to me about 9,000 frozen donor samples which had been tested for anti-HCV using the Chiron ELISA test [NHBT0000188\_038]. Dr Gunson said, "A logical extension of the evaluation of these tests is now to have a pilot study using the test routinely in three RTC's for a period of two weeks." He asked the DH to consider financing the purchase of 16,500 tests at a cost of £25,000.
- 2.47. On 5 September 1989, a meeting took place at Richmond House attended by me and Drs Metters, Jones, Pickles and Rejman. Dr Rejman drafted a note of the meeting [DHSC0003557\_009]. Two members of the ACVSB (Drs Gunson and Tedder) were due to travel to the US regarding Chiron testing. It was decided that if possible the next ACVSB meeting should be postponed to 31 October 1989 or early November. The actions points arising from the meeting that were assigned to me included contacting Research Management (RM), a branch of DH, regarding Dr Gunson's request for £25,000 funding for the pilot study in three Regional Transfusion Centres (RTC).
- 2.48. On 11 September 1989, I wrote to Committee members to confirm that the next (fourth) meeting would be deferred from 17 October to 6 November 1989 [DHSC0003557\_011]. The Inquiry asks what the reason was for the three week delay; as I explained, it was to allow reports from Drs Gunson and Tedder on

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their visit to the US. I also reminded members of the Chairman's request for contributions on NANB hepatitis.

2.49. On 3 October 1989, I minuted Miss Wheeler in Branch FA2B (DH Finance). I referred to an earlier conversation about the NBTS' request for £25,000 to purchase HCV test kits [NHBT0000188\_062]. I said,

"Only recently has a test been developed by Ortho to detect the hepatitis C virus which can be transmitted through blood transfusion. Recent pilot studies in the NBTS (for which Ortho supplied free tests) and elsewhere seem to have confirmed the effectiveness of the test. The Advisory Committee on the Virological Safety of Blood will be considering the results at its next meeting on 6 November and may well advise that the test should be used routinely in the NBTS to screen blood donations.

However the test is not without some practical drawbacks. As Dr Gunson states, the next logical step in its evaluation would be to carry out field trials in a small number of Regional Transfusion Centres to assess the operational implications of using the test routinely. Ortho would not provide free tests for this two week trial and they would have to be bought at one-off cost of £25,000.

You will appreciate that viral contamination through blood is a sensitive issue, particularly now that the HIV litigation is getting underway. The press has already run scare stories about HCV and commented on the need to adopt the new test as soon as possible. Clearly we need to keep up the monentums (sic) in evaluating the test by getting the field trial underway as soon as possible. I understand that Ortho have given Dr Gunson first refusal on a batch of tests and may make mischief if a decision is delayed.

I should be grateful if you could explore with FA1 as quickly as possible how the £25,000 might be found this year. I should say we approached Rearch (sic) Management but in their view the trial is not 'research' which could attract their support."

The minutes of the fourth ACVSB meeting confirmed that the Procurement Directorate (PD) had made available £25,000 for the pilot study.

### Q17: Minutes of the fourth meeting of the ACVSB, 6 November 1989

2.50. The Inquiry refers me to the 9 October minute from Dr Metters to Mr Hart, which I referred to at paragraph 2.42.b). In addition to Dr Metters' explanation (set out above) about the ACVSB's main points of concern with the Chiron test, he said,

- a) The Committee was influenced by the fact no country had yet put the test to routine use. It did not have an FDA licence and was unlikely to get one until Spring 1990 at the earliest.
- b) Ortho's symposium in Rome had taken place on 14 September where the experience of 100,000 tests at different European centres were reported. Three ACVSB members had attended (Drs Gunson, Mitchell and Mortimer). The ACVSB had not yet seen the Rome data, but "if it is comprehensive it could sway the balance".
- c) Dr Gunson's letter suggested that he was convinced that the Chiron test would eventually be introduced. Dr Metters' impression was that "other members were much more sceptical, particularly on validation".
- d) The Committee were well aware of the cost implication and the need for a uniform policy for all UK Blood Transfusion Centres (BTC). However, it was not a foregone conclusion that the ACVSB would recommend introduction in November and they may well opt "to wait FDA's consideration".
- 2.51. The Inquiry asks me whether I shared Dr Metters' impression from the third meeting (3 July 1989) about the scepticism of members (other than Dr Gunson). I recall that there was concern that the Chiron test results could not be validated and so the false positivity and negativity rates were uncertain. With the passage of some 33 years since the meeting took place, I cannot now recall my impressions of the views of individual members of the Committee. I would have relied on Dr Metters' ability to accurately sum up the mind of the ACVSB members.
- 2.52. The Inquiry also refers me to Dr Minor's (National Institute for Biological Standards and Control (NIBSC)) letter to me dated 9 October 1989, which enclosed findings of the Ortho-Chiron Hepatitis C testing for discussion at the fourth ACVSB meeting [NHBT0000072\_050]. On 17 October 1989, Dr

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Tuddenham (Medical Research Council (MRC)) wrote to me to say he strongly supported an extensive evaluation of the Chiron test and that "it may well be" the test could reduce NANB incidence in single donor products [NHBT0000041\_080]. His letter went before the Committee (ACVSB 4/4).

- 2.53. The fourth ACVSB meeting took place on 6 November 1989. I referred to the minutes previously, at paragraph 2.42.a). This was Dr Metters' first meeting as Chairman. The Chairman's brief was circulated by my HEO, Pam Reenay [DHSC0003557\_051, page 1]. It said, "The main issue for the Committee is whether the time is right to make a decision about adopting the Chiron test." [DHSC0003557\_051, pages 2-3].
- 2.54. Dr Gunson reported to the Committee on the Rome symposium. His paper on the subject (ACVSB 4/3), dated 10 October 1989, had been circulated to members in advance [NHBT0000041\_067].
- 2.55. The Inquiry asks me about the reference in the minutes to Dr Gunson's report that the "BTS committee" (I assume that this was a reference to the UK Advisory Committee on Transfusion Transmitted Disease (ACTTD)) had concluded that, "routine testing for anti-HCV will reduce NANB, but estimates of the extent of the reduction range from 20%-60%." I am asked to explain my understanding of why the Committee reached the conclusion not to introduce a routine test despite evidence that incidence of NANB hepatitis could be reduced by between 20 to 60%.
- 2.56. Although I cannot now recall my understanding of the position then, I would have taken my lead from the comments made by Dr Metters, both in his earlier minute to Mr Hart and in what he said in summarising the Committee's discussions. I do not recall any member expressing a view that particularly dissented from Dr Metters' summary.

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2.57. The feeling of the Committee, as summed up by Dr Metters, was that,

"the test represented a major step forward, but that the Committee need to know a great deal more about it, and acknowledged the need for a confirmatory test. It was agreed that while the UK would not want to go on in advance of an FDA decision, it could prove difficult if the FDA do not decide in favour of the test. Nevertheless, it was felt that if the UK do put the test into general use RTCs will need to have had experience with it, and therefore pilot studies should go on in Birmingham, Sheffield and Brentwood, to show the feasibility of adding this test to routine practice."

2.58. Dr Metters then said,

"ACVSB would support the general introduction of the Chiron test if the FDA approves it, and the pilot shows it to be feasible and non-problematic. For these reasons it was felt that the Committee should be developing an economic case (ie % of NANB that would be prevented and any other data to support) for the Department to fund the routine use of the test (some £5-6mill pa). Prof Zuckerman was seen as one person who would be able to help with such data collection [...]"

2.59. The next day, 7 November 1989, Dr Metters minuted Dr Rejman (copied to me and Dr Pickles) [WITN7115007]. He said,

"Following yesterday's meeting of ACVSB the Committee's advice to the Department is clear, but what will be far more difficult to demonstrate is the practical benefits from the introduction of the Chiron test.

This was discussed by the Committee and you heard their doubts. Nevertheless, if we are to convince Ministers that the test represents "good value" we need to produce data about the number of cases of hepatitis that might be prevented, and not just rely on the argument that it is just another screening test that will improve the safety of blood and blood products."

- 2.60. I had already started work on informing the cost/benefit analysis. Around this time, I was engaged in correspondence with the DH's Economic Advisers' Office.
  - a) I minuted Robert Anderson (EAO(B)) on 23 October 1989 with a request for an assessment of the benefits of HCV screening [NHBT0000188\_087]. My request was premised on the basis that, "HCV testing could produce savings in treatment costs and a wider economic

[NHBT0000188\_088].

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benefit by preventing some premature deaths from liver disease." I

enclosed an overview on viral hepatitis that Dr Rejman had prepared

- b) Robert Anderson replied on 2 November 1989 [NHBT0000061\_069]. He said, "a number of uncertainties cloud the picture" and that he would need fuller details on life expectancy in absence of infection; the test's detection rate; and number of deaths caused by transfusion with infected blood. He also said that any submission to the Treasury would "have to make the case more fully and in a more convincing way".
- c) Robert Anderson minuted me again on 3 November 1989 [WITN7115008]. He referred to a US paper and questioned whether US data could be used as a comparative. The handwritten comment (which I suspect may have been Dr Rejman) noted that this would not work "not without screening other than ALT".

## Q18: Oral evidence of Dr Robert Perry to the Inquiry

- 2.61. The Inquiry refers me to the oral evidence of Dr Robert Perry to the Inquiry, in which he suggested that there was insufficient public health expertise in the membership of the ACVSB. In his view, the data of up to a 60% reduction in the incidence of NANB hepatitis represented "a reasonable justification for implementing the Phase I test rather than delaying it" [INQY1000184, pages 138 to 139 of the transcript]. I am asked for my view on this position. I do not know where the 60% figure comes from. Dr Gunson reported to the fourth ACVSB meeting that his committee estimated that the extent of the reduction range of NANB with routine testing was 20%-60%. I also do not know by what point Dr Perry considered that implementation of the Phase I test had been unreasonably delayed. The context of his oral evidence suggests he may have been referring to sometime in 1990.
- 2.62. I am also asked whether consideration was ever given to broadening the membership of the ACVSB, in particular with regard to increasing public health expertise. As I alluded to at paragraph 2.18, the Committee membership was

Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") settled before I was in post. I do not recall any members casting doubt on the composition at the time. If Dr Metters thought that he was not getting enough input on an issue, he could have replaced them or he could simply have expanded the Committee.

## Q19: Minute from Dr Metters to Dr Rejman dated 7 November 1989

- 2.63. The Inquiry refers me to a (separate) minute from Dr Metters to Dr Rejman (copied to me) dated 7 November 1989, which noted that subsequent to the fourth meeting of the ACVSB, "It will be important to give Press Office an updated brief on the Department's position on HCV testing, before the decision to go ahead with a pilot study at the three RTCs becomes public knowledge" [NHBT000061\_072]. The context was that Dr Gunson had told Dr Metters that he had received regular media contact about the prospects for introducing HCV testing in the NBTS.
- 2.64. The Inquiry asks, first, why it was considered important to brief the Press Office on the Department's position. In general, on matters likely to attract media attention it was important to have lines prepared in response. This helped ensure that the Department's position was well understood by the public at large. The example here is the pilot study once news entered the public domain the media and public would have questions about it.
- 2.65. The Inquiry asks, secondly, whether there was a concern the Department might be criticised. I cannot now recall any specifics, but I suspect on a contentious issue such as HCV screening there would have been concern about potential criticism. The Department would have wished to make sure those who might have to respond to any criticism (often the Press Office) would be well briefed about the decisions taken and the reasons.

- 2.66. The Inquiry asks, thirdly, what input I had in preparation of this briefing to the Press Office. From the documents I have seen, I do not think there was in fact a press briefing on this occasion:
  - a) I think it is my handwriting that appears on the Dr Metters' minute. I think it reads, "Pam. I think something along the lines of the answers to the recent PQ would be appropriate. However as things are changing, be better to brief from Press Office when need arises." My comment appears to be dated 28 December 1989. The response (I assume from Pam Reenay) said "John. It has become public knowledge. It was in Hansard 2 weeks ago, following up Jim Cousins' PQs."
  - b) On 13 December 1989, Jim Cousins MP received a written answer from Roger Freeman to three Parliamentary Questions (PQ) [WITN7115036]. His second question asked whether the Secretary of State proposed to introduce screening for HCV. The written answer said that an evaluation of the test on 15,000 donations at three RTCs was in progress.
  - When they came into the Department, the Parliamentary Branch referred Jim Cousins' questions to Charles Dobson [WITN7115009]. My HEO, Pam Reenay, then passed them to Dr Rejman with the comment, "Contributions gratefully accepted for these 3" [DHSC0002495\_095]. Dr Rejman replied on 11 December 1989 with a series of handwritten notes [DHSC0002495\_103; WITN7115010].
- 2.67. The Inquiry asks, finally, who, if anyone, was responsible for briefing the Press Office on the Department's evolving position more generally on matters relevant to the Inquiry's Terms of Reference following ACVSB meetings. My recollection is that briefings to the Press Office were provided as and when developments warranted it, rather than as a matter of routine. I do not recollect that any one person had responsibility. I suspect that Dr Rejman or Dr Pickles would have been involved where the development related to a clinical / medical matter (see, for example, the response to Jim Cousins' PQs). Another example, from 11 May 1990, is Dr Pickles' minute to the Private Secretary to the then Secretary

Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") of State, Ken Clarke, with a line to take on the Committee's ongoing consideration of routine screening for HCV [NHBT0000061\_137].

2.68. My section (HS1A) may also have had some involvement. An example of this, from earlier in time, is the minute dated 24 August 1989 from Pam Reenay to Sir Donald Acheson (copied to me) [NHBT0000014\_061]. This attached a background briefing and lines to take on HCV screening in response to an article in the Guardian newspaper. The minute was copied to Press Office. The minute said that requests on the subject of HCV testing had been diverted from Press Office to Dr Gunson, who in turn had briefed the then Parliamentary Under Secretary of State in the Lords, Lord Trafford.

### Q20: Minutes of the fifth meeting of the ACVSB, 17 January 1990

- 2.69. The work that I had started on cost/benefit analysis (see paragraph 2.60 above) was picked up by Dr Rejman. He wrote to Professor Zuckerman (who was absent from the fourth meeting) on 7 December 1989 and asked for his views on the "cost/benefit ratio" of introducing routine HCV testing [NHBT0000061\_077]. Professor Zuckerman replied on 19 December 1989 [NHBT0000061\_081]. Dr Rejman also wrote to Dr Elwyn Elias on 7 December 1989 asking about the likely incidence of HCV and risk of chronic liver disease, the number of potential deaths and costs of treatment [NHBT0000061\_076]. Copies of these letters were passed to me.
- 2.70. On 29 December 1989, Dr Rejman sent me and Dr Pickles a draft cost benefit analysis on the introduction of routine HCV screening [DHSC0003557\_091]. The draft set out some figures on the number of donors and recipients and some potential financial and non-financial costs.
- 2.71. At the fifth ACVSB meeting, on 17 January 1990, Dr Gunson provided details of the pilot trial [PRSE0001477]. He referred to concerns about the number of

- Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") results in the "grey zone" and the time taken to complete the test. He said these would need to be discussed with Ortho.
- 2.72. On the issue of cost-benefit analysis, Dr Metters invited the Committee "to address the question of whether the time has now come for the introduction of routine Hep C testing". Professor Zuckerman discussed the comments that he had sent Dr Rejman and highlighted the lack of confirmatory test and apparent high number of false positive reactions (ACVSB 5/4). Dr Elias' reply to Dr Rejman was put before the Committee (ASVSB 5/5). The Chairman's brief noted that Dr Elias had been selected to give a clinical view [DHSC0003545\_034]. Dr Elias' letter said the appropriateness of introducing HCV testing of all blood donors "presents considerable difficulties and that the answer is not immediately obvious" [NHBT0000189\_003]. Dr Pickles presented a paper on cost-benefit analysis (ACVSB 5/6) [NHBT0000189\_001]. This appeared to have been based on Dr Rejman's draft. The paper said, "There are too many unknowns to permit a proper cost-benefit analysis." Dr Tedder emphasised that it was "very difficult to make any recommendations based on scientific criteria at this time" (original emphasis).
- 2.73. Dr Metters summed up the general consensus of the Committee. He said,
  - "- routine testing should not be introduced in advance of the FDA decision;
  - scientifically, not enough is known yet, but there is agreement that the test does detect some people who will transmit;"
- 2.74. The Committee discussed what action should be taken. It was agreed that,
  - "- the costs should be looked at now, with regions being called upon to consider the financial implications;
  - Prof Zuckerman's figures would be further refined, to present as close an estimate of cases of potential infection as possible. This would undoubtedly be called for by Ministers;
  - the Committee could give no further scientific advice at this point, but would discuss the matter further at the next meeting (April) which would be after the International Hepatitis Meeting in Houston."

2.75. The next day, 18 January 1990, Dr Metters minuted Sir Donald Acheson's Private Secretary with an update (copied to me) [NHBT0000061\_097]. He said,

"there remains considerable doubt what proportion of non-A and non-B hepatitis carriers will be identified through the use of the Chiron test. Furthermore the infectivity of blood donations positive to the Chiron test is uncertain, and no precise figures can be given of the number of cases of chronic hepatitis that would be prevented by routine use of the test.

Dr Tedder summed up the views of the Committee that "scientifically we do not know enough about the significance of a positive test result"."

Dr Metters said that a submission to ministers would follow setting out why the Committee were not recommending the test.

2.76. Dr Pickles minuted me and Dr Rejman on 2 February 1990 [DHSC0002496\_076]. She said,

"I do not know if you have had time for a formal debriefing after the meeting on the 17 January, but I trust that the enormous pressures you are experiencing on other fronts has not prevented at least initiation of action needed following ACVSB. In particular, we must not delay in seeking help elsewhere in the department in refining our assessment of the cost-benefit of hepatitis C screening."

- 2.77. "Enormous pressures" was, I believe, a reference to the HIV litigation. On 15 February 1990, my HEO, Pam Reenay, put a submission to the Private Secretary to the then Parliamentary Under Secretary of State in the Lords, Lady Hooper [NHBT0000189\_055]. Although I cannot now recall, it is possible that Pam Reenay drafted the submission and I commented on it before it went up. There was a handwritten comment at the top of the first page from Dr Metters to Lady Hooper's Private Secretary that read, "The clear advice from ACVSB is that, as yet, there is not enough scientific data about the test [...] for the Committee to recommend it".
- 2.78. The Inquiry asks me why a decision on the introduction of the test was deferred until the next meeting and why the Committee reached the conclusion that no

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further scientific advice could be provided. The reasons for the deferral of the decision are set out in the meeting minutes and in Dr Metters' minute to the CMO (i.e. the FDA decision was awaited and there were still too many scientific unknowns). As to not giving further advice, the documents (and Dr Metters reference to Dr Tedder's comment) indicate that the Committee considered that it had gone as far as it could with the data that was then available. It is apparent from Dr Metters' minute that it was anticipated that by the time of the next meeting three meetings would have taken place (Ortho's symposium in London and Abbott's symposium in Chicago in February, plus an International Hepatitis Meeting in Houston in April) that would give rise to further data.

2.79. The Inquiry refers me to a comment made by Dr Mortimer during the meeting ("as the perceived risk is higher than that of HIV, we would be inconsistent in our screening procedure if we did not introduce routine testing. If we began routine use of this test we should soon have a better test to move onto") and asks if any consideration was given by the Committee to the idea of recommending the routine use of the Chiron test as an interim measure. I have not been able to trace any other reference to such a proposal in the minutes and cannot now recall whether it was given specific consideration by the Committee.

# Q24: Committee's consideration of the economic viability of its recommendations (addressed early - out of Inquiry's sequence)

2.80. I address this question out of sequence. On 27 March 1990, my HEO (Pam Reenay) minuted Robert Anderson [NHBT0000061\_117]. She referenced the ACVSB meeting in January and said the Committee's decision had been deferred pending the International Hepatitis Meeting (Houston) in April and the pending FDA decision. She also said, "We believe that at the next meeting of the ACVSB (on 24 April) the Committee will decide to recommend introduction of the test" and requested a cost benefit analysis to incorporate in a submission to follow.

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- 2.81. The Inquiry refers me to a minute from Robert Anderson dated 20 April 1990 [NHBT0000061\_126] and his attached a note on the prospects for an economic analysis [NHBT0000061\_127]. The Inquiry's version carries various crossings out and handwritten comments, which I assume were made after it was received. The writing looks like mine, but I cannot be sure. I have also been shown another version with different handwritten comments in what appears to be different handwriting [WITN7115011]. I do not know for sure, but I think this might have been Dr Rejman's handwriting.
- 2.82. On 23 April 1990, Dr Rejman minuted Dr Metters (copied to me). He said he attached a "rewrite" of Robert Anderson's paper, to be copied to the Committee [DHSC0003973\_026]. Dr Rejman's rewrite of Robert Anderson's paper was put before the ACVSB (ACVSB 6/6) [WITN7115012]. I think it was considered that the ACVSB might have a better feel for some of the numbers that would have been required for any cost/benefit analysis.
- 2.83. The Inquiry refers me to Robert Anderson's comment in his minute of 20 April, "My main point is that there may be alternative more modest and selective options worth considering before going nap on screening... It always astonishes me that Committees feel able to recommend new procedures without having the slightest idea whether they are likely to be good value for money or not". I am asked to explain how much consideration the Committee gave to the economic viability of any recommendations, in particular with regard to routine screening for anti-HCV. The Committee would have given regard in the general sense to the cost implication for the blood transfusion service of a particular recommendation (see, for example, Dr Metters' comment in the fifth meeting referred to at paragraph 2.74 above), but it was not for the Committee to make recommendations on whether a particular course of action was economically viable.

## Q21: Minutes of the sixth meeting of the ACVSB, 24 April 1990

- 2.84. The sixth ACVSB meeting took place on 24 April 1990 [NHBT0000072\_098]. Dr Rejman circulated in advance the abstracts from the Ortho symposium [PRSE0004275] (ACVSB 6/2). The Committee also received updates from members who had attended the Ortho symposium, the Abbott symposium (ACVSB 6/3) and the Houston hepatitis conference. Dr Metters remarked, "from the reports the science seemed to have advanced little from the time of the previous meeting". In summary of the discussions he said,
  - "- there was inadequate scientific data to support the introduction of the Ortho test for routine screening;
  - a confirmatory test was needed which could be used in the RTCs and not just specialised laboratories;
  - the FDA had not yet approved the test and it would be reassuring if the regulatory authority in the country of origin had done so;
  - there was a need to learn more about the donor panels and the significance of positive reaction to the hepatitis C antibody test;
  - a prospective study involving 25-50,000 donors would generate sufficient positives for confirmatory testing."
- 2.85. The minutes record that it was agreed that a subgroup of Drs Gunson, Mitchell, Mortimer and Tedder would prepare a protocol for the pilot study and an estimate of the funds needed for the study and the laboratory services to support it.
- 2.86. The Inquiry asks me for my view on whether the Committee was addressing the matter of anti-HCV screening with sufficient urgency to minimise the transmission of HCV.
- 2.87. As to "sufficient urgency", the Committee met regularly (six times in the 12 months after it was first established). HCV screening was a substantive item on the agenda for each of those meetings (save the first). As can be seen from the minutes, it often took up a significant part of the discussion time. If members thought that there were scientific developments that warranted discussion then

- Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") the next meeting would have been brought forward. An example of this is the seventh meeting, which Dr Metters brought forward by three weeks because of developments in the science (paragraph 2.98 below).
- 2.88. Regarding my view on the conclusions drawn by the Committee about what steps to take (or not take), as I explained at the outset of this statement, I would not have been in a position to counter the consensus view of the Committee, made up as it was of senior medics and scientists who were leaders in their field and chaired by a distinguished DCMO.
- 2.89. Dr Pickles drew up a set of actions points following the meeting [PRSE0002073]. I was tasked with convening the HCV subgroup (i.e., arranging the date, time and venue for the meetings), exploring sources of funding for the study, drafting a note for ministers and booking the next ACVSB meeting. This is quite a good example of the sort of ACVSB work that typically fell to me to do.
- 2.90. The day after the sixth meeting, 25 April 1990, Dr Metters again minuted Sir Donald Acheson with an update (copied to me) [NHBT000061\_129]. He said that the main drawbacks remained the uncertainty about the significance of the test result and lack of an independent confirmatory test. The Committee had decided to recommend a much larger study, of approximately 100,000 donations, which should "show what the real risk of non-A non-B viral transmission may be among UK blood donors". An updated submission to ministers would follow.

# Q22: Minute drafted to Dr Pickles and Dr Rejman, 26 April 1990

2.91. The following day, 26 April 1990, I minuted Dr Pickles [DHSC0002497\_061]. I attached a draft note to ministers on the outcome of the ACVSB meeting [DHSC0002497\_063]. My minute said that Research Management (RM) and Procurement Directorate (PD) were two possible sources of funding for the pilot

- Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") study. I also copied in branch FA2B (DH Finance). I said to Dr Pickles that there was no point going to either RM or PD until we had a protocol. Dr Pickles made a handwritten comment to the effect that we would likely have more "joy" with PD.
- 2.92. On 2 May 1990, I wrote to my opposite number in the SHHD, Rob Panton, to tell him that Dr Mitchell, an ACVSB member and member of the SNBTS, was on the subgroup [ARCH0003310\_007]. My intention was to alert the SHHD about the likely approach for funding from the SNBTS.
- 2.93. The Inquiry asks me to explain how ACVSB proposals, both generally and in respect of this pilot study, were funded. I am asked to describe the process for securing funding. So far as I am aware, there were three ACVSB proposals that required funding (aside from funding related to routine screening itself). The first was the need for £25,000 funding for Dr Gunson's HCV test kits. I referred at paragraph 2.49 above to a request first to branch RM, which was turned down and then renewed to branch PD, who provided funds. The second proposal was the 100,000 donations pilot study recommended by the ACVSB in April 1990, but ultimately not required (for reasons below). The third was the Ortho/Abbott first generation pilot study in autumn 1990, which the DH agreed to fund in September 1990 (see paragraph 2.119). Mark Fuller of branch PD attended some ACVSB meetings and also sat on the HCV subgroup. He may be better placed to explain the detail of funding.
- 2.94. On 1 May 1990, I sent an update on HCV screening to Lady Hooper and Dr Metters (this was a final version of the draft that I sent to Dr Pickles on 26 April) [NHBT0000061\_130]. I referred to the fact that HCV screening had recently been introduced for all donations in France, Belgium, Luxembourg and Finland (and Italy on a voluntary basis). I said that the Committee had reaffirmed its view that routine screening was not yet justified. A working party had been set up to devise a protocol for a pilot study and this would be considered at the next

- Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") meeting in July. I said the Department would be asked to fund the study, which may cost several thousand pounds.
- 2.95. The Inquiry asks for my recollection of whether the Committee evaluated how and why it was possible for other countries to introduce anti-HCV screening at that stage. The minutes of the sixth meeting recorded that Dr Metters noted that these countries had introduced routine screening. He made the same point in his update minute to the CMO, on 25 April 1990. I do not recall that the decisions of governments of other countries were of great significance in the Committee's considerations. Developments abroad were generally noted by the Committee, but my impression was they did not override the Committee's consideration of the data or the situation in the UK. It seemed to me that the Committee was being guided by developments in testing and not the decisions of other countries.
- 2.96. On 4 May 1990, Dr Pickles minuted Dr Metters (copied to me). The DH had just heard that the FDA had licensed Abbott's HCV test kit (but not Ortho's). He said, "This news should not affect the decisions made for the UK at the last meeting of ACVSB. We need to press ahead with our study" [NHBT0000061\_136]. This seems to support my point about the significance of decisions of other countries.
- 2.97. On 23 May 1990, the HCV subgroup convened for the first time [WITN7115037]. The DH members included me, Dr Pickles and Mark Fuller of the Procurement Directorate (PD).

#### Q23: Correspondence with Dr Metters and Mr Anderson in June 1990

2.98. The Inquiry refers me to a minute dated 5 June 1990 from Dr Metters to medics in the Department, plus me [DHSC0003973\_104]. Dr Metters' minute said that the pilot study may no longer be appropriate in light of developments including additional scientific information and FDA approval of the hepatitis C antibody

Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") test. In the changed circumstances he said it would be prudent to bring forward the next ACVSB meeting to 2 July (originally scheduled for 24 July) as "events are now moving fast, and strongly indicate that we should consider again at an early date our advice to ministers on hepatitis C testing". He attached an annex of five specific questions which the Committee would need to address when formulating advice to ministers [WITN7115013].

- 2.99. While the minute was headed as if it was addressed internally, its contents were clearly addressed to ACVSB members. My section would have acted to communicate Dr Metters' comments to members and bring the meeting forward, indicated by my handwritten comment, "the letter has gone out to all members" (I had provided an early draft of letter to Dr Metters on 1 June 1990 [WITN7115014]).
- 2.100. On 14 June 1990, Dr Metters minuted me and Dr Rejman with a request for the best available date on "the sensitivity, specificity and predictive value of the Ortho and RIBA tests". He needed this for a meeting with Sir Donald Acheson on 27 June 1990 to discuss Hepatitis C testing [DHSC0002497\_115]. The minute carried a handwritten comment from me that read, "Dr Rejman I'll need to leave to you.". Dr Rejman replied to Dr Metters (copied to me) on 22 June 1990 [NHBT0000061\_148]. He had spoken to Dr Mortimer who had confirmed the lack of good data.
- 2.101. The background to Dr Metters' request was a minute from Dr Pickles to Sir Donald Acheson's Private Secretary (not copied to me at the time) which said,

"A minute from you on 9 May recorded that CMO, on seeing Dr Metters minute of 25 April, asked for estimates of specificity and sensitivity and predictive power of the anti HCV test at current levels of prevalence in the UK.

These questions are crucial and the simple answer is we do not know and the limited information we do have is sometimes contradictory. That is why we need the planned study. But there is still the question of what a genuine positive test means in terms of donor infectivity and it may be more difficult to obtain that information."

2.102. The Inquiry also refers me to my minute dated 14 June 1990 to Robert Anderson [NHBT0000061\_145]. The minute said,

"I am returning to the cost/benefit question as it seems likely the Advisory Committee for the Virological Safety of Blood will recommend anti HCV screening at its specially convened meeting on 2 July.

You will see from the draft minutes of the last meeting that a pilot study was the preferred next step at that time. However our experts now seem to think advances in knowledge about the anti HCV test and the means of confirming the results make it very difficult to resist the introduction of screening. A number of countries have already done so."

- 2.103. I asked Robert Anderson to prepare a cost/benefit analysis and enclosed Professor Zuckerman's paper tabled at the sixth meeting in April (ACVSB 6/9) [WITN7115015]. The Inquiry asks me a series of questions about my minute:
  - a) First, I am asked why it was my view that it "seems likely" the ACVSB would now recommend the introduction of screening. Although I cannot now recall, I imagine that this was my reading of the situation: Dr Metters had said there had been further developments, had indicated the pilot study discussed in April may no longer be necessary and had asked for the meeting to be brought forward so the Committee could revisit its advice to ministers. I think I would have seen that the tide was turning; the purpose of my minute would have been to get the economic advisory branch geared up as their input would be required for any submission to ministers. The minute said that I wanted to be ready to put a submission to ministers "immediately" after the July meeting.
  - b) Secondly, I am asked what developments made "it very difficult to resist the introduction of screening" and whether the Committee and/or DH had a preference to "resist" the introduction of the test. I would not have meant "resist" in any pejorative sense; rather that up until then the Committee had (so far) resisted making a recommendation because it did not consider it was supported by the scientific data.

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c) Thirdly, I am asked about my comment that, "In your minute of 20 April you suggested selective screening as a possible alternative to universal testing. However, I understand this is not a viable option because of the uncertainty about who is carrying the virus. I think, therefore, we must look at the cost/benefit of screening all donors". To the best of my recollection, my understanding was that selective screening was not viable because of the difficulty in knowing a basis for selection, e.g., people who inject drugs were already deferred from giving blood. I think my requests for cost/benefit analysis always related to screening all donors.

# Q25: Minutes of the seventh meeting of the ACVSB, 2 July 1990

2.104. On 14 June 1990, Dr Minor wrote to Dr Metters (copy forwarded to me on 20 June) with responses to questions annexed to the letter of 5 June [DHSC0002497\_117]. He also said,

"Published information on the use of HepC screening suggests that implementation of the test will prevent 50 to 80% of cases of post transfusion nonA nonB hepatitis. It has also been shown that about 0.5 to 1% of donations will be positive, and estimates of the cost to the NBTS have been made. I believe that these are the most relevant issues in considering the introduction of screening."

2.105. The seventh ACVSB meeting took place on 2 July 1990 [PRSE0000976]. At the Committee's invitation, Dr Rejman opened with a summary of events since the April meeting (this is obviously not something that I would have been asked to do). He said,

"the FDA had decided to approve hepatitis C screening and that America had already introduced screening and other countries were following. More studies had been carried out confirming that hepatitis C testing reduced infection, and RIBA was now available as a supplementary test. It was now felt that a study along the lines of those talked about in April was no longer viable and the meeting had therefore been brought forward so that a decision on the introduction of UK hepatitis C testing could be reached."

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2.106. The Committee concluded they should recommend to Ministers that hepatitis C testing should be introduced in the UK, but that first a pilot study using the Ortho and Abbott tests should "go ahead without delay". The proposal was to collect blood at RTCs in North London, Newcastle and Glasgow who would each perform 3,500 tests. The pilot was estimated to cost £150,000. The Procurement Directorate (Mark Fuller was in attendance) made £50,000 available immediately from their research budget. The Committee declined an offer of test kits from Abbott (at 50% cost) and Ortho (free of charge); Procurement Department would pursue pricing. It was estimated that the timescale for the study would be four months, after finance had been agreed.

## 2.107. The Inquiry asks me a series of questions:

- a) First, why was the introduction of routine screening deferred until a pilot study had been undertaken. The minutes said (paragraph 8) that the study was necessary to decide which was the better test (Ortho or Abbott) for the RTCs. In my minute of 7 August 1990 to Lady Hooper's Private Secretary I said that the pilot study would give the NBTS experience in using both test and indicate if either one had any particular advantages [NHBT0000061\_169]. After the passage of time, I do not think I can now add to what is said in these documents.
- b) Secondly, what other options were considered by the Committee, such as introducing both tests imminently and undertaking an assessment of which was better later. I do not recall any consideration being given to introducing both tests as an interim measure. I do not believe that I would have been in a position to suggest such a course of action; we were guided by the Committee's consideration, led by Dr Metters. Any such interim measure would of course have had significant operational considerations for the RTCs, in terms of staffing, equipment and donor counselling arrangements.
- Thirdly, why the start of the pilot study was delayed until 30 August 1990.I have responded to this question in paragraph 2.118 below.

### Q26: Minute from Dr Metters to the CMO, 3 July 1990

- 2.108. Dr Metters minuted Sir Donald Acheson with an update on 3 July 1990 [NHBT000061\_152]. Dr Metters said, "In view of the concerns that CMO has previously expressed about the sensitivity and specificity of HCV test procedures, I will ensure that you receive the submission while it is in draft form." The minute also recorded that should the ACVSB recommendation become public, "a further interval before HCV screening is introduced can be justified, as the Committee also recommended strongly that the research study...must be undertaken before HCV screening is introduced".
- 2.109. The Inquiry asks whether the DH was concerned that it might be criticised. From experience, there was always the risk of criticism in health-related matters. However, our expert advisers had strongly recommended that the research study should be carried out to establish the best protocol for routine testing.
- 2.110. Mike Malone-Lee, Director of Operations at NHSME, [NHBT0000061\_154] replied to Dr Metters on 9 July 1990 (copied to me). In relation to the resource consequences of the ACVSB's advice he said,

"Dr Gunson has calculated that the cost in a full year would be about £5m. In preparing a submission to Ministers we must bring out the resource consequences, the fact that we are not making a bid in the Public Expenditure Survey and that before any announcement is made regarding the introduction of the test we would need to discuss with the BTS how it would be funded."

2.111. Dr Metters replied on 26 July 1990 [WITN7115016] (copied to me). He confirmed Dr Gunson's estimate was £5.6m per year (set out in his letter to Graham Hart, dated 2 October 1989). He said.

"the fact is we did have prior warning of the likely cost. You will also be aware of the questioning Ministers have received about why this country has not yet moved on this form of screening when other countries have introduced it for the protection of recipients of donated blood.

The question Ministers will have to address is the added protection of blood recipients against non-A, non-B post transfusion hepatitis weighted

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against the additional cost to BTS. Another factor in the equation is the potential for litigation [...]"

2.112. I reported the ACVSB's advice to Lady Hooper by minute of 7 August 1990. I said a full submission setting out the case for screening, financial implications and cost/benefit study would follow.

#### Q27: Minute to Dr Metters, 8 August 1990

- 2.113. Dr Gunson wrote to Dr Metters on 4 July 1990 [NHBT000061\_153]. He proposed holding the next ACVSB meeting in mid-November, after he had attended an Ortho symposium in the US. On 11 July 1990, Dr Metters passed the letter to me and Dr Reiman for comment and a draft reply.
- 2.114. I responded to Dr Metters on 8 August 1990 [NHBT0000061\_171]. I said it was not clear what new information might become available at the symposium and, "there could be a difficulty in holding off a decision on choice of test very long after the evaluation has been completed. Ortho and Abbott will know we have the results and may prompt Parliamentary and Media interest if a decision is not announced within a reasonable time." The results of the study were expected in time for a ACVSB meeting in late October. I attached a draft reply [NHBT0000061\_172]. Dr Metters sent a final version, with minor amendments, to Dr Gunson on 9 August 1990 [NHBT0000061\_173].
- 2.115. The Inquiry asks whether parliamentary and media interest was an important consideration for the ACVSB when formulating recommendations and/or for the DH when deciding what to do in relation to testing. The point I was making here to Dr Metters was that if there was delay then there was a risk that the manufacturers would use the media to put pressure on the Department. To answer the Inquiry's more general point, media or parliamentary interest was not a matter that ought to have influenced the Committee's consideration (and whose meetings were confidential) but it was a legitimate issue for the

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Department to consider. Flagging the likelihood of adverse comment was a standard part of civil service advice.

- 2.116. The Inquiry also asks why I was conscious not to delay a decision on which anti-HCV test should be introduced. The background to my comment about the difficulty in holding off for too long was Dr Gunson's suggestion of delaying the next meeting until after his trip to the US. Dr Rejman and I did not think that would be a good use of time. More generally, I was conscious that by then the Committee had recommended that HCV screening should be introduced, so we ought to proceed with the next steps (i.e., the pilot study) without any undue delay.
- 2.117. Dr Gunson replied to Dr Metters on 30 August 1990 [NHBT0000189\_213]. He had been given the "go-ahead" for the study that day and had arranged for it to start on 10 September 1990. He said while the RTCs' results could be available in late October, it was unlikely there would be much information from the specialist laboratories.
- 2.118. The Inquiry asks why the "go-ahead" for the study was not given until 30 August 1990 (having been agreed at the ACVSB meeting on 2 July). Dr Gunson's letter refers to telephone conversations with me in August 1990, but I cannot now recall these. I have a vague recollection at one time of being told that there had been a delay in the manufacturers providing test kits, but this may have been later. I have also been shown a letter dated 30 August 1990 from Dr Gunson to those involved in the evaluation which enclosed a "final draft of the proposals for the proposed study" [NHBT0000189\_211]. I do not know if part of the delay was revision to the NBTS' protocol. Although Dr Gunson's letter also referred to pressing the DH hard for a positive response on the budgetary arrangements.
- 2.119. On 3 September 1990, I wrote to Dr Gunson to confirm that funding for the study had been approved [NHBT0000061\_184]. The DH's Procurement

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Division would settle the invoices. The Procurement Directorate wrote to Dr Gunson on 7 September 1990 to confirm the arrangements [NHBT0000015\_012]. Dr Rejman was named as the DH's Medical Project Officer.

- 2.120. In the period July to October 1990, Dr Rejman and I had further correspondence with Robert Anderson regarding his economic analysis:
  - a) 25 July 1990. Minute from Robert Anderson to Dr Rejman, which set out the figures as he understood them to be [DHSC0003581\_026]. He said he would proceed with the economic appraisal but would soon return to us with "searching questions" relating to "option appraisal" (i.e. evaluation of alternative options).
  - b) 3 August 1990. I replied with comments (in Dr Rejman's absence) [DHSC0002498\_031]. I said, "you have mentioned uncertainties about the 'facts' but I am afraid we too are in the position of not knowing." At that time, I anticipated I would put a submission to Ministers in August 1990, although, for reasons explained below, that was delayed.
  - c) 9 August 1990 [DHSC0032375\_075]. Robert Anderson sent his draft economic analysis paper to me and Dr Rejman for comment. The attached paper I have been shown was heavily annotated.
  - d) 14 August 1990 [NHBT0000189\_206]. I replied to Robert Anderson with comments from me and Dr Reiman on his draft.
  - e) 31 August 1990 [NHBT0000189\_214]. Robert Anderson responded to me with comments on our comments. He advocated considering in the paper options other than screening all donors.
  - f) 12 September 1990 [DHSC0002498\_055]. Elaine Webb replied to Robert Anderson with comments from Dr Rejman (I was on leave).
  - g) 8 October 1990 [NHBT0000061\_191]. Robert Anderson minuted Elaine Webb with a fresh draft of his economic analysis of HCV screening.

### Q28: Minutes of the eighth meeting of the ACVSB, 21 November 1990

- 2.121. The eighth ACVSB meeting took place on 21 November 1990 [NHBT0000073\_018]. The minutes said,
  - "18. The Chairman summed up the discussion by saying that there was agreement that the UK should introduce hepatitis C testing as soon as practicable. RTC's would decide individually whether to use Ortho or Abbott test. [...] A submission would go to Ministers regarding this significant policy decision and the Management Executive would consider the funding aspect."
- 2.122. Dr Metters stressed the importance of a common date of introduction throughout the UK. The Committee was also informed that better tests were about to be introduced.
- 2.123. The Inquiry asks what steps were taken by me and/or DH in response to this. There was an intense period of work following the meeting up until Christmas on putting together a submission to Ministers, which went up to Lady Hooper on 21 December 1990. I set out the detail at paragraph 2.133 below onwards.
- 2.124. The Inquiry also asks whether I had any concerns at the time or in retrospect that the pilot study should not have delayed the introduction of HCV screening (I assume the Inquiry refers here to the pilot study to compare first generation Ortho and Abbott that took place in autumn 1990). I addressed the issue of delay caused by the pilot study to compare the two tests at paragraph 2.116 onwards above. The clear advice from the Committee was that the pilot study was necessary before giving the recommendation to ministers. There would have been operational challenges for RTCs (equipment, training, staffing etc) if they had to introduce two tests rather than one. There was potential risk for loss of public money if a test was introduced without verification that the RTCs could make it work. For these reasons, it seemed a logical next step and although I cannot now recall what I thought at the time, I do not think that I would have been concerned that the pilot study was going ahead. The timescale for the

Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") study was estimated at four months after finance had been agreed (see minutes of seventh meeting at paragraph 20). The results were in fact reported to the Committee less than three months after finance was approved.

# Q29: Drafting of the minutes of ACVSB meetings

- 2.125. The Inquiry refers me to a minute dated 26 November 1990 from Dr Archie McIntyre to Mr Tucker (copied to CMO, Mr Panton and Dr Skinner) [SCGV0000210\_117]. Dr McIntyre attended ACVSB meetings as an observer from the SHHD. I assume that this minute is his report to colleagues in the SHHD. It is a Scottish Office, not Department of Health, document.
- 2.126. The minute attached a note of the ACVSB meeting on 21 November. The Inquiry refers me to where it is recorded that,

"It was anticipated that the cost of each test would be in the region of £2; there would also be on top of this the costs of the further tests some of which were expensive. I understand that some provision has been made in the current financial year for the introduction of Hepatitis C testing but it seems unlikely that the test will be introduced this current financial year"

- 2.127. The Inquiry notes that this "issue" was not reflected in the "official" minutes. The quotation highlighted by the Inquiry was immediately preceded by a reference to me and Dr Metters agreeing to send a copy of the draft submission to the Scottish Office. This discussion may have gone on outside the main meeting.
- 2.128. Further, while the reference to £2 per test is not in the minutes (although it may have been in one of the papers circulated to members), the remainder of the quotation concerns financial provision made by the Scottish Office. This would not have been a matter for the Committee's discussions.
- 2.129. The Inquiry further asks me how the minutes were prepared, whether the drafting was selective in respect of the discussions which were ultimately recorded and whether the minutes were censored and/or refined in anticipation

Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") of future examination and/or litigation. The minutes were emphatically not censored. Moreover, they were only selective in the sense that efficient meeting minutes were meant to select the main points of discussion, conclusion and action, not seek to be a verbatim record.

- 2.130. The Inquiry alights on Dr Metters' reference to having "tightened up some of the conclusions on NANB testing as the record of the Committee's deliberations may well be called into evidence in years to come" (minute of 15 February 1990 [DHSC0002496\_100]). This comment was made to my HEO, Pam Reenay, and related to the minutes from the (fifth) meeting on 17 January 1990. Pam Reenay was at the meeting; as the most junior official present, I assume it fell to her to do the first draft of the minutes. I surmise that Dr Metters was anxious to make sure the minutes reflected in full the reasoning for the Committee's decisions (which, in the case of this meeting, was not to recommend routine screening).
- 2.131. The general process of drafting minutes was that I, or sometimes one of my juniors, would prepare a first draft. It would often then be shared with Dr Rejman for his comment or amendment. The draft minutes would then go to Dr Metters for further amendment and approval before circulation to the members. The minutes would then be reviewed by the Committee at the subsequent meeting before being accepted formally by the Committee (with any corrections or omissions addressed in the minutes of that meeting).
- 2.132. The Inquiry asks me to explain whether in my view, a lack of financial provision resulted in a delay to the introduction of HCV screening. I address this question in my reflections at the end of this Section.

# Q30: Relevant bids for funding the cost of HCV screening, 30 November 1990

2.133. Nine days after the eighth ACVSB meeting, on 30 November 1990, I minuted my branch head, Charles Dobson, and others, with a first draft of a ministerial

draft submission said.

Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") submission recommending the introduction of anti-HCV screening [DHSC0002534\_055]. The attached draft submission, also dated 30 November 1990, ran to eight pages [WITN7115017]. It annexed a seven-page Economic

"this note sets out the case for and against the introduction of routine screening, the financial implications and the results of an economic appraisal, and seeks Minister's approval to commence screening in the NBTS. The other UK Health Ministers are also being asked to approve the introduction of routine testing in their transfusion services."

Appraisal produced by Robert Anderson of the DH's Economic Advisers'. The

2.134. The draft submission then referred to the 12 other countries that had introduced screening, to the results of the pilot trial and to the ACVSB's recommendation. The section on Financial Implications of Screening noted an estimated cost of £5.73 million in the first year. On Value for Money, the draft referred to the annexed Economic Appraisal and said, "based on reasonable assumptions the appraisal concludes that some form of screening programme could be cost beneficial". On funding, it said,

"12 No special provision has been made for HCV testing in the HCHS budget. The cost to RTCs of £4 -  $4\frac{1}{2}$  million would therefore have to be found from the general allocation. Since RTCs will be moving away from direct funding by Regions from 1 April 1991, it is likely that the additional cost of screening will be reflected in higher handling charges to hospitals for blood supplies. The PHLS would carry out the supplementary tests and they too would have to find the cost from their general allocation. The cost to them is likely to be of the order of £1 -  $1\frac{1}{2}$  million a year."

2.135. Similarly, my covering minute said,

"The bid for new HCHS [Hospital and Community Health Services] money to cover the cost of HCV screening was struck out earlier this year, so I have assumed that the RTCs costs will have to be found from the HAs' own resources.

I understand that PHLS bid for £100k from CFS [Centrally Funded Services] for the supplementary HCV testing but this, too, has been turned down."

2.136. The Inquiry asks me to provide context and explain why these bids were refused. I do not know why these specific bids were turned down. In general,

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there were bids for more money than could be met and something had to give way. My minute asked Mr Brown of EHF1B to comment further on the PHLS bid. I think he worked in Dora Pease's division and may have been the budget holder for PHLS. I recall generally that once PES (Public Expenditure Survey) bids went up the line we tended not to get much, if any, explanation for why they had been turned down. Mr Merrett in FA2B (DH finance branch), who was copied in, may be better placed to assist with this query, although he was likely my branch equivalent and any decisions would probably have been taken higher up the line in finance.

- 2.137. Returning to the draft submission, I set out the main arguments in favour and against the introduction of screening and commented on timing of introduction. The draft submission concluded,
  - "18 In view of the ACVSB's recommendation that routine screening should be introduced as a public health measure, the possible risk of litigation and the fact that other countries are routinely testing blood donations for the virus antibodies, any further delay in the introduction of HCV testing in the UK would be difficult to defend.
  - 19 We therefore recommend the introduction of routine screening for HCV antibodies."
- 2.138. On 3 December, Robert Anderson commented on the draft submission [WITN7115018]. He said,
  - "1. In my judgment the case is weak and the draft's confident and assertive tone is not justified by the evidence it presents [...]"
  - "2. Alternative, less costly testing options do not get a fair crack of the whip [...]"
- 2.139. He further complained that "virtually no use" was made of his economic appraisal. He further said, "More generally [...] the annex [i.e., the EAO's paper] does not specifically support the actual proposal recommended against alternative options" and, "There is running through the draft an underlying assumption that risk must be eliminated whatever the cost."

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- 2.140. On 4 December 1990, Mr Brown, as requested, commented on the PHLS bid [DHSC0002503\_067]. He said,
  - "2. Miss Pease, Mr Dobson and I met FA3 for a second bilateral on this year's PHLS PES bid yesterday, and the PHLS bid for hepatitis C testing came up in the course of our discussion. I mentioned that a submission was pending and that, if accepted, nationwide testing would follow with cost consequences for the PHLS of up to £1.5m pa for reference testing.
  - 3. Finance noted this likely development, but asked why PHLS should be funded for such work rather than recovering any costs by charging for it. In principle we could see no compelling reason why PHLS should not charge for such testing, provided that funds were earmarked somewhere (eg by HAs?) to meet the costs. We left it that we preferred to treat the PHLS bid for £100K as simply a marker at this stage, pending developments."

#### Q31: Draft submission dated 6 December 1990

2.141. On 6 December 1990, Dr Pickles minuted Dr Metters (copied to me) [NHBT000061\_195]. She asked Dr Metters for guidance on whether to attempt to clear the submission with others – particularly the NHSME. She attached a draft submission (the second version that I have been shown), which was similar in substance to the first, although with some revisions [DHSC0002498\_075]. Notably, Robert Anderson's paper had been removed. I think his paper would have been regarded as too detailed for the top of the office. It was replaced with a summary of the EAO's analysis at Annex B. We would have made sure that the main thrust of his paper was reflected in the submission. The summary said,

"The main conclusion is that the benefits for the estimated £5-6m first year cost is uncertain, but could be in the order of £6000 per QALY [Quality-adjusted life year] for the lives saved."

2.142. The next day, 7 December 1990, Dr Pickles minuted me [DHSC0002498\_078]. She had discussed handling of the draft with Dr Metters, who had suggested, "it should go round now for consultation in the usual way to NHSME colleagues and also CMO's office and Mr Heppell at this stage. Territorials also have to be kept in touch." Dr Pickles said we must press ahead without delay.

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- 2.143. On 12 December 1990, I sent a cover minute to the CMO's office, to Drs Metters and Walford (the DCMOs), to Strachan Heppell and to Mike Malone-Lee (NHS ME). I copied in the health departments in Scotland, Wales and Northern Ireland. I attached a further version of the draft submission dated 11 December (the third version that I have been shown) [WITN7115019]. In view of the urgency, I asked for comments by 18 December. I have been shown two separate copies of my cover minute, each with different handwritten comments from recipients [DHSC0002498\_082] and [DHSC0003581\_086].
- 2.144. On 17 December 1990, Robert Anderson commented on the 11 December draft submission [NHBT0000061\_200]. He suggested various changes, which included, in the section on Value for Money, the amendment "...appraisal points to a cost per life-year of the order of £6000, not particularly good value for money in view of the optimistic assumptions.".
- 2.145. The following day, 18 December 1990, Dr Metters minuted me (copied widely) with comments on the 11 December draft submission [NHBT0000061\_201]. He said,
  - "2. My major concern is that the submission does not properly reflect the views of ACVSB. The Committee in July reached the conclusion that HCV screening could prevent a significant proportion of post-transfusion hepatitis. You will remember that Professor Zuckerman spoke in terms of at least 30% of such cases could be avoided, possibly more.
  - 3. Furthermore, the Committee's view is that with the existence of the current test procedures, to continue a policy of not screening poses an unacceptable risk to the health of recipients of blood and plasma.
  - 4. The Committee recognise that detailed cost benefits of HCV screening could not be quantified. Nevertheless, their unanimous conclusion is that the UK should follow the lead of an increasingly long list of countries (your para 5 refers), who have now introduced HCV screening in order to significantly reduce the load of non A non B post-transfusion hepatitis.
  - 5. The submission must convey more clearly ACVSB's position and the Committee's assessment of the benefit/risk balance."
- 2.146. Dr Pickles replied to Dr Metters on 21 December 1990 with an explanation for why Dr Metters' point about Professor Zuckerman's views had not been

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incorporated into the draft submission [NHBT000061\_206]. Dr Pickles said current methods would in fact hopefully detect a much higher proportion of NANB, although it could not be substantiated. She further said, "the main reason for not mentioning this figure is we suspect those who did the economic appraisal would be surprised at a figure as low as 30% was quoted. We do not want to give them more ammunition." Dr Pickles' comment alluded to the resistance we had experienced (on economic grounds) against the case for HCV screening. This resistance was apparent in some of Robert Anderson's minutes to which I have referred already. I note also from the papers that in some of Robert Anderson's comments he rather strayed beyond his narrow EAO remit.

2.147. The Inquiry asks me to explain who had input into finalising the submission and what the process was, including any consultation. Much of this is apparent from what I have said already. In terms of process, the first draft was circulated to a relatively small group, namely Charles Dobson; Dr Pickles; Dr Rejman; Mr Brown (of EHF1B); Anthony Merrett (of FA2B, a DH finance branch); and Robert Anderson of the Economic Advisers' Office. I have referred above to the comments that I received in response, where these have been drawn to my attention. Dr Pickles shared a second draft with Dr Metters and it appeared they discussed it. I was then instructed by Dr Pickles to share a third draft (the 11 December draft) with the wider group described in paragraph 2.143 above. Comments received in reply would likely have been addressed to me, but I think I would have discussed amendments to the submission with Dr Reiman and. quite possibly, Dr Pickles. Dr Metters' contribution of 18 December 1990 would plainly have been influential. The Inquiry refers me on this point to Dr Rejman's oral evidence in which he said Dr Metters wanted the submission to leave "no doubt that this is what we must do" [INQY1000204, page 142 of the transcript]. I think that much is apparent from Dr Metters' minute.

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#### Q32: Final draft of submission dated 21 December 1990

- 2.148. Slightly earlier in time, on 19 December 1990, I minuted Mike Malone-Lee with a draft paragraph for the submission that put forward NHSME's view [NHBT000061\_202]. I assume that I must have discussed the wording with NHSME in advance. The NHSME's draft text noted that "the Health Authorities may question the need to impose the new screening requirement at present when the tests are as yet imperfect" and it was suggested that discussions would need to be had with RTCs and PHLS before announcing the new screening policy.
- 2.149. On 21 December 1990, I sent a final version of the submission (the fourth version that I have been shown) to the Private Secretary to Lady Hooper [PRSE0004667]. The final version was more emphatic than previous iterations about the ACVSB's recommendation (see paragraphs 6 to 8). It said, "They firmly recommend the introduction of screening as soon as practicable."
- 2.150. The Inquiry refers to the fact that in the final submission the factors "against" screening included the fact that the outlay on screening would add to the general pressure on health authority funds (this factor was in fact present from the first iteration of the draft).
- 2.151. The Inquiry asks me to what extent did costs considerations drive the timing of the introduction of HCV screening. The cost considerations would have been the same whenever screening was introduced. My recollection is that the intention was that screening would be funded by users, that is by the Health Authorities (whether through their allocations or via blood handling charges). As can be seen from Mike Malone-Lee's minute, he wanted there to be discussion with the RTCs and PHLS (who would bear the laboratory costs) but it did not influence the timing of, for example, when the submission was put to Ministers.

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- 2.152. The Inquiry also asks what was meant by the reference in the submission that the ACVSB had been "clearly influenced by the threat of litigation". I cannot now recall the specifics, but I note that at the fourth ACVSB meeting on 7 November 1989. Dr Metters said, "the Department must bear in mind the possible litigation that could arise from a prolonged delay in the introduction of general screening". Dr Metters minute to Mike Malone-Lee of 26 July 1990 also acknowledged litigation risk.
- 2.153. I do not think litigation had any bearing on the Committee's advice on the science, but litigation did feature as part of the Committee's discussion on cost/benefit. Inevitably, given the cost and resourcing implications of litigation, it would have been one of the factors for the DH to consider (this was also around the time of the HIV litigation). I do not think however that litigation risk was one of the main reasons that HCV screening was introduced; it was introduced because the Committee advised it was necessary on grounds of blood safety and public health grounds.
- 2.154. On 27 December 1990, Robert Anderson minuted me about the report of the NBTS trial of the performance of repeat initial testing using both Abbott and Ortho tests. He concluded, "There are essentially two results. Repeat initial testing is worthwhile. Single-stage testing now emerges as the least-cost option, followed closely by two-stage testing using RIBA" [NHBT0000061\_208].
- 2.155. Mark Fuller (by then of the DH's Medical Devices Directorate, which I think was an evolution of the Procurement Directorate) minuted me and Dr Rejman on 10 January 1991 about negotiations for provision of screening tests at less cost than was paid for the trial tests [WITN7115020]. He wanted to "lay some foundations" before a ministerial decision on screening. PD branch would lead negotiations and aimed to secure a cost of near £1 per test. Dr Gunson hoped for central procurement. Mark Fuller asked me to lead on coordinating with the NBTS to pre-empt individual RTC directors from entering into contracts. Mark Fuller also said,

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"I feel that we should exploit the insensitivity of these tests, as a predictor of "infectivity", as defined by PCR. Notwithstanding the difficult assumptions which this calls for, especially given our lack of knowledge - my point being that nobody really knows what we are looking at nor what the downstream cost consequences are, given the weakness of the economic advisors cost-benefit analysis. One of these will certainly be a high rate of negative "Supplimentary/Confirmatory tests", and we should look to reduction of the costs of screening as a consequence."

### Q33: Lady Hooper's agreement to HCV screening, 16 January 1991

2.156. On 16 January 1991, Lady Hooper's Private Secretary minuted me to confirm Lady Hooper's agreement to the introduction of HCV screening "as soon as is practicable" [NHBT0000191\_013]. The Inquiry asks me whether screening tests were introduced as soon as practicable. I set out below the practical steps that followed and return to this issue in my reflections at the end of this Section.

#### Q34: Dr Pickles' minute, 5 February 1991

- 2.157. Mark Fuller minuted me and Dr Rejman again on 29 January 1991 (the document said 1990 in error) with an update on PD's negotiations [WITN7115021]. His minute referred to Ortho's new competitors and suggested his branch should obtain data from alternative suppliers in the US (UBI) and Europe (Organon Teknika). Dr Metters added a handwritten comment, addressed to me and Dr Rejman, that said, "I agree we should try to expand the study to include new competitor tests, provided this does not cause too long a delay." There was a separate list of handwritten queries (in different handwriting) addressed to Dr Rejman.
- 2.158. The Inquiry refers me to Dr Pickles' minute to me dated 5 February 1991, which said,

"Dr Gunson has been in touch with all the RTCs about starting dates for HCV testing. There are all sorts of problems still, eg exact choice of test, supplies of this, confirmatory testing arrangements, training etc etc. There remains real concern about how the necessary money will get into the system. The starting date he wanted to try out on me was 1 July: would this be too late?

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My initial reaction was this would be OK. Attempting to go earlier would mean some stragglers would be left behind, the slight delay increased the chance of the finance being sorted out, and with diversion of RTC resources to Gulf-related activities a short time date might not be feasible. Even that date was dependent on blood collection having been stable for the preceding 4 weeks, which should apply provided the ground war is over by then." [NHBT0000062\_028]

- 2.159. I cannot now recall my reaction to the proposal of 1 July. Dr Gunson would have had a far better understanding than me of the issues that faced the blood transfusion service in preparing for the introduction screening. I understand from the papers that prior to his minute to Dr Pickles he had canvassed the opinions of the individual RTCs. I cannot recall any discussions within DH following the receipt of this minute.
- 2.160. The Inquiry asks me what steps the DH took to try to resolve the "problems" described by Dr Pickles. Taking them in turn, the choice of test (and confirmatory test) was at that stage still under consideration and would be the subject of further ACVSB advice. Test supplies were a matter in which DH Procurement Directorate (in particular, Mark Fuller) were involved and I address that elsewhere in this statement. "Training etc" would have been a matter for the NBTS.
- 2.161. I am reminded that the Gulf War air campaign started on 18 January 1991. I assume Dr Pickles' reference to "Gulf-related activities" may have concerned RTCs working to increase blood stocks in case of an emergency shortage. I do not recall whether the Gulf War had any impact on the timing of HCV screening and have not seen anything on this in the available documents.

# Q35 & Q37: Ninth ACVSB meeting, 25 February 1991 & Dr Rejman's minute to Dr Metters, 30 April 1991

2.162. The ninth ACVSB meeting took place on 25 February 1991 [PRSE0002280]. I was absent. The members agreed that proper evaluation of the first- and second-generation Ortho and Abbott screening tests would need to be carried

- Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") out before RTCs decided which test they would adopt. It was also agreed that all 10,000 archived samples should be tested by second generation tests, and MDD (Medical Devices Directorate of DH) would seek the necessary funding.
- 2.163. I have been shown a letter dated 26 February 1991 from the General Manager of North West Thames RHA, Alan Langlands, to Mike Malone-Lee [DHSC0003532\_048]. This was copied to me at the time for advice. Alan Langlands expressed concern about the resourcing implications for RHAs if the HCV screening was introduced. He also cited a paper by Dr Marcela Contreras due for publication in the Lancet that apparently suggested NANB hepatitis was not a significant problem in the UK.
- 2.164. The NHS Procurement Directorate wrote to Dr Gunson on 21 March 1991 [NHBT0000191\_115]. It noted that the DH had agreed there should be a "second-round comparative evaluation" of HCV kits at the Newcastle, North London and Glasgow RTCs. The screening kits involved in the evaluation had been ordered from Ortho, Organon Teknika and UBI. The NBTS would trial the tests between February and April, after which any repeat positive sample would be sent for confirmatory testing.
- 2.165. On 3 April 1991, Dr Gunson wrote to all Regional Transfusion Directors (RTDs) [NHBT000073\_065]. He referred to his earlier letter of 15 February, which had suggested 1 July as the start date for HCV screening. He explained that since the three-centre trial of anti-HCV tests was completed, Ortho and Abbott had produced second generation test kits. He said the "second-round" comparative evaluation had not started and one of the second-generation tests would not be available until late April (Dr Gunson's subsequent letter to Dr Lloyd confirmed this was Abbott's test). Dr Gunson said it was undoubtedly in the NBTS' interest to complete the evaluation, but that a revised date to commence routine screening was required. He aimed for 1 September.

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- 2.166. On 30 April 1991, Dr Rejman minuted Dr Metters (copied to me) regarding the decision of Dr Lloyd at the Newcastle RTC to unilaterally commence anti-HCV screening (using the Abbott second generation test) despite agreement that screening would be started simultaneously in all RTCs [NHBT0000062\_054].
- 2.167. Dr Pickles minuted Dr Metters on 10 May 1991 [NHBT0000192\_033]. In relation to the 'premature' testing introduced in the Northern Region, Dr Pickles said it had been agreed that it would be sensible to present the testing as part of the multicentre trial of second-generation tests. Dr Metters was invited to approve this extension of the study.
- 2.168. She also said, "Since the last ACVSB meeting, we have discovered the first generation tests are no longer available. The second generation tests are not FDA approved, hence proper evaluation is vital." She said a 1 September start date looked likely. The delay "quite excusable" because the scientific case for testing was "rather less clear cut than when the decision to go for testing was made". Germany, by comparison, would take a year to introduce testing.
- 2.169. On 15 May 1991, Dr Rejman minuted Dr Metters [NHBT0000062\_067] with a draft protocol for an extended pilot trial of second-generation tests. The suggested study was an extension of the agreed second round evaluation. It was proposed to ask three RTCs in Liverpool, Leeds, Newcastle and Glasgow to undertake an extended trial of the second-generation Ortho and Abbott anti-HCV tests.
- 2.170. Dr Metters minuted Dr Pickles (copied to me and Dr Rejman) on 15 May 1991 [DHSC0004006\_112]. He said he was not clear how the testing programme in the Northern Region would differ from the evaluation originally agreed for North London, Glasgow and Newcastle. He said it should be considered further by the ACVSB.

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- 2.171. The tenth ACVSB meeting took place on 21 May 1991 [NHBT0000042\_080]. Dr Gunson reported on the progress of the second-generation trials (which involved second generation Ortho and Abbott and first generation UBI and Organon Teknika). The minutes recorded,
  - "10. It was decided that 3 tests could be used for initial screening, Ortho II, Abbott II, or UBI. Individual RTCs would decide which was most appropriate and they would be guided by the results so far obtained as well as those from Newcastle, together with the funding of the supplementary kits. The results would be available by the end of June/early July and would be transmitted by the NBTS Directorate to the RTCs."
- 2.172. On the issue of Newcastle RTC's unilateral action, Dr Gunson said this could be used as an extension of the trial. Dr Gunson confirmed that one of the main aspects was to be an examination of RIBA and PCR supplementary tests on positive donations. Work in Glasgow was under way, Leeds were ready to start and Liverpool and Bristol were to begin trials in June.
- 2.173. Also on 21 May 1991, Dr Metters minuted me and Dr Rejman about a letter dated 13 May from Dr Cash to Dr Gunson [DHSC0004006\_181]. He said,
  - "3. As regards HCV screening the position is quite clear. We went to Ministers and obtained their agreement to recommendations from ACVSB. BUT the Newcastle Director chose to disregard the proposed vesting date and went ahead unilaterally. Dr Cash's question is legitimate, particularly if we are not intending to take any sanction against the Newcastle RTC. At the very least it seems to me we should take Ministers' minds on whether they wish, despite events in Newcastle, to maintain the policy that new screening tests will only be introduced on a uniform vesting date that will be decided centrally. Of course, when it comes to enforcement in the reformed NHS that could only be achieved through the ME's structures.
  - 4. The dangers of a 'free for all', particularly the legal dangers, are such that I suspect Ministers will want to retain control. In which case a letter reminding all RTC Directors would be timely."
- 2.174. The Inquiry asks me a series of questions about the second-round evaluation. My understanding was the evaluation was deemed necessary so the RTCs knew which test to adopt. The second-generation tests had not been used by RTCs and it was necessary to know what the advantages and disadvantages

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and which should be recommended for use. Although I cannot now recall I do not think that I would have raised any concern about further delay; as Dr Pickles said, "proper evaluation is vital". The Inquiry asks whether the Committee considered the imminent introduction of both test with evaluation later. I commented on a similar proposal (in relation to the Ortho and Abbott first generation tests) at paragraph 2.107.b) above. The Inquiry asks why the tests were unavailable between February and April 1991 for the pilot study. I have a hazy recollection of being told by Dr Gunson that the test manufacturers had had production problems. I do not think I can otherwise add to what Dr Gunson said in his letter to all RTDs on 3 April 1991 – Abbott's second-generation test was apparently not available from the manufacturer until late April 1991.

2.175. The Inquiry also asks about the DH response to the unilateral action by the Newcastle RTC. I do not particularly remember my reaction to this news, although I note from the November 1990 ACVSB minutes that Dr Metters wanted a universal start date. I am asked what steps were taken in response. There was passing mention of "sanction" for Newcastle RTC in Dr Metters' minute of 21 May 1991, but it does not seem this was ever pursued seriously. Dr Metters also referenced taking Ministers' views on whether to proceed with a uniform date.

# Q38: Advice on legal position regarding the Newcastle RTC's unilateral action

- 2.176. On 8 May 1991, Charles Dobson sought advice from DH legal on the position of the remaining regions in light of the Newcastle RTC's unilateral action [DHSC0003620\_001].
- 2.177. A response dated 8 May 1991 was provided by Alex Brett-Holt (Sol C2) [DHSC0004006\_195]. She said,

"I can see that it makes sense for the same systems and technology to be used everywhere, and for false positive results to be as few as possible but are these factors such as to outweigh the fact that months

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are passing and blood is not being routinely screened? Is there any reason why different regions should not select different tests during an initial period while comparative tests are carried out to select the eventual universal test system?"

#### 2.178. Her advice was that,

- "7. [...] the unilateral decision of the Northern Region does not greatly affect the position of the other regions, provided the others remain in line [...] What might be damaging to the majority position would be a suggestion that routine screening had been unnecessarily delayed while the best test is selected, when any one of a range of tests could have been safer than the current no testing system. If other regions followed Northern Region the position might alter.
- 8. There may, of course, be more to be said against the argument I have outlined above than is apparent to me at the moment. I would be very happy to consider the matter further in the light of more extensive information if you have it."
- 2.179. The Inquiry asks about the DH's response to this advice. Charles Dobson minuted Mrs de Peyer (RL3) on 23 May 1991 (copied to me) [DHSC0004006 175]. He said,
  - "2. The immediate difficulties appear to have been contained, and fortunately the remaining RTCs have remained firm by the agreed start date. However, I do not believe that we should allow Northern RTC to get away with what is at best an irresponsible piece of individualism and at worse a deliberate challenge to the coordination arrangements for the NBTS.
  - 3. I therefore propose that we should invite Mr Malone-Lee to write to the Northern Region RGM along the lines of the attached draft. Dr Metters [...] fully concurs."
- 2.180. The Inquiry also asks whether consideration was given to an unvalidated testing system. I do not think so; the Committee's position all along was that the test had to be tried before testing was started. The Inquiry further asks why the ACVSB or the DH did not recommend that different regions adopted different tests during an initial period while an evaluation was carried out. I do not recall and the available documents do not suggest the advice led to any specific consideration. But, I suspect such a proposal would have posed significant operational difficulties for the RTCs in terms of equipment, training etc. There would also be the issue that if one of the tests was subsequently found to be

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# Q36: Advisory Group on Hepatitis, 12 March 1991 – addressed out of Inquiry's sequence

2.181. The Inquiry refers me to remarks made by Dr Contreras at an AHG meeting on 12 March 1991. The minutes record that she had asked for the minutes of the last meeting to be changed to reflect the fact that she had expressed concern that no extra funding was to be made available for HCV testing [NHBT0000048\_001]. I have been shown the minutes of the previous AGH meeting, on 6 December 1990 [WITN7115022]. Both sets of minutes record that I had apologised for my absence. Given I was not present on either occasion when the concerns were apparently raised, I do not think I can comment further on the detail. As a general point though, managers in the NHS knew that operational funding came from their RHA's general allocations, or under the new blood handling charges arrangements should be recovered from the hospitals they supplied.

# Q39: The response on the line to take that "The risk of Hepatitis C being contracted through blood transfusion, though it exists, is remote"

2.182. The Inquiry asks me about a minute from Charles Dobson dated 9 May 1991 (copied to me) [NHBT0000062\_060]. The minute concerned potential press interest in Newcastle RTC's unilateral action. It attached a briefing note and line to take, which said, "The risk of hepatitis C being contracted through blood transfusion, though it exists, is remote." The Inquiry asks me if I agreed with that statement and what, if any, steps I took in response. I assume (but do not know) that the briefing was based on the advice of medical colleagues, perhaps Dr Rejman. I do, however, recall that in the period there was significant uncertainty about the infectivity of blood donations that tested positive. The minutes for 18 January 1990 record, "Dr Tedder summed up the views of the Committee that 'scientifically we do not know enough about the significance of a positive test result'."

#### Q40: Dr Garson's draft article on Hepatitis C Viraemia, September 1991

- 2.183. The Inquiry asks me to consider a letter from Dr Rejman to Dr Gunson dated 11 September 1991 regarding his comments on a draft article titled 'Hepatitis C Viraemia in United Kingdom Blood Donors' by Dr Garson [NHBT0000015\_117]. The final version was accepted for publication in the journal Vox Sang in October 1991 [PRSE0000281].
- 2.184. Dr Rejman's letter said he had discussed the paper with me and Mark Fuller and "give below some of our anxieties". I do not now recall any discussion with Dr Rejman (or Mark Fuller) on this article. I do not think I would have had any substantial contribution to make on the subject matter.

#### 2.185. Dr Rejman's letter said,

- "9. It might also be worthwhile making some comment to the effect that our understanding is that in the US no supplementary testing is currently being used and that all donors who are screened positive are being rejected. We believe this difference of attitude in the UK and US should be highlighted, particularly as it was a major feature which delayed introduction of Hep C screening in the UK."
- 2.186. The Inquiry asks whether the lack of supplementary testing was a "major feature" of why there was delayed introduction of anti-HCV screening in the UK compared with the United States. I think what Dr Rejman meant is that prior to the introduction of screening in the UK supplementary tests were not available to check the results of the screening tests (so there was concern about false positives). It appears that the US were satisfied simply to go ahead without supplementary tests.
- 2.187. The Inquiry also asks whether the ACVSB or the DH ever considered adopting a US-style approach of proceeding without a supplementary test and rejection of all donors who screened positive. I do not recall the USA approach being considered. ACVSB had to take account of the impact on blood supplies. There

Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") was concern that discarding donations on the basis of possibly false positive results might have put pressure on blood supplies.

# Q41: Consideration given during 1989-1991 to the introduction of HCV testing in other countries

- 2.188. The Inquiry asks me what consideration was given by me, others within the DH and those (such as the ACVSB) advising the DH, to the fact HCV testing was being introduced in other countries.
- 2.189. In terms of my consideration, the Inquiry refers me to my minute dated 1 May 1990 to Lady Hooper [NHBT0000061\_130]. I referred to this in paragraph 2.94 above. The minute's purpose was to update Lady Hooper on the recent (sixth) ACVSB meeting, which had taken place on 24 April 1990. The meeting minutes recorded that Dr Metters told the Committee that France, Belgium and Luxembourg (and Italy on a voluntary basis) had introduced screening. My minute recited the same information, save it added that Finland had also introduced screening.
- 2.190. I do not know where my information about Finland came from. It is possible that following Dr Metters' comments in the ACVSB meeting I did some further research and noted the development in Finland. The 6 December 1990 version of the draft ministerial submission listed several other countries who had introduced screening, so someone (possibly me) must have been engaged in some research into what was going on abroad. I have not otherwise seen any other references in the papers to me personally considering developments in other countries.
- 2.191. I do not recall having any personal contact with officials in other countries which introduced screening earlier than the UK. On reflection, I suppose that it would have been possible for DH officials to speak to their counterparts abroad to understand how things were working in practice in those other countries.

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Although there would still have been the issue of how to compare the particular situation in another country with that of the UK.

- 2.192. As to consideration by others within the DH, I am limited to what is apparent from the documents. As I have indicated, Dr Metters was clearly aware of developments (as well as his comments in the sixth ACVSB meeting, see his minute of 18 December [NHBT0000061\_201], which I referred to at paragraph 2.145 above). The position on screening in other countries was also referred to in the final submission to ministers dated 21 December 1990, so Ministers were aware.
- 2.193. I discussed the ACVSB's consideration of developments in other countries at paragraph 2.95 above. As I have noted elsewhere in this statement, ACVSB members occasionally travelled abroad to attend HCV symposia; I assume these would have provided opportunity for information sharing.
- 2.194. The Inquiry finally asks why, in my view, the UK was slower to introduce HCV testing than other countries. I had no particular knowledge of the specific situation that pertained to those countries and, so, I do not think I can give an informed answer to this question.

#### Q42 & Q43: Non introduction of HCV testing until September 1991

- 2.195. The Inquiry asks me two closely related questions, first, why HCV testing was not introduced until September 1991 and, secondly, whether it should have been introduced sooner.
- 2.196. I have set out above a detailed chronology of the introduction of HCV screening, insofar as my involvement was concerned. I do not think I can add any further to the detail of why it took until September 1991. In summary, it came down to a series of considerations and steps that seemed quite reasonable at the time.

- 2.197. The period up until the ACVSB's recommendation to Ministers in late November 1990 to introduce screening as soon as practicable involved close consideration of the issue by an expert committee. The chronology of the meetings shows a series of decisions guided by their interpretation of the developing science. The issues with the tests were an obstacle but once the data became clearer, the FDA had approved the test and the RIBA supplementary test had become available, the Committee acted and in July 1990 made its "in principle" recommendation (subject to evaluation of the test kits).
- 2.198. The Inquiry asks me what role the anticipated cost of such testing played in the DH's decision making and refers me to the ministerial submission dated 21 December 1990. Once the ACVSB made its recommendation, Lady Hooper agreed it. There was no pushback from Ministers on grounds of affordability. As the Inquiry would expect, the submission (and the research that led up to it, for example the analysis by the Economic Advisers' Office) had to consider the anticipated cost, in order that Ministers could make an informed decision. I do not believe there was an attempt by DH to avoid HCV screening because of fears about the cost. Indeed, it was recognised that the cost/benefit case was not particularly strong, but the decision was made anyway. In my minute to Mike Malone-Lee dated 3 June 1991 I said,
  - "4. As for HCV testing, I don't think anyone was under any illusions but that it was marginal in terms of cost benefit. But this is true of other NHS interventions. However the litigation factor, the introduction of testing elsewhere in Europe and the prospect of EC harmonisation of licensing requirements for blood products stacked up in favour of testing." [NHBT0000192\_076; DHSC0002499\_081].
- 2.199. The period from Lady Hooper's decision on 16 January 1991 to proceed with screening "as soon as practicable" until September 1991 was the "implementation" phase. The implementation was led by the NBTS, and of course they faced difficulty in obtaining supplies of the Abbott test, which delayed the second-generation evaluation pilot. As Dr Pickles said in her minute

Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") of 10 May 1991, this evaluation was considered by the DH to be "vital". There were also a whole series of other operational matters for the NBTS, such as recruiting extra staff, new equipment and liaison with the PHLS, who would carry out supplementary testing. The arrangements for counselling donors also had to be put in place. The system had to be workable before testing started.

2.200. The question of whether HCV screening should have been introduced earlier is really a matter for the Inquiry to determine. The Inquiry asks me to consider the minutes of the twelfth ACVSB meeting on 21 February 1992, in which Dr Rejman stated, "Since the introduction of anti-HCV screening there had been a marked decrease in the transmission of NANB hepatitis by blood transfusion." [NHBT0000079 017]. His comment was made in the context of explaining why ALT testing had lost its main use as a marker for HCV. The Inquiry asks if the decrease in transmission came as a surprise to the ACVSB or the DH. My recollection is that although it was acknowledged that screening would likely reduce the incidence of NANB hepatitis, there was significant uncertainty within the ACVSB about the extent of any reduction (see, for example, Dr Gunson's report reference at paragraph 2.55. While the data would have become clearer over the time HCV screening was under consideration by the Committee, I think that it was acknowledged that the level of reduction would not really be known until after screening had been implemented nationally. I do not remember any particular surprise at the decrease in transmission.

#### **ACVSB decision-making: HCV Look-back**

2.201. The Inquiry asks me certain questions about consideration of a look-back procedure for HCV. I understand look-back to be a process that starts when a donation is found to be infected and involves tracing possible recipients of the infected donation. I can recollect very little about the issue of Hepatitis C look-back in the period 1990 to 1994. The available documents do not suggest it was something in which I had any significant involvement. I am informed that the national HCV look-back exercise was announced in January 1995, by which

Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") time I had been out of my blood policy role for about nine months and was

working away from DH on secondment.

#### Q44: ACVSB decision to postpone look-back, 2 July 1990

2.202. The Inquiry refers me to the minutes of the seventh ACVSB meeting held on 2 July 1990 [PRSE0000976]. The minutes recorded,

"It was agreed that any donations found to be infected with the HCV antibody would not be used, but the donations would be retained for research purposes. Consideration of any look-back procedure was postponed."

- 2.203. Later, the minutes said, "blood found to be positive in the pilot study would not be used, with no look back at recipients of previous donations from positive donors."
- 2.204. I have also been shown the minutes of the next (eighth) ACVSB meeting, held on 21 November 1990 [NHBT0000073\_018]. The minutes recorded,
  - "5. The Chairman [...] emphasised that the reference to a "no look back" procedure in the previous minutes referred only to work done on the pilot study. A decision on this aspect of routine screening of donors was deferred to a subsequent meeting of the ACVSB."
- 2.205. Dr Gunson said that the ACTTD would consider the question of look-back in relation to routine screening at a forthcoming meeting (see paragraph 21 of the minutes).
- 2.206. The Inquiry asks me why the ACVSB decided in July 1990 to postpone consideration of HCV look-back. I cannot now recall what was discussed in the meeting. In the November 1990 meeting, Dr Metters clarified that he was referring to no look-back on the work done on the pilot study. I assume, but cannot be sure, that the consideration of look-back was postponed because the HCV tests were still evolving and there was uncertainty about what a positive result meant. I do not recall whether the DH gave any separate consideration

Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") to look-back at this time, the available papers do not indicate any involvement on the part of my section. On a matter such as HCV look-back DH would have been guided by the experts.

#### Q45: Consideration of look-back at ACVSB meeting, 25 February 1991

- 2.207. The Inquiry refers me to the minutes of the ninth ACVSB meeting held on 25 February 1991 [PRSE0002280]. The minutes recorded that,
  - "14. The Committee discussed the problems of look-back and recommended that it should not be undertaken as a service, leaving the option open for those carrying out research. However, all cases of post-transfusion hepatitis should continue to be investigated."
- 2.208. The Inquiry asks about my recollection of what problems with look-back were discussed. As I have said already, I was absent from the meeting, so cannot assist. The Inquiry also asks how it was envisaged that post transfusion hepatitis cases should "continue to be investigated". I do not think that I can assist; the other attendees with a medical background will likely be better placed to explain.
- 2.209. I have also been shown the minutes of the next (eleventh) ACVSB meeting held on 29 October 1991 [NHBT000079\_004]. Dr Gunson reported on the results of first HCV test trials. Results of the trial had been sent to Manchester PHLS where Dr Craske had produced a report which recommended, amongst other things, that donors whose donations had repeatedly tested positive should be interviewed. Dr Gunson told the Committee, "no decision had been taken as to a look-back study."
- 2.210. The Inquiry asks me to explain the other factors which contributed to the decision not to undertake a look-back exercise at this time. I am no longer able to recall. I draw the Inquiry's attention, however, to Dr Metters' briefing when he announced the national look-back exercise in January 1995, which I refer to at

Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee") paragraph 2.212 below. Again, I have no recollection of any separate consideration being given by DH to look-back at this time.

#### Q46: Advice to Ministers on look-back, December 1994

- 2.211. The Inquiry refers me to the minutes of the fourth MSBT meeting held on 15 December 1994 [PRSE0003635]. By the date of this meeting, I had been replaced on the Secretariat by Tom Kelly. The Committee agreed to advise Ministers that there was a duty of care towards those infected with HCV as a result of NHS treatment, that procedures should be put in place to identify those patients at risk and that guidance should be drawn up as soon as possible.
- 2.212. When anti-HCV screening was introduced in September 1991, there was no recommendation to implement a look-back programme. The Inquiry asks me to set out why a decision to provide advice to Ministers on look-back was not provided until late 1994. As I have said, my recollection of this issue is limited. I also left my blood policy role in March 1994, so cannot speak to events after that date. From the available documents, it is apparent that doubts about the long-term effects of hepatitis C infection, coupled with the lack of an effective therapy, were two factors in the delay in the recommendation to Ministers. When Dr Metters announced the national Look-Back Exercise on 11 January 1995, his briefing for supplementary questions stated,

"Until recently it was considered that look back to identify recipients of blood transfusion who are at risk would be technically difficult; and as there was no effective treatment, to inform people they were at risk, when there was nothing that could be done about it, would increase distress without any benefit.

The long term effects of the disease were also unclear and it was not easily transmitted.

This position is now clearer and a means of treatment has become available. There is now some confidence that many, but not all, recipients of blood infected with Hepatitis C can be identified and Interferon alpha has been licensed for the treatment of chronic hepatitis C. This may be of help to some people." [NHBT0005855].

### FIRST WRITTEN STATEMENT OF JOHN CANAVAN Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee")

#### **Destruction of Documents**

#### Q47: "Hepatitis Advisory Board" document destruction

2.213. The Inquiry refers me to a minute dated 20 July 1990 from Dr Rejman to Ronald Powell, a DH solicitor in branch SOLB3, (copied to me) [MHRA0025293]. The minute concerned Dr Roger Williams' second preliminary expert report prepared for the HIV litigation. The Inquiry further refers me to Dr Rejman's attached note of a meeting between Dr Williams and Counsel on 5 June 1990, which said,

"8. Dr Williams suggested checking minutes of the Hepatitis Advisory Board held in DHSS, and of which he was a member. [I have checked this out with administrators who believe that all these minutes have been destroyed]."

- 2.214. The Inquiry asks me whether I know who the administrators were and how they knew that all of the minutes had been destroyed.
- 2.215. I do not recall any Departmental group by the name of "Hepatitis Advisory Board". My advisers have identified a submission dated 23 December 1997 about membership of the DH's Advisory Group on Hepatitis (AGH) [DHSC0032349\_224]. Annex A to the submission listed Dr Williams as a member of the AGH since July 1980 [DHSC0032349\_225]. I assume that Dr Williams' comment to Dr Rejman may in fact have been a reference to the AGH. My comments that follow proceed on the basis that I am correct in that assumption.
- 2.216. I set out the background to the AGH and my involvement with it in Section 1. I have been shown the minutes of the AGH meeting on 7 February 1989 [DHSC0002567\_037]. The DH Secretariat was Dr R G Penn and Mr L T Wilson. I was not listed as an attendee, although I was copied into a minute that circulated a paper for the meeting [WITN7115023]. The next meeting appears to have taken place on 6 December 1990, so after Dr Rejman's note. The minutes show that I apologised for not attending [WITN7115024].

- 2.217. I have not seen any documents that suggest I had any significant involvement with the AGH prior to June 1990. I do not know who the "administrators" were in the years leading up to June 1990 (Dr Rejman's minute gives no detail of the date of the alleged destruction). One possibility is that Dr Rejman was referring to the AGH Secretariat, although I do not know.
- 2.218. The Inquiry asks what steps I took to find out who authorised the destruction. I was not aware of any destruction of AGH documents (if my assumption is correct that that was the body to which Dr Williams referred) prior to the Inquiry showing me Dr Rejman's note. The fact that I have been shown the minutes for 1989 suggests that, at least to some extent, Dr Rejman may have been mistaken to say, in June 1990, that all the minutes had been destroyed.

# Q48 to Q49: Policy, training or instructions on storage or destruction of papers

- 2.219. The Inquiry asks whether I was aware of any polices in place for dealing with the storage or destruction of departmental papers. I think I would have been aware of guidance on the storage or destruction of papers from the years I spent in various DH branches but cannot recall what I knew when or how I knew it. I understand that documents generally should have been retained if they were still required administratively (e.g. for policy or litigation reasons), as required by the Public Records Act.
- 2.220. The Inquiry asks whether I recall any training or government-wide instructions on this issue. I cannot now recall any specific training or government-wide instructions on this issue. This is not to say that there was no training provided. However, I do not now recall any details.

#### Q50 to Q56: destruction of the ACVSB papers

- 2.221. The Inquiry asks me a series of questions related to destruction of ACVSB documents. I do not believe that I was aware of this issue prior to receipt of the Inquiry's request for a statement. The Inquiry asks me to consider the following documents:
  - a) Minute dated 7 June 1995 from Dr Rejman to Anita James, DH solicitor [DHSC0200022\_002]. David Burrage had provided Dr Rejman with GEB volumes 1 to 14 for the purpose of HCV litigation discovery. Dr Rejman's minute reported that volume 4 had apparently been destroyed. He said David Burrage had asked for those responsible to write to him.
  - b) Final report following an investigation by DH's Internal Audit into the loss of documents relating to the Hepatitis C litigation, dated April 2000 [DHSC0046961 071].
  - c) Email dated 8 March 2007 from Linda Page to Elizabeth Woodeson, Ailsa Wight, William Connon and Alexandra Nicholas [DHSC6359061]. The email said, "One query responded relates to the missing documents. The ACVSB files lost related to post 1985 and is not part of this review [...]".
  - d) Email dated 13 July 2007 from Steve Wells, DH Information Services, to Zubeda Seedat, which referred to attached destruction dockets [DHSC0014975\_033]. The attached document appears to be the file cover sheets / dockets and print outs relevant to the destruction of the GEB/1 series volumes 4 to 17 from 1994. My advisers have referred me to a further set of file cover sheets / dockets for GEB/1 volumes 4 to 17 [WITN6955039].
- 2.222. I am advised that in June 1995 an issue was noticed about certain ACVSB papers having been destroyed. I have been shown Dr Rejman's minute about volume 4. By June 1995, I had left DH to go on secondment to the NHS

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Ombudsman. I returned to the Department in around October 1995 to take up
a role in a different branch (HP3).

- 2.223. Linda Page's email said that the ACVSB files were lost post 1985. The destruction dockets to which the Inquiry has referred me said that GEB/1 volume 4 was closed and sent to the Departmental Records Office (DRO) Repository on 9 February 1993. The initials of the person who made the branch review decision are redacted in the version provided by the Inquiry. My advisers have referred me to an unredacted version; it looks to me like the initials are "JR".
- 2.224. I was in CA-OPU2 by the date of the branch review decision for volume 4. It is possible that the initials "JR" denoted John Rutherford. He worked under me from around early 1991 (he is listed as having attended an ACVSB meeting as part of the Secretariat in February 1991).
- 2.225. The docket for GEB/1 volume 4 is stamped with the destruction date as 29 September 1994 and the initials "LB". The destruction date "29.9.94" is handwritten on another docket for volume 4. The dockets for the other GEB/1 files suggest they were destroyed after September 1994 (in 1997/1998). By September 1994, I was out of DH and on secondment. As I have said, I did not return to DH until October 1995.
- 2.226. For this reason, I do not think I can assist the Inquiry with the circumstances in which the Department became aware that papers from the ACVSB had been destroyed, which documents were destroyed or their contents, the identity of the person who destroyed them or authorised their destruction, or any steps that were taken to recall ACVSB papers still held by the DRO prior to destruction and when the Department became aware that it had to collect relevant information for the HCV litigation in 1994.

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2.227. The Inquiry has also asked whether I was contacted or interviewed as part of the internal audit into the destruction of the ACVSB papers, which I understand resulted in the final report dated April 2000 [DHSC0046961\_071]. I have a very hazy recollection that at some point someone came to my room and said he was doing an audit into missing papers. I cannot now recall when this was or anything else about it. It may have been on an unrelated issue.

# Relationship between the ACVSB and the UK Advisory Committee on Transfusion Transmitted Diseases ("ACTTD")

- 2.228. The Inquiry asks me about the relationship between the ACVSB and the UK Advisory Committee on Transfusion Transmitted Diseases (ACTTD).
- 2.229. As I have explained, the ACVSB was a Departmental committee (in that it contained departmental representatives and was formulated with the express purpose of advising Ministers). I understand that the ACTTD was a NBTS body, chaired by the NBTS Director, Dr Gunson.
- 2.230. I am informed that the ACTTD met on ten occasions in the period between 1989 and 1991. I was not present at any of those meetings; I understand that my name does not appear in any of the minutes.
- 2.231. My knowledge about the function of the ACTTD is based on what I have ascertained from the documents provided to me.

#### Q57: Dr Metters' minute to Mike Malone-Lee, 19 February 1990

2.232. The Inquiry refers me to a minute dated 19 February 1990 from Dr Metters to Mike Malone-Lee (copied to me) [DHSC0002496\_104]. I assume that I was copied in because of my role on the ACVSB Secretariat.

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2.233. The minute referred to Dr Metters having raised the issue of the relationship between the ACVSB and the ACTTD at the Coordinating Committee. The minute said.

"I believe there is a real issue here as we cannot have two Committees attempting to advise on policies to be followed. The ACVSB was specifically set up to ensure that any new virological screening of blood and blood products should be introduced uniformly across the UK rather than piecemeal at the behest of a single RTC Director...Whatever their virtues and expertise, the RTC Directors on their own are not the experts to decide on some of the virological, immunological and other specialist areas that need to be considered before Ministers are advised on the introduction of new screening policies."

- 2.234. I am asked about the tensions, if any, between the ACVSB and the ACTTD. While I would not necessarily have known, I do not have any recollection of there being any tensions. Dr Metters' minute showed that he was concerned to maintain a clear demarcation between the work of the ACVSB and any other committees.
- 2.235. The Inquiry asks about lines of communication. Dr Gunson would have been the main conduit for the flow of information between the two groups. He chaired the ACTTD and sat on the ACVSB. The Inquiry asks whether the information sharing was sufficient. I did not have enough involvement with the ACTTD to be able to provide any meaningful comment.
- 2.236. I do not believe there were any overlapping areas of responsibility. The ACTTD was concerned, largely, with NBTS operational matters. However, as it was composed of Regional Transfusion Directors it would have been welcome to comment (via Dr Gunson, I presume) on screening policy matters which were under consideration by the ACVSB.
- 2.237. As I did not attend ACTTD meetings (and I do not recall being provided with copies of their minutes) I cannot comment on whether the ACTTD viewed the introduction of screening policies any more favourably than the ACVSB.

#### Q58: Dr Metters' letter to Dr Gunson, 24 April 1990

2.238. The Inquiry refers me to a letter dated 24 April 1990 from Dr Metters to Dr Gunson [DHSC0006906\_017]. It stated,

"The ACVSB was set up specifically to advise UK Ministers on the virological safety of blood. It brings together the range of expertise and the various parties which have an interest in policy formulation on this subject.

On the other hand, the Committee you chair on Transfusion Transmitted Diseases has a three-fold purpose, namely:

- to consider the operational implications of implementing policy in the UK BTS:
- to give advice to the Health Departments on the need for safeguards against transmission of non-viral diseases;
- to comment on viral aspects of the safety of blood and to pass their views to ACVSB for consideration."
- 2.239. This letter had been foreshadowed at the ACVSB's sixth meeting on 24 April 1990 [NHBT0000072\_098]. Dr Gunson replied to Dr Metters on 1 May 1990 [WITN7115025]. He assured Dr Metters that there was no need to fear that Dr Gunson's Committee could come into conflict with the ACVSB. Dr Metters replied further on 4 May 1990 and said, "I am satisfied that our exchange of correspondence settles satisfactorily the relationship between ACVSB and the UK Transfusion Transmitted Diseases Committee." [DHSC0002497\_074].
- 2.240. The Inquiry asks why the responsibilities of each Committee were not formalised earlier. The letters were not intended to "formalise" each Committee's role (that would have been a matter for the Terms of Reference), rather Dr Metters was concerned to make sure there was no confusion over the committee's respective roles.
- 2.241. The Inquiry asks me to comment on the statement at paragraph 5 of the 24 April 1990 letter, which said, "there was last year an episode where an RTC Director put in a bid for money for tests which had not yet been recommended

### FIRST WRITTEN STATEMENT OF JOHN CANAVAN Advisory Committee on the Virological Safety of Blood ("ACVSB" or "The Committee")

by the ACVSB for Ministers' decision". I do not recall this, and the documents do not shed any light on it, except that Dr Gunson's letter to Dr Metters dated 1 May 1990 noted as follows:

"The request that you received last year for a bid for tests that had not been recommended by ACVSB came from the initiative of an RTD without reference to me or to the U.K. Transfusion Transmitted Diseases Committee. Unfortunately, the management arrangements within the Transfusion Service preclude me from instructing the RTDs on particular courses of action, but I will endeavour to ensure that they are aware of the fact that ACVSB has ultimate responsibility for all decisions concerning the virological testing on blood." [WITN7115025]

# Section 3: Microbiological Safety of Blood for Tissues for Transplantation ("MSBT")

#### **Anti-HBc testing**

Q59: Advisory Committee on the MSBT's inaugural meeting, 4 October 1993

- 3.1. The Inquiry refers me to the inaugural meeting of the Advisory Committee on the MSBT, which was held on 4 October 1993 and reached "the unanimous view ... that Ministers should be advised that introduction of routine screening for anti-HBc in blood donations was inappropriate" [MHRA0020214]. The Inquiry also refers me to:
  - a) Minutes of the tenth meeting of the ACVSB on 21 May 1991 [NHBT0000042\_080] and the fifteenth meeting on 9 February 1993 [NHBT0000079\_087], at which the topic of routine screening of blood for anti-HBc was considered.
  - b) Minutes of the MSBT's second meeting on 10 February 1994 [DHSC0020691\_169].
  - c) Minutes of the MSBT's third meeting on 29 September 1994 [PRSE0003670], in which I was no longer listed as an attendee.
  - Draft submission from me to the then Parliamentary Under Secretary of State for Health, Tom Sackville, regarding "Routine Testing of Blood Donations (and Tissues/Organs) for Anti-HBc Antibody (Anti-HBc)" [DHSC0004020\_007] and its Annex [DHSC0002543\_017]. My advisers have identified that the final version as sent was dated 4 November 1993 and included an additional sentence at paragraph 5 [DHSC0004709\_147]. This amendment reflected Dr Metters' feedback in his minute dated 4 November 1993 [DHSC0004709\_149].

- 3.2. The Inquiry asks what the arguments for and against the introduction of anti-HBc testing were at that time (i.e., at 4 October 1993) and how the Committee's decision was reached.
- 3.3. First, I make some general observations about my role on the MBST. As Administrative Secretary, my role was substantially the same as for the ACVSB. The MSBT members included virologists, microbiologists, blood transfusion experts, fractionators and some transplant experts [WITN5249040]. The MSBT made decisions based on the various reports and evidence supplied by these and other experts. I would not have been involved in the substance of the scientific discussions or the formulation of its recommendations. I attended the first and second MSBT meetings, but did not attend any subsequent meetings.
- 3.4. Prior to the inaugural meeting of the MSBT, the question of anti-HBc testing of blood donors with a history of jaundice had previously been considered by the ACVSB. For example, the minutes of the tenth ACVSB meeting on 21 May 1991 recorded that Professor Zuckerman said that anti-HBc testing by ELISA was "not cost-effective because of poor specificity" and "the quality of anti HBc tests would have to be improved markedly before it would be worthwhile introducing routine screening for any group" [NHBT0000042\_080]. The Committee had agreed that "there was no case for routine anti-HBc testing of blood donors with a history of jaundice". Further, the minutes of the fifteenth ACVSB meeting on 9 February 1993 recorded that four RTCs were undertaking a trial to test the general donor population for anti-HBc, but that the final results of all trials "were not yet known" and that the Committee "would discuss the matter again" [NHBT0000079 087].
- 3.5. As far as I can recall (assisted by the documents), the main consideration for the introduction of anti-HBc testing was the possibility (albeit limited) of prevention of viral infection. There was also a concomitant public perception/relations consideration. As the minutes of the 4 October 1993 MSBT meeting recorded, "there was a growing perception among RTC Directors that

anti-HBc screening should be introduced because of the possibility of prevention of hepatitis infection" [MHRA0020214].

- 3.6. The main considerations against the introduction of anti-HBc testing were recorded in my 4 November 1993 submission, including the Annex, "Points considered important by the Expert Advisory Committee in giving its advice that routine screening for anti-HBc should not be introduced" [DHSC0004709\_147].
- 3.7. Within the submission, I summarised the "major considerations" as follows (original emphasis):

"The factors which the Committee considered to be important in reaching its review are set out in the Annex. The major considerations were

- i. major deficiencies in the tests (a high number of false positives, and lack of reliable confirmatory tests)
- ii. uncertainty over the benefits of the tests, set against the considerable costs, estimated at £3m annually, which could be put to better use. The introduction of testing might prevent a very small number of transfusion transmitted infections (probably nearer 10 than 100) but even in that small number half would have no clinical symptoms and the majority of the remainder would have no permanent effects. The Committee considered that the cost-benefit argument was strongly against routine testing."
- 3.8. Building on the above, the Annex recorded ten considerations that were considered important by MSBT [DHSC0002543\_017]:
  - a) lack of specificity of the tests (high number of false positives);
  - b) lack of reliable confirmatory tests to confirm the validity of the initial finding;
  - c) consequent difficulties in counselling donors;
  - the numbers of infected transfusions was unknown (but likely to be at the lower end of 10 to 100 and not all of these would be prevented by anti-HBc screening);

- e) the majority of those likely to be anti-HBc positive due to drug abuse are already detected by other tests;
- f) the recipients of 50% of blood transfused in a given year will die within the year of their underlying condition;
- g) even if a small number were given hepatitis infected blood, 50% of these would have no clinical symptoms at all, and the majority of the remainder would have no permanent effects;
- the considerable cost of testing (estimated at £3 million for the UK as a whole) should not be ignored;
- anti-HBc is not a requirement of the WHO, Counsel of Europe, or EC guidelines; and
- j) paradoxically, anti-HBc positive blood donors can make a beneficial contribution to the plasma pool from which blood products are fractionated (because: the majority of anti-HBc positive donors have a significant amount of anti-HBs and if the anti-HBs level is sufficient, are themselves not infectious; and donations which have this level of anti-HBs can neutralise any infectious donations in the plasma pool which have remained undetected).
- 3.9. The original record of the above points, as raised by various Committee members, were set out in the minutes of the MSBT meeting on 4 October 1993 [MHRA0020214].
- 3.10. The Committee reached its final, unanimous decision that "the introduction of routine screening for anti-HBc in blood donations was inappropriate" following discussion of the above points. As Dr Rejman noted in a letter to Dr George, the Welsh Deputy Chief Medical Officer, on 22 October 1993 (to which I was copied) [DHSC0004019\_012], "[t]he discussion on anti-HBc testing was

very thorough, and it was interesting to see that none of the members of the Committee felt that the introduction of this testing was justified".

- 3.11. I am then asked to explain why screening for anti-HBc was discussed periodically without a final decision and whether continued reassessment was appropriate.
- 3.12. Screening for anti-HBc was discussed periodically because there was a persistent and significant degree of uncertainty in relation to such screening in short, the information that was required to make a final, fully-informed decision was not available in the years leading up to October 1993.
- 3.13. The extent of the uncertainty and the need for such periodic assessment is illustrated by the minutes of various ACVSB meetings. For example:
  - a) At the ninth ACVSB meeting, held on 25 February 1991 (and at which I was not present), the minutes recorded that Dr Rejman observed that doubts had been raised about the value of anti-HBc testing and that "it was agreed that the Committee needed more information on the issues raised" [PRSE0002280].
  - b) At the fifteenth ACVSB meeting, held on 9 February 1993, the minutes record that "Dr Gunson said that the ACVSB had considered the case for testing donors with a history of jaundice for the presence of anti-HBc but there had been an insufficient case to justify the introduction of such testing", and that while four RTCs had now been undertaking a trial to test the general donor population for anti-HBc, the results of all trials were not yet known [NHBT0000079\_087].

- 3.14. While a unanimous decision was reached in October 1993 on the basis of the information available at that time, it was clear that subsequent developments would also require further assessment. Towards this, I note that:
  - a) In my submission dated 4 November 1993, I confirmed that the Committee had "agreed to review the position in light of any further relevant data which becomes available" [DHSC0004709 147];
  - b) The minute from the Private Secretary to Tom Sackville to me, Dr Metters and Dr Rejman dated 4 February 1994, mentioned in my statement below, referenced a meeting with Tom Sackville at which it was agreed "the situation [anti HBc testing] should be kept under review by the Advisory Committee" [DHSC0042296\_061]; and
  - c) On 10 February 1994, at the second meeting of the MBST, the minutes recorded that the Minister "wished to look at the matter again when the Committee could advise that a test with better specificity and information about a confirmatory test were available" [DHSC0020691\_169].
- 3.15. The Inquiry then draws my attention to the discussion regarding the cost-benefit ratio of introducing anti-HBc screening, as recorded in the minutes of the meeting on 4 October 1993 [MHRA0020214]. The minutes recorded that "[t]he Committee questioned whether the very substantial cost of removing the risk to very small numbers, estimated at around £3m, or between £15,000 or £20,000 per District, would be worthwhile, and thought that the BTS could use the money more effectively" [MHRA0020214].
- 3.16. I am asked to explain the extent to which cost was a consideration for the MSBT when formulating recommendations and whether I considered it to be the role of the MSBT to consider the financial implications of any advice to Ministers.

3.17. The role of the MSBT was:

"To advise the Health Departments of the UK on measures to ensure the microbiological safety of blood and tissues for transplantation.

In making recommendations in relation to blood, the Committee will bear in mind the need for maintaining an adequate supply of blood of appropriate quality for both immediate use and for plasma processing." (see proposed Terms of Reference annexed to submission dated 12 January 1993) [WITN7115026].

3.18. Further, my submission dated 13 January 1994 said,

"The Committee considers each suggested test under several headings:

- i. Morbidity and mortality
- ii. Incidence in the general population and donor population
- iii. Sensitivity of the test (number of false negatives)
- iv. Specificity (false positives)
- v. Confirmatory tests
- vi. Feasibility of use of tests
- vii. Costs" [DHSC0042296 065]
- 3.19. As part of the MSBT's role in advising Ministers on the introduction of new screening tests, there was no prohibition on the MSBT drawing the Ministers' attention to the financial costs involved. Indeed, it was important for the MSBT to highlight key financial implications, in so far as they could be identified, in its advice to Ministers. Ministers would take a particular course of action on scientific/medical grounds as well as an evaluation of the financial implications, which would fall to the DH to undertake on behalf of the Ministers.
- 3.20. Reflecting the above, the minutes of the 4 October 1993 meeting recorded that "[t]he Committee's advice was sought on the feasibility of introducing [routine screening of blood for anti-HBc] and the resource implications" [MHRA0020214].
- 3.21. As I explained in my submission dated 4 November 1993, the Committee also "suggested that the Department should consider further the cost benefit of

introducing new screening tests, where the available data shows there are minimal numbers of donors potentially at risk of transmitting infection, but the cost of universal screening of all donations would be totally disproportionate to the risk involved" [DHSC0004709\_147]. As set out at paragraph 3.1.d) above, this sentence was not included in the draft version of my submission cited by the Inquiry [DHSC0004020\_007].

# Q60: ACVSB and/or MSBT consideration of compensation via ex-gratia payments

- 3.22. The Inquiry refers me to:
  - a) Email dated 26 October 1993 from Dr Metters to me and Dr Rejman, in which Dr Metters noted that the MSBT's unanimous recommendation not to introduce anti-HBc screening of blood donations had entered into the public domain before Ministerial review [DHSC0020689\_011];
  - b) My response to Dr Metters dated 2 November 1993 in which I noted that the question of compensation by way of ex gratia payments had never been formally raised by the ACVSB or MSBT and that such payments "would sit uncomfortably with the Department's stated policy of resisting no fault compensation for medical accidents" [DHSC0020689\_006].
- 3.23. Within the latter, the Inquiry draws my attention to my suggestion that it would be better to show that the decision against the introduction of routine screening "stands on its own merits (the benefits are very uncertain whereas the cost is substantial). Linking the advice against testing with the suggestion of possible payments in the future might send the wrong message" [DHSC0020689\_006]. The Inquiry also refers me to the response from Dr Metters, dated 4 November 1993, in which Dr Metters stated that "[b]oth ACVSB and MSBT have discussed in outline the question of 'compensation', although as you say it has never formally been raised with the Committees by the Department" and "[w]hile I agree it would sit uncomfortably with the Treasury's policy of resisting no fault

compensation, I do not believe we can simply disregard what ACVSB and MSBT have said already" [DHSC0004709\_149].

- 3.24. First, I am asked whether the question of compensation by way of ex gratia payments was ever raised informally by the ACVSB or MSBT.
- 3.25. I do not recall the issue of ex gratia payments being raised informally during my time on the Secretariats of either of these two bodies, nor do I recall "the question of 'compensation'" being discussed "in outline" (per Dr Metters' reference above). In addition, I understand that the minutes of the ACVSB and MSBT prior to November 1993 made no reference to compensation for medical accidents.
- 3.26. Second, I am asked why I was concerned (in my 2 November 1993 letter to Dr Metters) that "[I]inking the advice against testing with possible ex gratia payments might send the wrong message". As best as I can recall, I was concerned that linking the advice and possible payments might be seen as a step towards no-fault compensation, which I was aware that the Ministers were firmly against.
- 3.27. I am supported in this recollection by the email from Dr Metters on 4 November 1993 [DHSC0004709\_149], referred to already, and a further email to Dr Rejman and me on 8 November 1993 [DHSC0042296\_119], both of which indicated that my concern was also understood in this manner. In the former, Dr Metters "agree[d] it would sit uncomfortably with the Treasury's policy of resisting no fault compensation" [DHSC0004709\_149]. In the latter, Dr Metters stated [DHSC0042296\_119]:

"It has been suggested this discussion [of ex gratia payments] would reopen the question of 'no-fault compensation' on which the Government has a firm policy. This is not correct. If a decision was reached not to introduce an effective screening test simply because the infection in question was so rare and the cost of universal screening was so great, issues of non-negligent harm do not arise. Instead where a negative

decision was to be made on grounds of cost-effectiveness alone ... it would have to be clear that proper arrangements were in place to compensate any blood recipients who suffered consequential harm."

#### Q61: Submission on screening for rare viral infections, 18 January 1994

- 3.28. The Inquiry refers me to a submission that I drafted with Dr Rejman on 13 January 1994 seeking Ministerial views on, "the principle of whether an effective screening test for a very rare transmissible infection, including for anti-HBc, should be introduced just because it is available, even when the cost of general introduction throughout the blood service would cost millions of pounds a year", and whether ex gratia compensation should be considered as an alternative [DHSC0042296\_065]. My advisers have identified a later version of the submission, dated 18 January 1994 [WITN5249040]. I note that a number of contemporaneous documents refer to the version dated 18 January 1994 (see below at paragraphs 3.43 and 3.45), which I assume was the final version as sent.
- 3.29. The relevant submission was sent to Dr Metters and Tom Sackville. It was entitled "The Biological Safety of Blood: Screening for Rare Viral Infections".
- 3.30. First, I am asked to explain what prompted me and Dr Rejman to prepare a submission regarding the cases for and against special ex gratia payment arrangements.
- 3.31. I have been shown an email sent from Dr Metters to Dr Rejman and me on 8 November 1993, which appears to have been the direct prompt for our submission [DHSC0042296\_119]. Within the letter, Dr Metters observed,

"Now the submission conveying MSBT's recommendation against the introduction of Anti-HBc screening has gone forward, we need to follow-up the Committee's further question of principle regarding the cost-effectiveness of introducing screening tests for very rare infections."

- 3.32. Within this, Dr Metters noted that, "[f]or such rare infections transmissible through blood transfusion, would it not be more cost-effective to provide exgratia compensation for any blood recipient whose infection was demonstrably the result of transfusion?" and that, "[w]hile this argument had no influence on MBST's recommendation on anti-HBc screening, the question will inevitably recur at future meetings of the Committee". He furthered noted that, "Ministers are already alert to the public and political sensitivity of ensuring a safe blood supply", but questioned: "does 'safe' mean that every effective test must be performed no matter how expensive and how few donors will be deterred as a result" [DHSC0042296\_119].
- 3.33. In light of the above, Dr Metters continued (emphasis added): "That a submission on this tricky subject is now needed, you have only to look at the current demand for HIV tests in Germany, and the earlier Court cases in France". He added, "we need a steer from Ministers before MSBT are driven to consider the introduction of a new screening test simply on the basis of its cost-effectiveness" and concluded with the request (emphasis added), "[w]ould you please prepare a first draft" [DHSC0042296\_119].
- 3.34. Second, I am asked to explain my view at the time on whether ex gratia payment arrangements should have been introduced instead of introducing further screening tests.
- 3.35. I do not recall my views (if any) at the relevant time. To assist Ministers, the submission set out, inter alia, the "present position on compensation" and an overview of the "case for and against special ex gratia payment arrangements" [DHSC0042296\_065].
- 3.36. Third, the Inquiry refers me to paragraph 20 of the submission (in which Dr Rejman and I noted that "blood transfusion is inherently unsafe") and asks me to explain why I held this view.

- 3.37. The simple answer is that I understood that any medical intervention carried a degree of risk and, in the specific case of blood, the virus risks had been clearly highlighted by, inter alia, HIV.
- 3.38. Fourth, the Inquiry refers me once again to paragraph 20 of the submission (in which Dr Rejman and I stated that "[n]o matter how many how many tests are applied, transmission of infection will occur and this is something that the public and the media seem to have difficulty in understanding") and asks me to explain what consideration (if any) was given by me and/or others within the DH to providing education, advice and/or information to overcome this "difficulty in understanding".
- 3.39. I do not recall any such consideration, whether by me or others within the DH. Reflecting on this suggestion now, however, I suppose that a public campaign directed as transfusion recipients would have carried the risk of putting patients off what may have been life-or-death treatment in some circumstances. The Department would also have legitimately expected the treating clinicians to advise their patients on the risks of transfusion.
- 3.40. Finally, I am asked about the response to the submission, and am referred to [DHSC0042296\_063], [DHSC0042296\_061], and [DHSC0042296\_060] (set out below) for this purpose.
- 3.41. On 26 January 1994, the CMO, Dr Kenneth Calman, minuted the Private Secretary to Tom Sackville (copied to me). Dr Calman observed that the submission "sets out clearly the difficult issues involved in this area" and that "[t]he balance between sensitivity of the test, effects of the resulting disease and costs clearly must be considered" [DHSC0042296\_063]. Dr Calman continued:

"I agree with the Perm Sec that a decision not to introduce screening solely on the grounds of cost is not acceptable, unless for the very rare case and should then be supported by suitable compensation arrangements. In addition, the public and the profession should be aware of the 'ordinary' risks inherent in blood transfusion, which are much more commonly the cause of morbidity."

- 3.42. Dr Calman noted that, "[b]efore proceeding further, if Ministers agree, more work on cost benefits is needed".
- 3.43. On 4 February 1994, the Private Secretary to Tom Sackville minuted Dr Metters, Dr Rejman, and I. He "record[ed] the points agreed by PS(H) at the meeting last week to discuss the submissions of 18 January and 4 November" [DHSC0042296\_061]. In relation to the issue of ex gratia payments, he said that he "did not approve the principle of ex-gratia payments as set out in the 18 January submission" and "understood that this line could be defended on the grounds that the test in question were not yet scientifically robust enough to be introduced". He said further that, "the position would be reviewed by Ministers if the tests were developed to such a point that routine testing by NBTS was viable" [DHSC0042296\_061].
- 3.44. The "upshot" of the minute was that "no further work is needed on this by DH at present except to ask the Advisory Committee to keep the situation under review" [DHSC0042296\_061].
- 3.45. On 14 February 1994, Mr Mogford, Private Secretary to the then Secretary of State for Health, Virginia Bottomley, sent me a Note in which he confirmed that the Secretary of State had seen the submission of 18 January 1994, the CMO's minute of 26 January 1994, and Tom Sackville's minute of 4 February 1994. Mr Mogford advised that the Secretary of State, "noted with approval the Perm Sec's comments that it would be difficult not to institute on a routine basis tests to screen out infected blood unless the cost benefit ratio was very poor indeed" and also "agree[d] that a decision not to introduce screening on the cost ground"

needs to be complemented by generous compensation to any victims" [DHSC0042296\_060].

#### Section 4: HIV Haemophilia Litigation

#### Q62: Role in the HIV Haemophilia Litigation

- 4.1. I have been asked to explain my involvement in the HIV litigation, to the best of my recollection and in overview terms.
- 4.2. The Inquiry has drawn my attention to a large number of documents in this respect, which I have read and briefly summarise in this section.
- 4.3. [MHRA0017673] is a minute dated 16 March 1989 from me to Charles Dobson and Graham Hart, Director of Operations (Grade 2) of the National Health Service Management Board Operations Group, which suggested that at that time, insufficient information was available to the Department to say what the Department's line of defence would be in the HIV litigation or to assess its strength.
- 4.4. [DHSC0004776\_039] is a submission dated 15 June 1989 from Charles Dobson to Strachan Heppell, who was the Health and Personal Social Services Group Grade 2 lead, and the Parliamentary Under Secretary of State for Health (at that time Roger Freeman), that provided information on the litigation and sought ministerial views on handling. I appeared on the (extensive) copy list for this submission, along with other administrative, medical, and legal colleagues.
- 4.5. [DHSC0003849\_113] is a draft of the 15 June 1989 submission referred to above. As I was a copy recipient, it is unclear whether I would have seen any such drafts. There was a long list of copy recipients for this submission, and I believe I was the most junior official on the copy list.

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- 4.6. [MHRA0017681] is a submission dated 26 June 1989 from Charles Dobson to the Minister of State for Health (at that time David Mellor), that provided information on the litigation and sought ministerial views on handling. The contents of this submission were similar, but not identical, to the 15 June 1989 submission. I appeared on the copy list for this submission, along with other administrative, medical, and legal colleagues.
- 4.7. [DHSC0043529] is a submission dated 26 June 1989 from David Hagger, a Grade 5 civil servant in Branch MB1 in the Department, to David Mellor, stated to "complement" the submission from Charles Dobson of the same date. It dealt specifically with the litigation in light of the Ministers' role as the Licensing Authority for human medicinal products. I appeared on the copy list for this submission, along with other administrative, medical, and legal colleagues.
- 4.8. [DHSC0003849\_099] is a handwritten minute dated 27 June 1989 from Mike Arthur to me and Ronald Powell, a departmental solicitor, which discussed the litigation and referenced a recent meeting with counsel.
- 4.9. [DHSC0006272\_047] is a minute dated 28 June 1989 from Ronald Powell to me, which informed me of the likelihood that a number of writs would be likely to be served on the Secretary of State in the coming months. It also asked specifically whether I wished to be informed of every case in which a writ was served.
- 4.10. [DHSC0006481\_030] is a handwritten minute dated 19 July 1989 from me to Ronald Powell. It was stated to contain "our combined comments on the Plaintiff's Opening and Summons". From context (the copy list) I surmise that the comments came from myself, Charles Dobson, Dr Rejman, and Richard Gutowski.

- 4.11. [DHSC0006481\_003] is a minute dated 31 July 1989 from Ronald Powell to me, that dealt with co-ordination within the litigation between the Department and the Regional Health Authorities.
- 4.12. [DHSC0006401\_072] is a minute dated 7 August 1989 from Mike Arthur (HS1A) to me and Janet Walden, who worked in the AIDS Unit within the Department. It sought the views of the AIDS Unit on the Main Statement of Claim, in particular views on the categories of Plaintiffs.
- 4.13. [DHSC0006275\_030] is a minute dated 10 August 1989 from me to Jane Wheeler (FA2), which requested a search for certain records relating to the funding of the CBLA and the Regional Transfusion Centres for the purposes of future document discovery in the HIV litigation.
- 4.14. [DHSC0002471\_067] is a minute dated 14 August 1989 from Mike Arthur, addressed to me and Baroness Hooper's Private Office. It dealt with a number of matters in relation to the litigation, including a draft response to the Haemophilia Society, some preliminary hearings, and an article in the Sunday Times.
- 4.15. [MHRA0017687] is a minute dated 23 August 1989 from Dr Rejman to the Chief Medical Officer (at that time Sir Donald Acheson), that contained briefing materials for the CMO's meeting with David Mellor. I appeared on the copy list alongside other administrative, medical, and legal colleagues.
- 4.16. [DHSC0046937\_111] is a minute dated 29 August 1989 from Ronald Powell to me, that covered correspondence from Plaintiffs' solicitors, and noted a potential conflict of interest between the Welsh health authorities and the Welsh Office.

- 4.17. [DHSC0041034\_021] is a minute dated 16 October 1989 from Charles Dobson to administrative, medical, and legal colleagues, including me. It requested options which could be offered to Ministers if they were minded to be more responsive to the haemophiliacs' case.
- 4.18. [DHSC0041034\_009] is a minute dated 23 October 1989 from David Mellor's Assistant Private Secretary, to the Secretary of State for Health (then Ken Clarke). I was a copy recipient along with other administrative, medical, and legal colleagues. The minute asked the Secretary of State to consider some papers (which are not attached to the version of the minute which has been shown to me by the Inquiry).
- 4.19. [DHSC0006279\_004] is a minute dated 26 October 1989, from Ronald Powell to Mike Arthur. I was one of a number of copy recipients. The minute dealt with legal advice that was provided by counsel and departmental solicitors.
- 4.20. [DHSC0006271\_035] is a minute dated 15 November 1989 from Peter Brand, a departmental solicitor, to me. It sought my comments on a proposed approach by the Under Secretary of State for Health (then Roger Freeman) when answering questions on the HIV litigation.
- 4.21. [DHSC0046948\_041] is a submission dated 18 December 1989 from Clive Wilson, of the MCA, to the Minister of State for Health (then Virginia Bottomley) and Charles Dobson that sought a decision on certain procedural issues within the litigation. I was a copy recipient along with administrative, medical, and legal colleagues. It was also copied to Ken Clarke.
- 4.22. [DHSC0004415\_045] is a submission dated 3 January 1990, from Ken Clarke's Private Secretary to Virginia Bottomley's Private Secretary. It referred to the submission of 18 December 1989, and informed the Minister that the Secretary

of State agreed with the conclusions in that submission. I was a copy recipient along with administrative, medical, and legal colleagues.

- 4.23. [DHSC0012688] is a note dated 4 January 1990, which described a telephone conversation which took place on 3 January 1990, between myself and another person, who wrote the note. The telephone conversation concerned the North West Thames Regional Health Authority. I cannot now tell who the author of the note would have been, nor do I recall the conversation, but from context it appears likely to have been with a Departmental lawyer.
- 4.24. [DHSC0003657\_102] is a submission dated 11 January 1990 from Charles Dobson to Ken Clarke that provided an update on progress towards settlement of the litigation. I was a copy recipient along with administrative, medical, and legal colleagues.
- 4.25. [DHSC0044876] is a minute dated 18 January 1990 from Dr Rejman to me that provided a summary of discussions at a conference with counsel on 17 January 1990.
- 4.26. [DHSC0046948\_010] is a minute dated 22 January 1990 from me to Ronald Powell, that sought his views on some issues that arose from the conference with counsel on 17 January 1990 about North West Thames acting as agents for DH in relation to BPL/CBLA.
- 4.27. [MHRA0017634] is a note of a discussion dated 26 January 1990. The note records that Dr Rejman, myself, and Peter Brand participated in the discussion, as well as the author of the note. The discussion related to the potential identity of persons who might have been able to give evidence on the Department's behalf. I cannot now tell who the author of the note would have been, nor do I recall the conversation.

- 4.28. [DHSC0003674\_010] is a minute dated 31 January 1990 from Dr Rejman to Dr Pickles, a Principal Medical Officer in the Department, which gave a note on a court hearing which took place on 22 January 1990.
- 4.29. [DHSC0045270] is a fax dated 1 March 1990 from Dr Rejman. The covering note suggests it was sent to Peter Brand but it is clear that the minute contained within the fax was addressed to Jayant Desai, in the Treasury Solicitor's Department. The minute dealt with comments upon the Defence of the Department in the litigation. I was not copied into this minute but it purported to incorporate my comments, along with those of Charles Dobson, Peter Brand, and those of Dr Rejman. It cannot be ascertained from the minute who made which comments contained therein.
- 4.30. [DHSC0046942\_036] is a minute dated 18 April 1990 from David Burrage, an HEO in the Department, to me (with Dr Rejman copied), that dealt with the identification of stored samples which could be tested for HIV in the context of the potential scale of the HIV litigation.
- 4.31. [DHSC0038699\_055] is a minute dated 3 May 1990 from Dr Rejman to David Burrage, that responded to his minute dated 18 April 1990 on the issue of stored samples.
- 4.32. [DHSC0038699\_048] is a minute dated 14 May 1990 from Dr Rejman to me, that enclosed a note and provided an update in respect of a court hearing which took place on 8 May 1990. I have been shown a copy of the note enclosed with Dr Rejman's minute, which provided a more detailed account of the same court hearing [DHSC0038699\_049].

- 4.33. [DHSC0038699\_037] is a minute dated 15 May 1990 from me to legal, medical and administrative colleagues which confirmed a meeting on litigation issues on the 17 May 1990 and suggested an agenda.
- 4.34. [DHSC0038699\_023] is a submission dated 30 May 1990 from me to Virginia Bottomley, copied to Ken Clarke, the Parliamentary Under Secretary of State for Health (Lords) (then Baroness Hooper), and administrative, medical, and legal colleagues. The submission sought ministerial views on whether the Central Defendants should plead the defence that the haemophiliacs' action for damages was out of time.
- 4.35. [DHSC0012680] is a minute dated 31 May 1990 from me to Ronald Powell about the division of responsibility (and associated costs sharing) for the Blood Products Laboratory in the litigation between the Department and the North West Thames Regional Health Authority.
- 4.36. [BPLL0010879] is a fax dated 11 June 1990 from Sue Chapman, who was an employee of the Central Blood Laboratories Authority, to me. The fax attached a response to a Parliamentary Question, which confirmed that the earliest known seroconversion to HIV attributable to a BPL factor VIII or factor IX concentrate was in January 1985.
- 4.37. [DHSC0044287\_217] is a draft submission dated 16 July 1990 from Charles Dobson to Virginia Bottomley and Ken Clarke, which invited Ministers to review the tactics in the litigation in the light of Mr Justice Ognall's comments, counsel's advice, and a submission from RMOs critical of the Government's stance. The submission looks to have been copied to Baroness Hooper, Sir Donald Acheson, and a list of medical, legal, and administrative colleagues, including myself, however the version of the submission provided by the Inquiry is in draft form.

- 4.38. [DHSC0043017] is a minute dated 23 August 1990 from Dr Rejman to Jayant Desai, that dealt with proposed lead cases within the litigation. I am a copy recipient along with other administrative, medical, and legal colleagues.
- 4.39. [DHSC0044139\_045] is a minute dated 3 September 1990, from me to a number of administrative, medical, and legal colleagues. It enclosed two draft letters on litigation issues based upon drafts provided by counsel, and requested comments before they are passed to the Law Officers' Secretariat.
- 4.40. [DHSC0043124] is a minute dated 7 September 1990 from me to Ronald Powell, that sought the views of the Law Officers' Secretariat upon attached draft letters.
- 4.41. [BNOR0000386] is a note providing a line to take on the Prime Minister's statement in the House on 16 October 1990 about future available funding for the Macfarlane Trust. The final page of this document is a minute dated 31 October 1990 from David Burrage to Ronald Powell, which asked for comments on the line to take. It was marked for me "to see", from which I understand that I was not expected to respond or input into the draft, unless I had any particular comment I wished to make.
- 4.42. [DHSC0046936\_019] is a minute dated 23 October 1990 from Dr Rejman to me, which provided some information in respect of the numbers of people in various categories within the litigation.
- 4.43. [DHSC0038657\_111] is a submission dated 24 October 1990 from me to Ken Clarke, which responded to a query about no fault compensation schemes in Sweden and New Zealand.

- 4.44. [DHSC0003110\_007] is a minute dated 26 October 1990 from me to Strachan Heppell, which provided information about the potential obstacles to using the existing MacFarlane Trust to pay any settlement. It invited Ronald Powell to comment on the legal element of the issue.
- 4.45. [DHSC0046962\_367] is a minute dated 7 November 1990 from Richard Gutowski (in the MCA Litigation Unit) to Roy Alder, Dr Wood, and Dr Jefferys. It provided an update on the litigation in light of the potential change of policy due to the incoming new Secretary of State for Health (William Waldegrave). I was one of a number of copy recipients.
- 4.46. [DHSC0014940\_006] is an action note arising from a meeting on 20 November 1990, on a number of issues relating to the litigation. The majority of action points appear to have been for medical and legal colleagues.
- 4.47. [DHSC0014940\_005] is a collection of documents with an apparent date of around 22 November 1990 (judging by a minute which appears within the collection with that date). It provided information on the costs of disregarding payments to haemophiliacs infected with HIV for the purposes of social security benefits, and a summary of the Plaintiffs' main allegations. The final document in the collection is a minute dated 22 November 1990 from David Burrage to a number of legal, medical, and administrative colleagues, including myself. It is not clear that the minute is related to the documents which precede it.
- 4.48. [DHSC0003655\_028] is a submission dated 17 December 1990 from Charles Dobson to the Secretary of State (then William Waldegrave), which provided an update on settlement proposals following a meeting with junior counsel. I was one of a number of copy recipients.

- 4.49. [DHSC0004523\_114] is a submission dated 18 December 1990 from Charles Dobson to William Waldegrave, that reported on a meeting with the Regional Health Authorities and invited Ministers to consider some proposals made by counsel. I was one of a number of copy recipients.
- 4.50. [DHSC0003655\_018] is a response dated 19 December 1990 from William Waldegrave to Charles Dobson's submissions of the 17 and 18 December 1990. The copy recipient list mirrors that of the 18 December submission, including myself.
- 4.51. [DHSC0003655\_003] is a submission dated 20 December 1990 from Charles Dobson to William Waldegrave that concerned the health authorities' proposal to split clinical management cases into three categories. I was one of a number of copy recipients.
- 4.52. [DHSC0003656\_075] is a minute dated 21 December 1990 from Charles Dobson to Mr Kendall (Grade 5, FA2), which provided some information about issues in relation to the settlement of the clinical management cases in the litigation. I was one of a number of copy recipients.
- 4.53. [DHSC0020866\_016] is a response dated 3 January 1991 from William Waldegrave to Charles Dobson's submission dated 20 December 1990. I was one of a number of copy recipients.
- 4.54. [DHSC0004523\_108] is a document dated 31 January 1991, which provided an analysis of the position in relation to the clinical negligence cases at that time. I believe this to be the annex referred to in Charles Dobson's submission of 6 February 1991, in respect of which I was one of a number of copy recipients.

- 4.55. [DHSC0004523\_107] is a submission dated 6 February 1991 from Charles Dobson to William Waldegrave, which considered possible options for the Department of Health and health authorities to take in order to resolve the clinical negligence cases. I was one of a number of copy recipients.
- 4.56. [DHSC0003658\_078] is a response dated 11 February 1991 from William Waldegrave to Charles Dobson's submission of 6 February, that endorsed one of the options suggested in that submission. The copy list mirrors that of the 6 February submission, which included myself.
- 4.57. [DHSC0002432\_018] is a letter dated 13 February 1991 from Charles Dobson to the Regional General Manager of the South East Thames Regional Health Authority, that communicated William Waldegrave's decision in relation to the clinical negligence cases and asked for details of cases to determine costs sharing. It is not clear from the face of this document whether I would have seen it, or had any involvement in its creation.
- 4.58. I have no recollection now of the vast majority of these documents, even those that were drafted by me. In the absence of any actual recollection, I am only able to comment on them by reviewing them now and effectively re-constructing what the thinking may have been. In many of these documents provided to me by the Inquiry I was named as one of a large number of copy recipients alongside a combination of ministerial, administrative, medical and/or legal colleagues, mostly senior to me.
- 4.59. My involvement in the HIV litigation was largely in relation to policy issues arising from it, as well as assisting with the responses to the Parliamentary and public campaigns for early settlement. Also, the section in which I worked took the lead on discovery of documents.

- 4.60. My section was led by my Branch Head, Charles Dobson, to whom I reported. I have provided my recollections of Charles Dobson within the opening section of this statement. I was a Principal (or a "Grade 7"), which was not a very senior official.
- 4.61. I was assisted by David Burrage, an HEO in the Department, who managed the document discovery process in the HIV litigation. I had general oversight of his work, as his manager, would take an interest in deadlines etc being met. Because some of the issues raised, in particular in relation to the claim for public interest immunity, required a policy view, I would have been available to check individual documents. I also would have checked he had the necessary resource (for example I brought in a temporary assistant during a busy period). David Burrage himself would have had a direct line to departmental lawyers.
- 4.62. We worked very closely throughout the HIV litigation with Dr Rejman, on the medical side, and Ronald Powell, who was a senior departmental solicitor.
- 4.63. The Inquiry has asked about my role in decision-making within the HIV litigation and my role in providing advice to Ministers and to more senior civil servants about the HIV litigation. The political sensitivity of the litigation was such that I would not be making decisions on major points. The actual advice which would go to Ministers and more senior civil servants would come from officials more senior than me, as well as from subject matter experts such as counsel and medical professionals. I would sometimes have a role in obtaining and collating those views in order to present a single piece of departmental advice to Ministers, but the advice being provided would not be advice that I myself was giving. My role was to set out the points from those with an interest upon which more senior officials and Ministers had to make decisions.
- 4.64. An example of this is that on 30 May 1990 I sent a submission to Virginia Bottomley (the Minister of State for Health), copied to Ken Clarke (the Secretary

of State), Baroness Hooper (the Parliamentary Under Secretary of State for Health (Lords)), and administrative, medical, and legal colleagues [DHSC0038699 023]. The submission sought a ministerial decision on whether the Central Defendants should plead the defence that the haemophiliacs' action for damages was out of time. The contents of the submission and the recommendation that was given at the end of this submission, that Ministers should follow option (ii) and instruct counsel not to plead the limitation defence, was not my own personal advice to Ministers. In this instance, I obtained and collated the views of counsel as well as departmental policy and medical colleagues in order to present a single piece of departmental advice to Ministers. This is illustrated by the chain of correspondence that preceded my final submission to Ministers on this issue: Ronald Powell's minute to me dated 11 May 1990 [DHSC0038699 045]; Dr Reiman's minute to Dr Pickles dated 14 May 1990 [DHSC0038699\_044]; Alan Barton's (AIDS Unit) minute to me dated 16 May 1990 [DHSC0038699 036]; Dr Pickles' minute to Dr Rejman dated 21 May 1990 [DHSC0038699 032]; and my minute to DH colleagues dated 22 May 1990 [DHSCD0046957 117]. This correspondence is explored further below in my statement, however I refer to it here in order to illustrate the administrative role that I played within the context of decision-making during the HIV litigation and providing advice to Ministers and more senior civil servants on the same.

4.65. In terms of instructing counsel for the Central Defendants in the HIV litigation, the instructions themselves would have come from the solicitors. I have been shown a copy of the instructions sent to counsel on 7 September 1989 by Jayant Desai, in the Treasury Solicitor's Department [WITN7115027]. It is possible that, at various stages, solicitor colleagues would have checked any relevant policy points with Charles Dobson or myself, but we would not have drafted the instructions. I did attend a few conferences with counsel, this would have mainly been to provide any clarification or additional background information which they may have required.

#### Q63: The Central Defendants in the HIV litigation

- 4.66. When working on the HIV litigation I was working for and on behalf of the Department of Health. I was not working on behalf of the Licensing Authority or the Committee on the Safety of Medicines (the other Central Defendants in the HIV litigation).
- 4.67. Whenever a submission on policy or other important issue such as litigation was in preparation for Ministers, lead branch on the policy subject would routinely circulate a draft for comments from other interested parts of the Department. Different parties looked out for their own interests and would ensure that their views were captured and delivered to Ministers. An example of this was the Licensing Authority deciding to put up its own submission as it disagreed with the departmental position on reliance upon limitation. The Central Defendants closely followed each other's draft submissions in order to take a similar approach to the same issues or bring out any differences of view which needed to be resolved, for example by meetings between officials or circulation of a further draft. Wherever possible advice to Ministers would contain a consensus view, otherwise parties could put up their own submission.
- 4.68. Ultimately, it was for Ministers to decide the strategic direction to be taken by all three Central Defendants in the HIV litigation, so in that sense they were working in concert. However, the three Central Defendants had different issues to respond to within the litigation, so where the need arose, individual submissions would be put up on discrete issues. I was not aware of any tension or conflict between the three Central Defendants in the HIV litigation nor would it have fallen within the scope of my role as Principal to manage any such tension or conflict.

#### Q64: Involvement of the Welsh Office in the HIV litigation

- 4.69. The Inquiry has asked me to set out, in my experience, how much influence the Welsh Office had over the conduct of the litigation. I am not personally aware of how much influence the Welsh Office had in the conduct of the legal case.
- 4.70. The normal process would have been to copy the Welsh Office in on key submissions and other relevant papers, and I believe that our solicitors kept in touch with theirs.
- 4.71. For example, on 3 October 1990, Strachan Heppell wrote to Jayant Desai of the Treasury Solicitor's Department, to communicate the Secretary of State's decision on how to respond to the comments made by Mr Justice Ognall on 26 June 1990 [DHSC0046936\_091]. I can see that included in the copy recipient list was M Jones in the Welsh Office.
- 4.72. Another example I can see from the documents provided to me by the Inquiry is that on 8 October 1990, I wrote a minute to Ronald Powell, setting out the Secretary of State's approval of a draft letter to the Plaintiffs' solicitors on the recovery of costs in the HIV litigation [DHSC0020866\_116]. Among the copy recipients of that minute was M Jones in the Welsh Office.
- 4.73. I have reviewed the transcript of the oral evidence given to the Inquiry by Justin Fenwick QC [INQY1000213]. In particular in relation to this issue I have looked at pages 192 and 193 of the transcript, where Mr Fenwick was asked questions (which are stated to have been raised by Core Participants) about the Welsh Office. Counsel to the Inquiry stated that "[documents] which we didn't provide you with indicate that the Treasury Solicitor was acting not only for the Department of Health but also for the Welsh Office in respect of claimants who had been infected in Wales". Mr Fenwick was then asked whether he recalls whether there was any significance to the fact that the Welsh Office were also part of the litigation. He responds:

"No, I don't. I mean I think that, very often, Wales is treated the same as England, whereas Scotland is not, because of the way devolution was working in 1990. There were, of course, a number of other defendants, and I can't now remember who they are, but looking at the — some of the documents. Whether the Welsh Office were a separate defendant or whether it was dealt with - I don't know, but there was certainly nothing different in the way that I acted because of Wales, and I don't remember any Welsh-specific advice."

4.74. As far as I recall, the Plaintiffs' allegations against the Welsh Government were the same as those against the Department. The medical negligence claims against the Welsh Government would have been particular to Wales and a matter for them.

#### **Q65: Expert witnesses**

- 4.75. The Inquiry has asked me a number of questions in relation to the role that I played in finding expert witnesses on the Central Defendants' behalf in the HIV litigation.
- 4.76. In addressing these questions, the Inquiry has asked me to consider a number of documents, which I summarise below.
- 4.77. [DHSC0046937\_035] is a minute dated 11 October 1989 from Mike Arthur addressed to me and Ronald Powell, with Dr Rejman as a copy recipient. It provided a list of (potential) expert witnesses on a number of subjects relevant to the HIV litigation. It noted that some of the potential witnesses had already been approached by the regional health authorities, and suggested writing to everyone on the list of prospective expert witnesses at that time.
- 4.78. [DHSC0006271\_011] is a minute dated 17 November 1989 from Dr Rejman to Ronald Powell. I was one of a number of copy recipients. The minute updated Ronald Powell in respect of the position of one potential expert witness, Dr Roger Williams, and asked for confirmation as to whether the Department's

solicitors believed that it would be reasonable for him to act as an expert witness for the Department, given that he had attended a meeting with the Plaintiffs' solicitors. There is a handwritten note at the bottom of the minute, timed at 16.30 on 17 November 1989, which stated that the author had spoken with Peter Brand, a departmental solicitor, who believed it would be acceptable for Dr Williams to appear on behalf of the Department, but urgent confirmation (it is not immediately clear by whom) was sought.

- 4.79. [MHRA0025271] is a minute dated 17 April 1990 from Dr Rejman to Ronald Powell. I was one of a number of copy recipients. The minute provided an up to date list of the Department's expert witnesses at that time.
- 4.80. [MHRA0019894] is a minute dated 27 April 1990 from Dr Rejman to Ronald Powell that enclosed the preliminary report from Dr Perry. It noted that there were a few paragraphs in the report which were critical of the Central Defendants. I was one of a number of copy recipients.
- 4.81. [DHSC0038699\_065] is a minute dated 27 April 1990 from Dr Rejman to Roland Powell, that enclosed the preliminary report from Dr Williams. Dr Rejman suggested that the report erred on the side of being too supportive of the Central Defendants, and highlighted a number of points which may need factual amendment (presumably because he considered that they were factually inaccurate). I was one of a number of copy recipients.
- 4.82. [DHSC0038699\_004] is a minute dated 26 June 1990 from Dr Rejman to Ronald Powell, that enclosed the preliminary report from Dr Mayne, the Central Defendants' haemophilia expert. It was stated that the report was generally helpful to the Central Defendants' case, but pointed out that there were some criticisms of the Department of Health, which Dr Rejman suggested would be expected. I understand that it would be entirely usual for unhelpful or critical passages of an expert's report to be flagged to the solicitors for their attention.

I was one of a number of copy recipients. The preliminary report itself is also exhibited to my statement [CBLA0000072\_024].

- 4.83. On 27 June 1990, Keith Maybank in the AIDS Unit forwarded the report and Dr Rejman's covering minute to a number of Doctors [DHSC0038699\_003]. I cannot see any comments which were returned from that. In December 1990 a telephone call took place between Dr Mayne and Dr Rejman, where she was informed that she would not be required to give evidence (presumably due to the progression of the settlement). Dr Mayne wrote to Dr Rejman on 12 December 1990 summarising that phone call and indicating that she had done an additional ten hours of work "reading all the reports and making further notes regarding possible changes in my own report." [WITN7115028]. There is a further document from David Burrage to Jayant Desai about payment of Dr Mayne's fees [WITN7115029]. That document lists only 2 items for payment 51 hours for "preparation and report writing", and the additional ten hours as per her letter. I believe therefore that this was probably all of the work she undertook in this respect.
- 4.84. [INQY1000203] is the transcript of Dr Rejman's oral evidence to the Inquiry, dated 10 May 2022. The Inquiry has drawn my attention to pages 134 to 152 of that transcript. In this part of his oral evidence, Dr Rejman gave his understanding of how the search for experts was conducted, what the Department was looking for in an expert, and the Department's response to criticism within a preliminary report.
- 4.85. It is notable that with the exception of the minute of 11 October 1989 at the outset of the search for expert witnesses (where I was one of two addressees), none of the above documents listed me as anything other than a copy recipient, nor is it apparent I responded to or took any other action in consequence of any of these exchanges. Dr Rejman's oral evidence of 10 May 2022 mentioned a minute from me to him dated 15 August 1989 at the very beginning of the relevant section [DHSC0040903\_018]. I explore this correspondence below

however I was not mentioned again in connection with expert witnesses in this part of Dr Rejman's oral evidence.

- 4.86. My recollection is that I had very little involvement in finding expert witnesses to give evidence on the Central Defendants' behalf. As medical expertise was being sought, this search would have been conducted by those with medical knowledge. My recollection, and this is supported by the documents to which the Inquiry has referred me, is that Dr Rejman took the lead on this, along with Ronald Powell (who, as a departmental lawyer, was well placed to advise on what was required of an expert witness from a legal perspective).
- 4.87. The Inquiry has asked me to consider a minute which I sent to Dr Rejman on 15 August 1989 in relation to the search for expert witnesses in the HIV litigation [DHSC0040903 018]. In this minute I stated that:

"In a discussion Mr Arthur had with Mr Powell before his annual leave, SOL C3 asked again for names of expert witnesses for the defendants. We advised the difficult, if not impossible task of finding a Haemophilia Centre Director untouched by the litigation, and who could give independent testimony supportive of the Department's case."

- 4.88. Although I am the author of this minute, it appears to be a note of a discussion (and actions arising for Dr Rejman) following a conversation between Mike Arthur, Ronald Powell, and myself. Although I have no recollection of the discussion, it appears that the above passage was a summary of what "we" (which, from context, must have meant myself and Mike Arthur) advised Ronald Powell about the difficulties of finding experts in the HIV litigation. I cannot now tell whether the comment itself was made by me, or by Mike Arthur.
- 4.89. My recollection is that all that was meant by the above comment in my minute dated 15 August 1989 was that it might be difficult to find experts who were both willing and able to offer independent testimony in the HIV litigation. Haemophilia Centre Directors (who had the necessary expertise) might be defendants in individual cases brought by those infected, and even if they were

not involved in the litigation, they might be involved in treating patients who had been infected and so could be reluctant to risk compromising their relationships with them. An example of this is explored at pages 137 to 145 of the transcript of Dr Rejman's oral evidence at the Inquiry dated 10 May 2022 in relation to Professor Bloom [INQY1000203]. As pointed out in the transcript of Dr Rejman's oral evidence, Professor Bloom was Chair of the UKHCDO:

"at the most material time...and had been involved in attending the Subcommittee on Biologicals of the Committee on Safety of Medicines in July 1983, which had looked at question of whether to ban the import of concentrates."

4.90. On 27 July 1990, Dr Rejman sent a minute to Ronald Powell in respect of an expert witness report of Professor Bloom, the Health Authorities' expert regarding haemophilia treatment at that time [DHSC0004360\_114]. I was a copy recipient to this minute. Dr Rejman made the following observation about Professor Bloom's expert witness report in his minute:

"In general, the report is interesting to read and contains some important information. However, in certain parts it reads like a Defence of the actions of the Haemophilia Centre Directors and Professor Bloom in particular, rather than a dispassionate view of an independent expert witness."

- 4.91. This example illustrates the difficulties the Department had at the time in finding a Haemophilia Centre Director "untouched" by the events of the litigation that could give independent expert evidence to support the Department's case in the HIV litigation, which is what was meant by the above passage in my minute to Dr Rejman of 15 August 1989 [DHSC0040903 018].
- 4.92. As illustrated by the documents that the Inquiry has referred me to, I did not direct the search to find expert witnesses for the HIV litigation, and so I have no specific knowledge of whether the search was specifically directed at finding supportive experts. While I expect the Department would not have sought to instruct experts who had already been publicly significantly hostile or critical of the Department over the relevant issue, I believe our main interest was to find

witnesses who were genuinely expert in the requisite areas and who had the necessary independence to act as expert witnesses.

- 4.93. The Inquiry has asked whether, to the best of my knowledge, any experts were excluded from the search on the basis that it was known or thought that they might not be supportive of the Department's case. I was not involved in the search, but to the best of my knowledge no one was excluded from the search on the basis that they were unsupportive of the Department's case. Solicitors and counsel would ultimately have to look at the list of experts and be content that they could give an independent medical view, and were capable of covering the ground required.
- 4.94. The minute dated 27 April 1990, from Dr Rejman to Ronald Powell, in relation to Dr Williams, refers to the preliminary report as being "too supportive" of the Department [DHSC0038699 065]. Given this, it does not appear there was an emphasis on finding experts who would be uncritical of the Department, or supportive of the Department's case. The various minutes from Dr Rejman which dealt with the preliminary reports of various experts pointed out areas in which the expert was critical of the Department, but to the best of my knowledge those experts were not discounted on the basis of those criticisms. I understand that there was nothing unusual or objectionable about highlighting areas where expert witnesses were critical of the Department, for example in Dr Rejman's minute to Ronald Powell dated 27 April 1990 in respect of Dr Perry's preliminary report [MHRA0019894]. Experienced counsel were advising on the Department's case in the HIV litigation and, from the documents I have seen and to the best of my knowledge, experts were not excluded from the search on the basis that it was known or thought that they might not be supportive of the Department's case.
- 4.95. My minute to Dr Rejman dated 15 August 1989 also contained a list of the possible types of expert witnesses required by the Department in the HIV litigation and some suggested names [DHSC0040903\_018]. I do not recall

where the names of these potential experts came from. It is likely that they came from contact with colleagues around the Department. For example, the AIDS Unit would have known the names of the members of the Expert Advisory Group on AIDS. It appears from my minute dated 15 August 1989, to which the Inquiry has referred me, that Ronald Powell, Mike Arthur and myself put together a list of categories within which we might wish to identify an expert, along with any names which happened to be known to us, and thereafter tasked Dr Rejman with searching for appropriate experts within those categories. This is supported by the minute dated 17 April 1990 from Dr Rejman to Ronald Powell, to which I refer above, which showed Dr Rejman providing an up to date list of experts, which further suggests that he was responsible for the identification of the names of potential experts, presumably taking advice from colleagues as he thought necessary [MHRA0025271].

- 4.96. I do not know how the experts ultimately instructed were identified, I was not involved in that process. I believe the decision would have been taken by Dr Rejman, Ronald Powell, and counsel.
- 4.97. I do not recall having any concerns about how expert witnesses were identified or instructed, or about the way in which their reports were drafted. I was not involved in their instruction, and would not have had the necessary technical medical or legal knowledge to form a view on the accuracy or appropriateness of the expert reports, which were reviewed by Dr Rejman, Ronald Powell, and counsel.

#### Q66: Meeting with MS(H) and the CMO on 30 August 1989

4.98. I can see from a minute from Dr Rejman to Dr McInnes dated 23 August 1989, that on 30 August 1989 I attended a meeting with Sir Donald Acheson (CMO) and David Mellor (MS(H)) about the HIV litigation [MHRA0017687]. The minute indicates that I was one of a number of attendees for the meeting, which included my branch head, Charles Dobson, and Strachan Heppell.

- 4.99. The Inquiry has asked about the frequency with which I attended meetings with Ministers and the CMO to discuss the HIV litigation. I am unable to recall exactly, but I do not believe I would have attended all such meetings. This was particularly the case in the later stages of the litigation, when I would have had less of a role to play, and it would have been appropriate for more senior staff, such as Charles Dobson, to attend.
- 4.100. In terms of the selection of who was to attend these meetings, my understanding is that individuals were chosen because they could speak to a certain aspect of the work on the HIV litigation to be discussed at the meeting.
- 4.101. Dr Rejman's minute to Dr McInnes enclosed a briefing for the meeting on 30 August 1989. Within that briefing, there is a statement to the effect that the Haemophilia Society had been advised (2 to 3 years prior to the briefing in 1989) that claims in negligence were unlikely to be successful. I am unaware of how the Department came into possession of that information, and given the dates it appears likely that such knowledge pre-dated my time working in blood services in the Department.
- 4.102. I do not know the basis of the Department's reported belief that "negligence would be difficult to prove in most cases but that in some individual cases the particular circumstances would favour the Plaintiffs". I believe it probably would have come from counsel.
- 4.103. At that time, I do not recall Sir Donald Acheson, David Mellor, or any other Ministers expressing any particular concerns or raising any specific issues in relation to the litigation.

Q67: Departmental work to establish the facts of the HIV litigation by August 1989

- 4.104. At this stage in the HIV litigation, i.e. August 1989, the work which had been done within the Department to establish the facts surrounding the events that were in issue in the litigation would have involved examination of the discovery documents and official files to throw light on the issues raised by the litigation.
- 4.105. The same process would have applied to assessing whether there were acts, omissions or failings by the Central Defendants that caused or contributed to people becoming infected with HIV or hepatitis.
- 4.106. By that date, as the briefing note for the 30 August 1989 meeting with Sir Donald Acheson and David Mellor sets out, the Department had received a main statement of claim, but not individual statements of claim from individual Plaintiffs. The Department would have been able to see the allegations contained within the main statement of claim, and the Department could have reviewed its documentary holdings to ascertain whether those allegations were borne out.
- 4.107. The section I worked within would have been involved in this process. Various members of my section would have been involved. I cannot now recall the extent of my role specifically in this process.
- 4.108. Further work of this nature would have been undertaken in the months that followed, for example when new allegations were made. The process would have continued as the need arose.

#### Q68: October 1989 Ministerial review of options in the HIV litigation

- 4.109. The Inquiry has asked me a number of questions specifically about a sequence of events which occurred in October 1989 in relation to the approach to the HIV litigation.
- 4.110. In a minute dated 16 October 1989, which was sent to me and several others, Charles Dobson, my branch head, wrote that there were "growing signs that ministers are becoming increasingly uneasy at the current advice from officials that, on balance, the government should resist the claim of HIV-infected haemophiliacs and if necessary fight it out in court." Charles Dobson called for a review of what options could be presented to Ministers if they were "minded to be more responsive" [DHSC0006279 025].
- 4.111. Following on from this, under cover of a submission dated 26 October 1989, Charles Dobson provided a paper to David Mellor that set out various options, which he said had been prepared in consultation with medical and legal colleagues, with Medicines Division and with Finance [DHSC0002536\_078] (covering submission), [DHSC0002536\_079] (attached paper), [DHSC0007045 014] (Annex A).
- 4.112. The submission recorded that "Our advice...remains that ministers should continue with the litigation...".
- 4.113. In answering questions on this topic, the Inquiry has asked me to consider a number of documents, which I summarise below.
- 4.114. [MHRA0017687] is the minute from Dr Rejman to Dr McInnes that enclosed the briefing material for the 30 August 1989 meeting with Sir Donald Acheson and David Mellor, which is addressed in my statement, at paragraphs 4.98 to 4.103 above.

- 4.115. [DHSC0003315\_004] is a minute dated 5 September 1989 from Mike Arthur to myself and Strachan Heppell, copied to Dr Rejman. It attached a briefing note for a meeting with the Macfarlane Trust, which was scheduled for 7 September 1989 [DHSC0003318 006].
- 4.116. [DHSC0046937\_085] is a minute dated 13 September 1989 from Ronald Powell to me. It dealt with the difficulties in the setting up of the original Macfarlane Trust and suggested that these issues would be likely to arise again, if David Mellor was minded to make further funds available to haemophiliacs.
- 4.117. [DHSC0003511\_067] is a submission dated 14 September 1989 from Strachan Heppell to David Mellor. I was a copy recipient. The submission summarised a recent meeting between Strachan Heppell and the Macfarlane Trust. It enclosed a proposed draft letter which sought to address concerns which the Trust had about future funding [DHSC0003317\_001]. I believe I may have attended this meeting, and it is possible that I provided Strachan Heppell with the draft to be exchanged with the Haemophilia Society.
- 4.118. [DHSC0003511\_066] is a response dated 22 September 1989 from David Mellor to Strachan Heppell, that approved his draft letter which accompanied Strachan Heppell's submission dated 14 September 1989. It included an indication that the Minster would be "most sympathetic to the idea of increasing the fund in due course".
- 4.119. [DHSC0041034\_037] is an undated minute from Mike Arthur to Dr Pickles and others, which attached a draft submission dated 23 October 1989 [DHSC0041034\_038]. I was one of a number of copy recipients. The submission dealt with the current policy with regards to the HIV litigation at that

time. The draft submission contained a number of handwritten comments and I do not recognise them.

- 4.120. [DHSC0041034\_041] is a minute dated 23 October 1989 from me to a number of copy recipients. I note that the Inquiry has not been able to locate the draft which accompanied the minute, but from context I suspect it may have been a further draft of the submission on current policy in the HIV litigation which is described in the preceding paragraph. In the minute I stated that the new draft incorporated a paragraph (paragraph 9) on the cost of settlement of the litigation which was omitted from the earlier version. I believe that version to be [WITN7115030].
- 4.121. [DHSC0041034\_042] is a handwritten note dated 24 October from "John", that recorded a comment from Susan Leder requesting an amendment to the draft submission. The handwriting is mine, but the comment itself obviously comes from Susan Leder. Given the tight timeframes, comments were often provided over the telephone and so comments may not have been in the handwriting of the person who provided them.
- 4.122. [DHSC0004415\_156] is a submission dated 7 November 1989 from Strachan Heppell to Ken Clarke. I was one of a large number of copy recipients. The copy list included the Minister of State for Health (Virginia Bottomley), the Parliamentary Under Secretary of State for Health (Roger Freeman), the Parliamentary Under Secretary of State (Lords) (Baroness Hooper), the Permanent Secretary (Sir Christopher France), the Chief Medical Officer (Sir Donald Acheson), and the Deputy Chief Medical Officer (Dr Metters). The submission was stated to act as an agenda for a meeting the following day with Ken Clarke. It set out the aims of Virginia Bottomley, which in essence were to avoid the litigation proceeding further, to do so in such a way that would be acceptable to the public and (if possible) campaigners, and avoided setting any unacceptable precedent. This document is one which demonstrates the very

senior level at which discussions were being had and decisions being taken on the approach to the HIV litigation at this stage.

- 4.123. [DHSC0006485\_015] is a submission dated 17 November 1989 from Marian Stuart, a Finance Director in the Finance Division, to Ken Clarke, that provided some options for arranging for financial assistance for haemophiliacs infected with HIV by giving an additional grant to the Macfarlane Trust. I am one of a number of copy recipients. [DHSC0002949\_010], to which the Inquiry has also drawn my attention, appears to be a duplicate of that submission. The submission included details of possible cuts that may be required to fund an additional grant to the Macfarlane Trust including to wheelchair and AIDS services.
- 4.124. The Inquiry has asked me what role I played in the preparation of the papers sent with Charles Dobson's "email" (which I assume refers not to an email, but to the submission of 26 October 1989 referred to above [DHSC0002536\_078]).
- 4.125. I am unable to recall the specifics of my role in relation to the preparation of the papers which accompanied Charles Dobson's submission of 26 October 1989. My section was there to support Charles Dobson and would have responded to his requests for input where he thought it appropriate. As the documents to which the Inquiry has drawn my attention set out suggest, and as the submission itself states, views were also sought from medical and legal colleagues, from Medicines Division and from Finance. Those working in support of Charles Dobson, myself included, would have been responsible for collating those views into a coherent paper to present, so that the Minister was fully appraised of the options available. I cannot recall now specifically what my involvement was with this process on this occasion.
- 4.126. In terms of the division of responsibility between the various individuals and departmental divisions in providing the advice, who provided advice at any

given time would depend upon the subject matter, the nature of the advice sought, and the expertise required to provide it. The political sensitivity of the issue would also be relevant. In the later stages of the litigation, as things became more politically sensitive, any advice would have been likely to have come from the Branch Head or further up the hierarchy.

- 4.127. The Inquiry has also asked me about what my personal views were on the best approach to the litigation at that time. I do not recall what my views on the litigation may have been at that time, or even if I would have formed a specific view. As an experienced civil servant, any personal views I had on the matter would not have influenced my briefing, which would come from a departmental policy view point, rather than a personal one. Nor would any such views have influenced the conduct of the litigation, where decisions were made further up the hierarchy or by Ministers.
- 4.128. The Inquiry has also asked me to provide any further comment which I consider may assist the Inquiry on these documents and the issues referred to within them. Other than the details to which I have referred in my statement above, I confirm that I have no such further additions which might assist.

#### Q69: May 1990 submission on the limitation defence

- 4.129. In May 1990, I drafted a submission for Virginia Bottomley on whether or not the Central Defendants in the HIV litigation should plead the defence that the Plaintiffs' claim was out of time. [DHSC0046957\_111] is an undated draft version of that submission (probably the version circulated for comment with my minute dated 22 May 1990 [DHSC0046957\_117]). On 30 May 1990, I sent the final submission to Virginia Bottomley, copied to Ken Clarke, and Baroness Hooper [DHSC0038699\_023].
- 4.130. Although the Health Authorities and the CBLA had pleaded the limitation point in response to the individual statements of claim, the policy advice to Ministers

was that, on balance, the Department should not take the limitation point at all (option (ii)). The other options presented were to plead the limitation defence in every case where it was technically possible (option (i)), or to reserve the position on limitation (option (iii)), which was the option favoured by counsel.

- 4.131. On 6 June 1990, a minute to me conveyed the views of Baroness Hooper, who was stated to "[feel] strongly that we should not plead the limitation defence at all" [DHSC0046957\_044].
- 4.132. On 19 June 1990, Virginia Bottomley's Private Secretary responded to the submission and noted the Minister's preference "to go for option iii) ie reserve our position. She very strongly feels that <u>not</u> to plead would be a sign of weakness, but would like to defer to the Secretary of State's legal expertise in this. I am therefore copying this to Mrs Shirley-Quirke for her to put to S of S" [DHSC0046957\_045].
- 4.133. Ken Clarke later (on 25 June 1990) agreed with the approach of reserving the Department's position on limitation [DHSC0046957\_026].
- 4.134. In answering questions on this topic, the Inquiry has indicated that it wishes me to consider a number of documents. I have read and reviewed these documents and summarise them below.
- 4.135. [DHSC0038699\_047] is a letter dated 3 May 1990 from Pannone Napier Solicitors (the Plaintiffs' solicitors), to Davies Arnold Cooper (who were acting for some of the Defendants). It set out some of the issues Pannone Napier perceived to be likely to arise if the Defendants decided to plead a limitation defence.

- 4.136. [DHSC0038699\_046] is a minute dated 4 May 1990, from Jayant Desai (in the Treasury Solicitor's Department), addressed to "Don Powell" (from context I surmise this to be a typographical error, and the intended recipient to be departmental solicitor Ronald Powell). The minute is stated to enclose the letter from Pannone Napier on limitation, and stated that the view of counsel was that the position on limitation should be reserved (although noting it to be likely that the Court would exercise its discretion to extend the time for bringing the actions). It asked for the Department's policy position on whether the Department would wish to raise the defence of limitation.
- 4.137. [DHSC0038699\_045] is a minute dated 11 May 1990 from Ronald Powell to me, copied to Dr Rejman. It attached the 4 May minute from Jayant Desai and the 3 May Pannone Napier letter. It gave a brief summary of the issue of limitation, and made it clear that (in Ronald Powell's view) a firm policy decision needed to be made on this issue one way or the other (on whether to raise limitation as a defence in the HIV litigation).
- 4.138. [DHSC0038699\_044] is a minute dated 14 May 1990 from Dr Rejman to Dr Pickles, with a number of copy recipients. It attached (for most copy recipients, but not me, as I already had the relevant documents) the 4 May minute from Jayant Desai and the 3 May Pannone Napier letter. It asked that the views of Dr Pickles and the other copy recipients upon the limitation issue be passed to Dr Rejman and myself, and suggested that Ronald Powell's offer of a meeting on the issue be taken up. There was a handwritten comment upon the copy of the minute which I have been provided which read "I have minuted Mr Canavan saying I do not think the Dept should invoke the Limitation Act". The comment is dated 15/5. It is not clear to me who the author of this comment is. I do not recognise the handwriting, but from context it is possible that it comes from Alan Barton in the AIDS Unit.
- 4.139. [DHSC0038699\_036] is a minute dated 16 May 1990, from Alan Barton. It is addressed to me, but it is a response to Dr Rejman's minute of 14 May. It gave

his view that to take the limitation point would be "disastrous from a public relations point of view".

- 4.140. [DHSC0038699\_032] is a minute dated 21 May 1990 from Dr Pickles to Dr Rejman. I was one of a number of copy recipients. It stated that Dr Pickles had not had time to consider the issue in detail, but in general thought that Department should do "nothing which might get interpreted as inconveniencing the plaintiffs". From context I take that to mean that she was minded to consider that the limitation defence should not be pursued.
- 4.141. [DHSC0046957\_117] is a minute dated 22 May 1990 from me to Ronald Powell, Dr Rejman, Peter Brand, Christine Bendall, and Richard Gutowski. It was stated to enclose a draft submission for Virginia Bottomley on the question of whether or not to raise the limitation defence, and requested comments upon that draft from the recipients of the minute.
- 4.142. The Inquiry has asked why the task of drafting this submission on the limitation defence dated 30 May 1990 fell to me. It would have fallen to me because the branch in which I worked as a Principal/Grade 7 had responsibility for the policy aspects of the litigation. As such, when inviting Ministers to make a policy decision, this branch would be responsible for collecting and presenting relevant views from within the Department. As can be seen from the documents to which the Inquiry has drawn my attention, the views contained within the final submission which went to Ministers represented those from across the various interests in the Department, and were not a statement of my personal views, or even just the views of the branch in which I worked. The views of medical, legal and policy colleagues were all obtained to inform the final submission dated 30 May 1990, for example, Dr Pickles (a Principal Medical Officer in the Department and therefore my senior) provided her input that she thought the Department should do "nothing which might get interpreted as inconveniencing the plaintiffs" [DHSC0038699\_032].

- 4.143. The Inquiry has asked why I considered that "the legal considerations [were] outweighed by the presentational ones", such that I recommended not running the limitation defence in the submission dated 30 May 1990 [DHSC0038699\_023]. I feel it is important to emphasise that although the responsibility for the drafting of the submission fell to me, as I have set out above, I was not expressing my own views on the merits of the Central Defendants pursuing the limitation defence in the HIV litigation. The recommendation against pursuing the limitation defence arose as a result of the views expressed by the various interests within the Department who were asked to provide their opinions on the issue. My role in drafting the submission was to provide the view of my branch as the leading policy branch on the issues, and to collate those views provided by those with an interest, and then to present them in a way which would assist Ministers in their decision-making. I personally would not have been responsible for advocating for any particular viewpoint, but rather for presenting the "Departmental" view, based upon input from those with the relevant expertise.
- 4.144. In determining whether to run the limitation defence, Ministers received advice from departmental officials as well as from counsel before making their decision. This process would have been representative of how strategic decisions were generally made in relation to the HIV litigation.
- 4.145. In developing advice in this manner, a divergence could arise between the view among policy colleagues, and the legal advice. This could happen where, for example, something which could provide a strategic advantage within a particular case (i.e. make it more likely that the Department would win that litigation) might have knock on effects on other areas of departmental policy, or create presentational issues. Counsel would be best placed to advise on the litigation strategy, but would not necessarily be sighted on all of the relevant policy and presentational issues.

- 4.146. A divergence of view of this type appears to have happened in relation to the advice provided on limitation in the HIV litigation. As the documents demonstrate, the advice from counsel was that the position on limitation should be reserved, whereas the view from departmental officials was that there were presentational risks which outweighed the legal considerations in favour of either running the limitation arguments or reserving the position. These views are particularly illustrated by the minute of 16 May 1990 by Alan Barton which stated that he felt that taking the limitation point would be "disastrous from a public relations point of view", and the memorandum of 21 May 1990 from Dr Pickles, which stated that she thought the Department should do "nothing which might get interpreted as inconveniencing the plaintiffs" [DHSC0038699 036]; [DHSC0038699 032]. As the submission which went to Ministers clearly shows, this divergence, and counsel's views, were made clear to Ministers, who were free to come to a different conclusion to that of their officials. As the Inquiry will be aware, the eventual decision of Ken Clarke was that the position on pleading limitation should be reserved.
- 4.147. The Inquiry has asked about the process which would have been followed in obtaining advice from departmental colleagues in order to inform my submission to Ministers. The minute dated 22 May 1990 from me to departmental colleagues shows the process which was followed [DHSC0046957 117]. A first draft of the submission, which would have been crafted using what was already known about the various views, for example following responses to Dr Rejman's minute dated 14 May 1990, was circulated to various interested departmental officials for comment, and then the final submission would have been prepared to reflect agreed views. This would have been standard practice. In some instances, if there were serious differences in views, a second draft might go around, perhaps after discussion between officials. In instances where distinct issues arose for one part of the Department, they might put their own submission to Ministers at the same time as the general one. Broadly speaking, however, the process followed in this instance was the way in which submissions in relation to other strategic decisions in relation to the HIV litigation would have been prepared.

#### Settlement of the litigation

- 4.148. In addition to the documents to which the Inquiry has drawn my attention in relation to specific questions, the Inquiry has set out a number of documents at the outset of this section which it considers may assist me in responding to questions in respect of the settlement of the HIV litigation. I have set out and summarised these documents below.
- 4.149. [DHSC0046964\_024] are the remarks of Ognall J dated 26 June 1990. Those remarks were stated to "invite the parties to give anxious consideration to the prospects of any compromise of these proceedings."
- 4.150. [DHSC0046964\_018] is a minute dated 29 June 1990 from Richard Gutowski, to Roy Alder, both of whom worked within the MCA. It was copied to a number of people, mostly within the MCA but also a departmental solicitor and myself. The minute set out the (continued) concerns of the Licensing Authority and Committee on Safety of Medicines over any out of court settlement setting a precedent for Government bodies awarding compensation in circumstances where they had not been found to be at fault, which it was stated "could lead to over-defensive licensing decisions and a reluctance of academics to serve on the Section 4 advisory committees."
- 4.151. [DHSC0044287\_228] is a minute from Charles Dobson to a number of departmental officials, including legal and medical professionals. I appeared at the end of the list of copy recipients. The minute stated that a submission would need to be sent to Ministers in respect of Ognall J's comments, shortly after a planned meeting with counsel. It attached a draft copy of that submission [DHSC0046957\_009].
- 4.152. [DHSC0044139\_109] is a second draft of the submission to Ministers, dated 9 July 1990. I appeared at the end of a long copy list. There is handwriting on the

draft which I do not recognise. The submission set out that the advice from departmental officials at that stage was that the Department continue to fight the litigation, notwithstanding the indication from Ognall J, but offered to provide further options and briefing if Ministers "judge that the political cost of that line cannot be sustained". The draft submission concluded that the reason for that recommendation was because "[officials] believe that to offer an out-of-court settlement to this particular group, without any effective way of avoiding creating a precedent for other groups, would be the worst of all worlds."

- 4.153. [DHSC0044287\_216] is a minute dated 16 July 1990 sent from Charles Dobson to a number of policy, medical, and legal colleagues. I was a copy recipient. It set out the fact that, because "views on this difficult topic diverge right to the top of the office...the submission will not attempt to reach a consensus". It stated that this approach had been agreed by Strachan Heppell (Grade 2) and Sir Donald Acheson. The further draft of the submission was attached [DHSC0044287 217].
- 4.154. [DHSC0046964\_003] is a submission dated 24 July 1990 from Strachan Heppell to Sir Donald Acheson, Virginia Bottomley, and Ken Clarke. It covered the note from Charles Dobson, explaining that it had been prepared following wide consultation with colleagues within the Department and laid out a range of options on how Ministers might want to respond to the HIV litigation in light of Ognall J's comments. The note itself was enclosed [DHSC0004360\_147], as was a note providing the views of the regional directors of public health as an annex [DHSC0046964\_006]. Strachan Heppell's view was that there were two real options for Ministers: "First, we continue to resist firmly the present action against the Government whilst being ready to consider further help through the MacFarlane Trust; or Second, seek a settlement out of Court, in one form or another." I appeared at the bottom of a long list of copy recipients, which included Baroness Hooper, Sir Christopher France and Dr Metters as well as a number of medical, legal and policy colleagues.

- 4.155. [DHSC0046964\_008] is a minute dated 27 July 1990 from Virginia Bottomley to Ken Clarke. I appeared at the bottom of a very lengthy copy list. The minute provided the Minster's view that the Department should maintain its present position in the HIV litigation noting that "[once] we move towards conceding on cases like these it will have inevitable long-term implications for the Department."
- 4.156. [DHSC0046964\_007] is a response from Ken Clarke to Strachan Heppell's submission of 24 July 1990 dated 31 July 1990. He commented that "he is in favour of sticking to our legal defence and continuing to fight the action."
- 4.157. [DHSC0020866\_150] is a newspaper article dated 3 August 1990 from The Guardian, titled "Clarke urged to settle AIDS claims". It suggested that Sir Donald Acheson was exerting pressure on Ken Clarke to settle the litigation. It is not clear how this information became public.
- 4.158. [DHSC0044139\_045] is a minute dated 3 September 1990 from me to a number of legal, medical, and policy colleagues, with Strachan Heppell and Charles Dobson as copy recipients. It enclosed two letters for comment, stating that they were based largely on drafts by counsel. The first letter conveyed Ken Clarke's decision on declining an out of court settlement at that stage in the HIV litigation [DHSC0044139\_046]. The second letter was intended to underline the possible cost consequences for the Plaintiffs of continuing with the full range of their allegations [DHSC0044139\_047]. My minute invited comments from colleagues on both letters.
- 4.159. [DHSC0020866\_140] is a minute dated 5 September 1990 from Ronald Powell to me, which commented upon the draft letters sent on 3 September 1990, above.

- 4.160. [DHSC0020866\_134] is a letter dated 7 September 1990 from Pannone Napier solicitors to the Treasury Solicitor, which proposed a settlement in the HIV litigation in light of the comments made by Ognall J.
- 4.161. [DHSC0043124] is a minute dated 7 September 1990 from me to Ronald Powell, which copied a number of legal, medical, and policy colleagues, including Strachan Heppell. It enclosed revised drafts of the two letters conveying Ken Clarke's decision declining a settlement and on costs that incorporated comments provided to me by colleagues. My minute asked Ronald Powell to seek the views of the Law Officers' Secretariat on those letters.
- 4.162. [DHSC0020866\_091] is a submission dated 18 September 1990 from Charles Dobson to Ken Clarke. I appeared at the end of a long list of copy recipients, which included the other Department of Health Ministers, Sir Christopher France, Sir Donald Acheson, and medical, legal and policy colleagues. It conveyed the advice of counsel and of the law officers on the handling of Ministers' recent decision to continue with the HIV litigation, and informed the Ministers of some recent developments.
- 4.163. [DHSC0020866\_119] is a minute dated 25 September 1990 from Charles Dobson to Ronald Powell. I was on the copy list to be provided with a copy "o/r" (on return), as I was out of the office when this was sent. It attached a revised draft of the letter to the Treasury Solicitor conveying Ken Clarke's decision declining settlement in the HIV litigation and asked for comments to be sought from counsel and the Solicitor General [DHSC0020866\_120].
- 4.164. [DHSC0046936\_091] is a letter dated 3 October 1990 from Strachan Heppell to Jayant Desai within the Treasury Solicitor's Department. It was the final version of the letter to be shown to the judge, which was included in draft form in the minutes referenced above. It conveyed Ken Clarke's view that the Central Defendants should not agree to settle the HIV litigation, citing the reasons for

this including that it would set a precedent for establishing a duty of care in circumstances where the Government had not been found to be at fault and "lead to very large numbers of costly and time-consuming claims against the Department, Licensing Authority and CSM." The letter highlighted Ken Clarke's view "that the best and indeed the proper way of meeting the need referred to by Mr Justice Ognall is through the machinery of the Macfarlane Trust or similar means" and reiterated the Government's commitment to this. I was not a copy recipient to the final letter sent to Jayant Desai.

- 4.165. [DHSC0020866\_116] is a minute dated 8 October 1990 from me to Ronald Powell, copied to a number of policy, medical and legal colleagues. It enclosed an amended draft of the letter to the Plaintiffs' solicitors about the recovery of costs in the HIV litigation, to take account of the outcome of the appeal hearing on PII [DHSC0020866 117].
- 4.166. [DHSC0046962\_067] is a submission dated 9 November 1990 from Charles Dobson to Strachan Heppell and the Secretary of State, William Waldegrave (who had taken up office on the 2 November 1990). I was a copy recipient to the submission. It was stated to attach a proposed scheme of compromise from the Plaintiffs' solicitors, which has not been included with the version provided to me by the Inquiry.
- 4.167. [DHSC0020866\_057] is a minute dated 27 November 1990 from Charles Dobson to Sir Christopher France. I was a copy recipient to the minute. It attached a note on the HIV litigation which it was stated could form the basis of briefing for new Ministers [DHSC0046962 374]<sup>3</sup>.

<sup>&</sup>lt;sup>3</sup> The Inquiry has suggested that the note attached to the minute of 27 November 1990 is [DHSC0002431\_082], but I believe this to be an error and the note actually attached to be [DHSC0046962 374].

4.168. [DHSC0003654\_108] is a minute from Ronald Powell to me dated 4 December 1990 which summarised a conversation between Ronald Powell and counsel, Justin Fenwick, about the risks involved in the HIV litigation.

#### Q70: Comments made by Ognall J – 26 June 1990

- 4.169. I have been referred to the comments made by Ognall J at a hearing in his chambers on 26 June 1990 [DHSC0046964\_024]. In making those comments, the judge took what he described as a "rare…initiative" and invited the parties to "give anxious consideration to the prospects of any compromise of these proceedings."
- 4.170. I am asked about my personal response to these comments. I do not recall whether I had any personal feelings about the comments, but I would have been informed by the legal team (and in fact it is stated in the comments themselves) that this was something "rare" and unusual to be happening. The documents made available to me in connection with the preparation of this statement appear to indicate that the first time I was made aware of the judge's comments was as a copy recipient to Richard Gutowski's minute to Roy Alder dated 29 June 1990, which stated that "[it] would appear that the judge appointed by the Lord Chief Justice to hear the litigation Mr Justice Ognall has made an unprecedented move from the legal into the political arena. The Judge commenced the proceedings by issuing a statement urging all parties in the litigation to seek a compromise of the proceedings" [DHSC0046964\_018].
- 4.171. It was not my role to take a personal view on the approach and strategy in the HIV litigation, and so Ognall J's comments would not have altered my view in that respect. Whilst I did provide advice to others in the Department on the HIV litigation, as I have set out earlier in this section of my statement, such advice was based upon a collective view within my branch and the wider Department, after collating views from various interested officials and experts. As the section in which I worked led on the litigation from a policy perspective, we were expected to take a lead on these issues.

- 4.172. In terms of the advice provided to Ministers following Ognall J's intervention, it was my branch's responsibility to canvass and collate views on the same, but the advice which was provided to Ministers came from a senior level, given the political sensitivity and the precedent and financial implications of the issue. The key submission on this issue was the submission of 24 July 1990 from Strachan Heppell (who was a Grade 2) [DHSC0046964 003]. That submission covered a note on "how Ministers might now respond to the current aids litigation in the light of a statement from the judge. Mr Justice Ognall, advice from counsel and a submission from Regional Directors of Public Health" by my branch head, Charles Dobson [DHSC0004360 147]. It is notable that a minute by Charles Dobson dated 16 July 1990, which enclosed a draft of the Ministerial submission for comment from a variety of sources, made it clear that there was not going to be an attempt to find a consensus within the Department on the view to take [DHSC0044287 216]. The reason for this was that "views on this difficult topic diverge right to the top of the office", and this approach was endorsed by Strachan Heppell, as well as Sir Donald Acheson. The draft of the submission attached to Charles Dobson's minute dated 16 July 1990 is at [DHSC0044287\_217]. I was a copy recipient to the minutes circulated by more senior colleagues with their views on Ognall J's comments, the drafts of the submission to Ministers on the same and the final submission from Strachan Heppell dated 24 July 1990, however I appeared at the bottom of a long list of copy recipients and I do not now recall if I played any role personally in canvassing and collating the views of colleagues to prepare the final submission to Ministers following Ognall J's intervention dated 24 July 1990. The documents made available to me indicate that I did not. The additional documents made available to me indicate that Ronald Powell provided his comments on the draft submission on 11 July 1990 [DHSC0044139 099].
- 4.173. In light of this, I would not have been responsible for the change of advice from the advice that Ministers "continue with their present tactics and fight on" in the draft submission of 2 July 1990 [DHSC0046957\_009] attached to Charles Dobson's minute of the same date [DHSC0044287 228], to an invitation to

"consider whether to fight on" in the draft submission of 16 July 1990 [DHSC0044287\_217] attached to Charles Dobson's minute of the same date [DHSC0044287\_216], which was the wording included in Charles Dobson's note attached to Strachan Heppell's submission dated 24 July 1990 [DHSC0004360\_147]. As I have explained, the advice being given was coming from sources far more senior than I and I was copied to this correspondence for information. However, I think it is clear that the reasoning for this change was as set out in the minute by Charles Dobson dated 16 July 1990 [DHSC0044287\_216]. In that minute he set out that "views on this difficult topic diverge right to the top of the office", so there would be no attempt to find a consensus in the advice to be given to Ministers. As there was no departmental line from officials (due to views diverging) the matter would be put to the Ministers for their decision.

- 4.174. My understanding of this was that the intention was to leave the issue open for Ministers to consider all aspects in deciding whether to continue with the litigation in Court or to follow the judge's suggestion and explore settlement with the Plaintiffs. I am unable to assist on the precise nature of the diverging views, and I would not necessarily have been privy to discussions taking place at the "top of the office", but it seems self-evident that some senior people must have favoured actively pursuing settlement or another form of compromise, whilst others opposed that course of action.
- 4.175. I appear to have provided the first drafts of letters that were intended to be sent to the Plaintiffs' legal team following Ognall J's intervention. As the covering minute, which was sent to medical, legal, and policy colleagues including Strachan Heppell shows, the letters were based upon drafts provided by counsel [DHSC0044139\_045]. The letters would not have been my own views, but also the views of other interested parties. The letters incorporated comments from Ronald Powell provided on 5 September 1990 [DHSC0020866\_140]. In my minute to Ronald Powell dated 7 September 1990 I also requested that Ronald Powell seek the views of the Law Officers'

Secretariat and Charles Dobson on the letters [DHSC0043124]. Charles Dobson's submission to Ken Clarke seeking the Secretary of State's approval of the letters also indicated that "[the] Solicitor General has been consulted and has indicated that he is content with the overall tone and content of the two letters: his detailed suggestions have incorporated" been [DHSC0020866\_091]. Charles Dobson provided further comments on the letters in his minute dated 25 September 1990 and requested any final urgent comments from counsel and the Solicitor General on the letter to the Treasury Solicitor before it was issued [DHSC0020866 119]. On 1 October 1990 Charles Dobson sent a further amended draft of the letter to the Treasury Solicitor in light of discussions with the Solicitor General and noted that a further version incorporating comments from counsel would be submitted later that day [WITN0758079]. It is clear from the documents, therefore, that the first drafts of the letters to the Plaintiffs' legal team were: (i) based upon drafts provided by counsel in the first instance; and (ii) subsequently considered and/or amended by departmental lawyers, counsel, Charles Dobson, the Solicitor General (then Sir Nicholas Lyell) and Ken Clarke before being issued. Because I worked within the section which had been identified as policy lead for the litigation, it would have been natural for people to look to us as the people who would put the drafts together.

# Q71: Settlement and setting any precedent for the Department, the CSM and the Licensing Authority

4.176. One of the concerns in Government at the time in relation to settling the HIV litigation or otherwise coming to a compromise with the Plaintiffs was the danger of setting a precedent for the Department, but also for the CSM and the Licensing Authority. Charles Dobson's note enclosed with Strachan Heppell's submission to Ministers on the response to Ognall J's intervention dated 24 July 1990 summarised these concerns as follows:

"iv) if we settle (especially at this stage) it will raise expectations that Government will be prepared to give substantial compensation in any similar case in which NHS patients suffer as an unintended by-product of their treatment. In effect, we would be opening the gates to the principle

- of no-fault compensation for medical accidents without any rational debate of its merits;
- (v) if a settlement for the haemophiliacs had the feared result of encouraging litigation in other comparable cases this would not only be hugely expensive: it might also encourage over-defensive licensing decisions, medical treatment and prescribing, undermine confidence in the licensing arrangements and make it more difficult to persuade experts to sit on the Committee on Safety of Medicines (CSM) and other advisory committees" [DHSC0004360 147].
- 4.177. My understanding at the time was that there was concern about the impact of settling this litigation upon wider funding considerations, particularly if it generated an expectation of settlement or compensation in other claims, or encouraged the Plaintiffs' solicitors to bring claims in other areas. Given the pressures on health funding, I believe I felt this concern to be understandable. Given the difficult issues at hand, I was not in a position, nor was it my role, to come to a conclusion on where the balance lay on the strengths and weaknesses of the argument of setting a precedent for the Department, the CSM and the Licensing Authority. I certainly understood the concern that colleagues senior to me and Ministers were grappling with when considering Ognall J's comments that the parties should consider settlement.
- 4.178. Looking back now, I can still see the validity of those concerns, and I still feel as though I would not be in a position to make a judgement call on how such a situation should be navigated.

#### Q72: Briefing materials for William Waldegrave

4.179. The Inquiry has asked me what role I played in preparing a set of briefing materials for the new Secretary of State for Health (William Waldegrave) about the HIV litigation dated 7 November 1990. A summary of the briefing meeting was provided in a minute dated 8 November 1990 from Peter Kendall to Mike Brownlee [DHSC0020866\_101]. It seems clear from that note that Strachan Heppell attended the briefing. I cannot recall whether I would have attended personally.

- 4.180. The Inquiry has drawn my attention to the documents which it understands made up the briefing material which was provided. I have set out and summarised these documents below.
- 4.181. [DHSC0004365\_008] is the covering submission dated 6 November 1990 from me which enclosed the briefing for William Waldegrave. Its recipients were Charles Dobson and Stephen Alcock, who was the Principal Private Secretary of the Secretary of State. Copy recipients included medical, legal, and policy colleagues including Strachan Heppell.
- 4.182. [DHSC0046962\_374] is "Item A" referred to in the covering submission and provided a general background note on the litigation and the underlying issues. It is not clear who authored the note.
- 4.183. [DHSC0046962\_182] is "Item B" referred to in the covering submission and was a two-page document providing "key facts" in relation to the litigation. It is not clear who authored the document.
- 4.184. [DHSC0046964\_003] is "Item C" referred to in the covering submission and was a copy of the 24 July 1990 submission to Ministers from Strachan Heppell sent in the wake of Ognall J's comments, and described in detail above.
- 4.185. [DHSC0046962\_187] is "Item D" referred to in the covering submission and was a three-page summary on the present position within the litigation. It is not clear who authored the document.
- 4.186. It is clear that I authored the covering submission for this briefing, which is likely to have meant that I at least collated the accompanying documents. It is possible that I drafted or contributed to the drafting of the three notes (items A,

B, and D), but I cannot recall doing so, and had I produced the drafts I would expect that, in the usual way, they would have been circulated for comments from colleagues first. It is also possible that by that stage in the litigation, much of the background material would have been available already from our files.

- 4.187. The Inquiry has asked me what was meant by the use of the term "defensive briefing", when used by Richard Gutowski in a minute dated 7 November 1990 in relation to this briefing for William Waldegrave [DHSC0046962\_367]. To me, the term "defensive briefing" is a term of art applied within a policy context, understood to mean a briefing designed to equip the Minister to understand and deal with potential criticisms or pressures (in other words, to equip the Minister to defend themselves). Defensive briefing should not necessarily be interpreted as denoting a resistance to change. To provide an example of its use in this way in another context, in a submission dated 18 September 1990 from Charles Dobson to the Ken Clarke, paragraph 7 spoke about it being "prudent to prepare defensive press briefing" to be used in the event of leaking of Ognall J's comments in respect of settlement and pressure/negative comment from the press [DHSC0020866 091]. Until there was any change in policy at a Ministerial level, briefings would obviously also tend to be defensive in the sense that they would state the existing policy and explain the reasons that are considered to justify the current policy.
- 4.188. In my view the aim of the briefing was to give the incoming Secretary of State background information and the current state of play around the HIV litigation issues, which could be described as a "defensive briefing" in the sense that the new Secretary of State could rely on the information provided to him by officials to answer any questions, including criticisms, on the current policy position on the HIV litigation in public. The briefing from Strachan Heppell dated 24 July 1990 which was included as "Item C" set out a range of options and suggested different courses for Ministers to take.

4.189. The Inquiry has asked me to comment on a statement which was contained in Item B of the briefing pack which stated that either the settlement of the HIV litigation with an establishment of Government liability or settling without an admission of liability would increase "the sense of unfairness to any group not benefitting". My understanding is that this statement would have related to other groups of people pursuing claims against the CSM and the Licensing Authority who would be likely to feel a sense of unfairness if their claims did not result in a settlement or an offer of payment, in circumstances where the HIV litigation had been settled.

#### Q73: 1990 change of Ministers and of Prime Minister

- 4.190. I am asked to consider the extent to which I observed a noticeable change in November and December 1990 to the Government's approach to the HIV litigation. I am asked whether I consider whether any such change was caused by Cabinet and Ministerial changes, including the Prime Minister, Ministers within the Treasury, and the Secretary of State for Health.
- 4.191. I am asked to consider a range of documents in responding to this question, which I set out and summarise below.
- 4.192. [DHSC0020866\_101] is the 8 November 1990 minute which summarises the 7 November 1990 briefing meeting with William Waldegrave. This is discussed in more detail in my statement above. Specifically on the subject of Minister's views, the minute opined that there was "little formal difference between [William Waldegrave's] line and Mr Clarke's: that it would be sensible to reach a settlement with the plaintiffs if that could be done at acceptable cost. Behind that similarity however lay a greater inclination to settle, and I suspect some willingness to settle at somewhat higher cost". I should emphasise that I was not a recipient of this minute, cannot state with certainty whether I ever saw it at the time, and cannot say whether I agreed with the view expressed on the differences between Ministers' views discussed in light of the meeting on 7 November 1990.

- 4.193. [DHSC0004365\_032] is a letter dated 26 November 1990 from William Waldegrave to Mr R Anderson Cowe, the Vice Chairman of the Haemophilia society, which set out the Government's (then) position on the HIV litigation.
- 4.194. [DHSC0003511\_039] is a Q and A briefing dated 3 December 1990 on the proposed settlement. Particularly relevant to this issue is a suggested answer for a question on whether the proposed settlement represents a change in course, "resulting perhaps from the Government's new leadership?". The answer which was suggested was:

"No. We have always promised to keep the level of assistance available to haemophiliacs under review. This was the first proposal we have received from the plaintiffs which seemed to offer the basis of a fair settlement."

- 4.195. [PRSE0001936] is an extract from The Scotsman newspaper dated 12 December 1990, comprised of an article entitled "Haemophiliac victims of AIDS offered £51m deal". The article reported that William Waldegrave "argued that the proposal, which he claimed could lead to one of the most generous settlements for haemophiliac victims in the world, had not occurred as the result of a U-turn."
- 4.196. [DHSC0032267\_105] is an extract from the Daily Telegraph dated 12 December 1990, comprised of an article entitled "£50m offer to haemophiliac victims of Aids". The article painted the settlement as a reversal of a Thatcher policy by John Major, although it did state that "Ministers insisted [this] was not a U-turn".
- 4.197. [HSOC0022095] is an extract from the Daily Mirror dated 12 December 1990, comprised of an article entitled "£42m BLOOD MONEY 'ISN'T ENOUGH". It described the settlement proposal as the "Government's sudden U-turn on compensation" which "followed massive pressure".

- 4.198. [HSOC0012427\_179] is an extract from the Financial Times dated 12 December 1990, comprised of an article entitled "Haemophilia cash pledge". It described the settlement proposal as a "sharp policy shift".
- 4.199. [DHSC0003655\_032] is an extract from The Sunday Times dated 16 December 1990, comprised of an article entitled "BITTER BLOOD The government surrenders but the victors are implacable". It described the settlement announcement as coming after "a week of secret Whitehall talks", and claimed to have a great deal of information on how and when the negotiations were done.
- 4.200. It is evident from the above documents shown to me, and I recall I was aware at the time, that the press linked the announcement of the settlement agreement with the change of Ministers and of Prime Minister.
- 4.201. However, I do not consider this to necessarily have been the reason for the settlement happening when it did. Ministers had (already by this stage) recognised the special circumstances of haemophiliacs infected with HIV via the Macfarlane Trust. Additionally, there was a great deal of political (and public) pressure to settle the litigation, and this had been steadily building over time. Following the remarks of Ognall J, the Plaintiffs' solicitors approached the Department with a settlement offer, and both sides worked together to find a solution acceptable to everyone.
- 4.202. Given all of the circumstances, and the mounting pressure, it is not possible to speculate what would have happened had there been no changes in Ministerial post-holders. I do not have any recollection about the views of the new departmental Ministers on the settlement of the litigation.

#### Q74: Comments on proposed scheme of compromise

- 4.203. On 9 November 1990, Charles Dobson sent a submission to Strachan Heppell and William Waldegrave [DHSC0046962\_067]. It enclosed a proposed scheme of compromise which had been received from the Plaintiffs' solicitors [DHSC0003654\_117]. A "very preliminary assessment" of the proposal was included in the submission, with the promise of "our considered advice" to follow the next Monday.
- 4.204. Also on 9 November, Strachan Heppell sent a submission to William Waldegrave, agreeing with Charles Dobson's initial assessment and stating that the "proposals as they stand look on the high side especially as the plaintiffs counsel are looking for high legal costs and disregard of all payments for social security purposes" [DHSC0046962\_065]. It also highlighted the fact that the proposals from the Plaintiffs' solicitors had not actually at that stage been put to the Plaintiffs themselves. It promised full advice to follow as soon as possible.
- 4.205. That full advice came in the form of a submission dated 12 November 1990 from me to William Waldegrave and Charles Dobson, which set out a "considered assessment of those provisions which present difficulty" [DHSC0046962 028].
- 4.206. I would have prepared and drafted this submission by collating views from those within the Department with an interest. The submission itself would have been cleared through Charles Dobson before being sent to Ministers. From the documents made available to me, I can see that I received comments from Dr Rejman and Ronald Powell on the proposed scheme of compromise in separate minutes dated 12 November 1990 [DHSC0046962\_061]; [DHSC0003654\_101]. These documents illustrate that the usual process of obtaining and collating the views of departmental colleagues was followed in respect of my submission on this topic dated 12 November 1990. The submission did not represent my personal view or work on the proposed scheme of compromise. Indeed, it can clearly be seen that I incorporated Dr

Rejman and Ronald Powell's comments into the final submission. There may have been others within the Department who provided comments on the proposed scheme of compromise that I then incorporated into the submission dated 12 November 1990 however I have not seen documents outlining these and I do not now recall who else may have commented on the proposed scheme of compromise.

- 4.207. I do not recall having any personal view about the reasonableness of the settlement offer, nor do I recall having had any basis for comparison, as I did not have any particular experience in litigation of this kind or its settlement. In commenting on the likely costs of the settlement I was reflecting the view of Charles Dobson and subsequently Strachan Heppell in their submissions of 9 November, as outlined above. The sum of £42 million did not take account of legal costs, or the value of the social security disregard for payments under the settlement.
- 4.208. I do not recall having any information at that time in relation to the extent to which individual Plaintiffs were aware of, or in support of, the proposed settlement. My understanding is that the Plaintiffs' lawyers developed the original proposals and put them to the department. I do not recall the basis upon which those proposals were put or whether the department would have known whether the Plaintiffs were aware of the offer.
- 4.209. The Inquiry has asked me to address the fact that the submission stated that the "two main sticking points to the proposals" would be the need for the Plaintiffs' lawyers to convince other Plaintiffs to accept the settlement, and that the medical negligence claims would also need to be settled (in relation to paragraphs 2 and 8 of the proposed scheme of compromise respectively). In writing this, I would not have been conveying a personal view, but the view of departmental officials following consultation and comment. I can see from the submission itself that the rationale for the view appeared to be that if either one

of those things were not achieved, the litigation would continue in some form, which would obviously undermine and devalue any "settlement".

4.210. In his minute to me dated 12 November 1990, Ronald Powell noted the following, which I then reflected in my submission of the same date:

#### "Para 2

There must be some doubt about whether everyone can be persuaded to sign up to these terms. The lawyers must be satisfied that they can convince the Court of the wisdom of settling the minors' cases on these terms...

#### Para 8

What do you want to do about clinical negligence? Are you happy for these claims to continue?"[DHSC0003654\_101]

- 4.211. Dr Rejman's comments on paragraph 8 of the proposed scheme of compromise were also incorporated into my submission:
  - "8. Point 8 I think this should be totally resisted. What number, and in particular which cases, do the Plaintiffs believe would be covered by this? The whole Point of any potential agreement would be that the Litigation would stop completely. A major reason put forward for any settlement is to stop problems for HAs of having to defend their actions, doctors etc. Would the Central Defendants be removed from the list of Defendants in these cases, or would the Department still have to continue work on the Litigation?" [DHSC0046962\_061]
- 4.212. Having assessed the comments received from colleagues in the Department on the proposed scheme of compromise I must have deemed these two issues as the "two main sticking points to the proposals" based on the comments that I received. It is also possible that others in the Department other than Ronald Powell or Dr Rejman told me that they thought these two issues were the main sticking points and I incorporated this point into the submission dated 12 November 1990, however I have not been shown any further comments from departmental officials on the proposed scheme of compromise in connection with the preparation of this statement so I cannot be certain.

4.213. At least part of the rationale behind the comments in relation to paragraphs 4, 6 and 7 of the proposed scheme of compromise, which note that Category G claimants should be restricted to sexual partners and exclude parents, siblings and others, appears to have been derived from the comments provided to me by Ronald Powell and Dr Rejman (as well as possibly the views expressed by other policy, legal, and medical colleagues who may have fed into the drafting of this submission).

#### 4.214. Ronald Powell noted:

#### "<u>Para 4</u>

It is small beer, but I'm very dubious about paying anything to category G plaintiffs (uninfected intimates)." [DHSC0003654\_101]

#### 4.215. Dr Rejman highlighted:

- "5. Point 4 If Category G is at all accepted, and I think it should not be, then I think these payments should be made only to sexual partners and should specifically exclude all parents, siblings and others. As you are aware, there are several cases where two or more individuals are claiming on the back of one infected haemophiliac. Surely this is wrong. In addition I think Category G payments should not be paid to Plaintiffs where the infected haemophiliac has died, and in some cases the surviving spouse has had negative HIV tests several years after his death and would already receive a payment in respect of the deceased.
- 6. As regards the infected intimates it might well be made a condition that there should be some proof required, since as you know there is one case where two girlfriends are supposed to have been infected in quick succession by one haemophiliac who is now, conveniently, deceased. There are also two cases of supposed in utero infection, which have subsequently tested negative and as such should be excluded.
- 7. I am very unhappy about <u>Para 6.</u> What guarantee is there that an individual will not put herself at risk and subsequently become infected and then claim a sum in the future? Among the ISCs that I have read, there are several cases where wives have put themselves at risk against the express advice of their medical attendances. How would one deal with such individuals? It would be easier to state that there is a cut off point after which time no additional infected intimates are accepted." [DHSC0046962\_061]
- 4.216. Those comments were made by Dr Rejman, and as he stated in his oral evidence, were made in the very early stages of discussion after receiving the

Plaintiffs' solicitors' opening offer [INQY1000203]. I understood his views to be in consequence of his medical knowledge about who was and was not at risk of HIV infection (and therefore reasonably might be included in any scheme, whether in consequence of their actual infection, or the fear and distress caused by worrying about potential infection). I would not have been in a position to comment upon that. Looking back, I can see how some of the wording used by Dr Rejman might be seen as insensitive or poorly chosen, and that is something he accepts in his evidence (p185, lines 4-6), but given his expertise I believe that the underlying rationale for the reasons why Category G claimants might be restricted was legitimate from a medical perspective.

#### Q75: Briefing of the Secretary of State ahead of meeting with the Treasury

- 4.217. I am asked to consider a submission dated 23 November 1990, sent from Charles Dobson to William Waldegrave, which enclosed a number of speaking notes ahead of a meeting that he was due to attend with the Treasury [DHSC0003654\_115]. A supplemental briefing was provided by Charles Dobson on 5 December 1990 [DHSC0003383\_006]. I was not listed as a copy recipient of either submission. The first submission makes reference to (and attaches) "Mr Canavan's analysis" of the Plaintiffs' proposal, but as set out above, this analysis (which I assume to be the analysis contained within the 12 November 1990 submission [DHSC0046962\_028]) was a reflection of the departmental view, arrived at by drawing out views from within the branch and across the Department. The submissions from Charles Dobson and Strachan Heppell would likely have been what I had in my mind. It was picking up comments such as the lack of inclusion of costs.
- 4.218. I have no recollection of this briefing, or the meeting it was prepared for. I do not recall playing any part in its preparation, and it is possible that I never saw it. Charles Dobson may have completed it alone. It is possible that there were time pressures, but it was also the case that more politically sensitive pieces of work would often be dealt with at a higher level and not copied as widely. I can see, for example, that on 22 November 1990, a draft of the briefing was sent to

Ronald Powell and Mr Kendall, copied to Strachan Heppell [DHSC0020866\_075]. Indeed, Charles Dobson stated in the final submission dated 23 November 1990 that the briefing material for William Waldegrave's meeting with the Treasury had "been cleared with Mr Heppell and with legal and finance colleagues". There is no mention of policy/administrative colleagues having commented on the material and, as mentioned above, it is likely that the meeting with the Treasury was deemed sensitive enough to be handled at a certain level of seniority. I do not appear on the circulation for either the draft or the final version of the submission.

4.219. I do not recall whether I saw the briefing or the speaking notes at the time, and therefore cannot comment upon whether there was anything in them with which I disagreed at the time. Looking at them now, I do not see anything I would disagree with.

# Q76: Discussion between Ronald Powell and Justin Fenwick – 4 December 1990

- 4.220. The Inquiry has drawn my attention to a minute dated 4 December 1990 from Ronald Powell to me, that recorded a discussion he had with Justin Fenwick that day [DHSC0003654\_108]. I am further asked to consider Note C of the submission dated 5 December 1990 when answering this question [DHSC0003383\_006].
- 4.221. I believe the reason for that conversation between the lawyers was that Ronald Powell had been asked to get counsel's view of the Department's chances of successfully defending the litigation for the Minister. I do not believe I played any part in the discussion. Paragraph 1 of Ronald Powell's minute stated that he had spoken to Justin Fenwick and "asked him if he was able to quantify the various risks involved in this litigation." The minute then goes on to give Justin Fenwick's assessment of "the risk factors of various aspects of the case" separately and outlined the Department's likely prospects of success in percentage terms in respect of the same.

- 4.222. The minute would have been Ronald Powell's way of feeding the outcome of that discussion into my branch, so that it could in turn be used to inform briefing material for Minister. This is evident from Note C of the submission dated 5 December 1990, which is stated to be "LEGAL ADVICE ON LIKELIHOOD OF LOSING THE ACTION" from Junior Counsel (which I assume is a reference to Justin Fenwick's advice). Both Ronald Powell's minute dated 4 December 1990 and Note C of the submission dated 5 December 1990 recorded that Junior Counsel approximated that the Department had roughly a one third chance of losing entirely (although Note C stressed the imprecision of figures such as this and Ronald Powell's minute recorded that the views of other counsel may differ slightly).
- 4.223. I do not recall precisely what my role would have been in disseminating the information that was obtained from that discussion. It may be that I simply passed the minute to Charles Dobson as he had not been copied it. The discussion was covered in his submission of 5 December and copyees would have learned of counsel's assessment through it.

#### Q77: Q&A sheet on the settlement

- 4.224. On 11 December 1990 William Waldegrave announced to Parliament that the Government had agreed in principle to the settlement proposals put forward by the Steering Committee of Solicitors from the Plaintiffs and their Counsel [DHSC0003654\_023]; [DHSC0004415\_036].
- 4.225. On 12 December 1990 I sent a minute to legal, medical and policy colleagues attaching "a copy of Q and A briefing which contains more detailed information about the Government's position on settlement of the litigation, funding and distribution of the £42 million" [DHSC0003511\_036]; [DHSC0003511\_039]; [DHSC0003511\_040]; [DHSC0003654\_079].

- 4.226. It is likely that I had some role in the drafting of the Q and A briefing, but I have no recollection of how much. It would have been something that was put together from a variety of sources, drawing on information from across the Department, including medical, legal, and policy colleagues.
- 4.227. I am asked specifically to address question and answer "x", which deals with the question of people infected with HIV through blood transfusion or transplants. The suggested response was as follows:

"The Government believes that haemophiliacs are a very special category, because they were already affected by a serious hereditary condition before their tragic infection with HIV. [If pressed: people infected with HIV as a result of blood transfusion/transplants are no different in principle from other groups of patients harmed as an unfortunate side result of NHS treatment.]"

- 4.228. I do not know who authored this question and answer. There is a handwritten annotation on the copy shown to me by the Inquiry by this answer which reads "weak". I do not recognise the handwriting, but it is not mine.
- 4.229. I do not recall how much consideration I, personally, had given to those infected with blood transfusions and transplants. I understand that the line that was taken in that answer was the line which was adopted by senior officials and Ministers, and I do not recall objecting to it at the time.
- 4.230. I recall at the time that the priority objective was to ensure that the litigation was settled, and there were no plans at that time to extend payments to blood transfusion or transplant recipients. I believe it was thought likely that pressure would be exerted at some point, as there had been pressure in this regard following the setting up of the Macfarlane Trust and the additional payment of £20,000 which was made to haemophiliacs.
- 4.231. I do believe that I agreed with the position that there was a distinction in that haemophiliacs were doubly disadvantaged by their HIV and their underlying

condition which affected their employment, mortgage and insurance prospects. There could also be more than one haemophiliac in a family.

4.232. I am not able to provide a view on why there was no extension at that time to blood transfusion and transplant recipients, save as set out above.

#### Q78: Drafting the terms of the settlement

- 4.233. I am asked to set out the role, if any, which I played in advising on and drafting the terms of the settlement. I am also asked to identify by name and role those who were also involved, insofar as this is within my knowledge.
- 4.234. In responding to this question, the Inquiry has drawn my attention to a large volume of documents, which I summarise below.
- 4.235. [DHSC0046962\_067] is a minute dated 9 November 1990 from Charles Dobson to Strachan Heppell and William Waldegrave. I am listed as a copy recipient of the "minute only" (not the attached documentation). It informed recipients of the settlement proposals being made by the Plaintiffs' solicitors, and noted that advice on these proposals was to follow. This document demonstrates the high level at which these issues were being considered.
- 4.236. [**DHSC0003654\_117**] is the proposed scheme of compromise from the Plaintiffs' solicitors which accompanied the above minute (although it would not have been attached to the version sent to me).
- 4.237. [DHSC0003937\_020] is a submission dated 9 November 1990 from Strachan Heppell to William Waldegrave. I appeared at the end of a list of copy recipients. The submission gave an initial view from Strachan Heppell of the proposals, which he considered "as they stand look on the high side". There is a handwritten note on the face of the submission, which suggests to William

Waldegrave that a meeting should be set up fairly promptly between the him and leading counsel, Andrew Collins. I do not recognise the handwriting, but from the context it appears to have come from a senior level. This document clearly shows that the approach to be taken to the proposals was being coordinated at the very top of the Department.

- 4.238. [DHSC0046962\_066] is a minute dated 9 November 1990 from Dr Rejman to me, copied to Ronald Powell. It provided Dr Rejman's comments on the proposed scheme of compromise and suggested areas for amendment. There is a handwritten note at the top of the document which reads "(Draft to be amended!)". It is therefore by no means clear to me that I would ever have seen this version of this document.
- 4.239. [DHSC0046962\_061] is a minute dated 12 November 1990 from Dr Rejman to me. It provided Dr Rejman's comments and suggested areas for amendment in respect of the proposed compromise. I believe this document to be the final (as sent) version of the draft dated 9 November to which the Inquiry has also drawn my attention above.
- 4.240. [**DHSC0003654\_101**] is a note dated 12 November 1990 from Ronald Powell to me, which gave his comments on the Plaintiffs' counsel's proposals.
- 4.241. [DHSC0046962\_028] is a submission dated 12 November 1990 from me to Charles Dobson and William Waldegrave. It is stated to be the further advice on the proposed scheme of compromise promised by Charles Dobson in his submission of 9 November. It set out "our considered assessment of those provisions which present difficulty". As explained in my statement above and to the best of my recollection, I would have drafted this submission by providing the views of the branch, as the section with responsibility for the policy aspects of the litigation, and collating the comments sent to me by the copy recipients of the submission, such as Dr Rejman's and Ronald Powell's comments of the

- 12 November to which the Inquiry has referred me. I would not have been in a position to assess the proposals or provide the substantive comments alone.
- 4.242. [DHSC0003654\_115] is a submission dated 23 November 1990 from Charles Dobson to William Waldegrave. It provided briefing material for a meeting the following week with the Treasury. I was not a copy recipient. I can see that the briefing was stated to consist of a number of items, including "[the] text of the plaintiffs' proposal and Mr Canavan's analysis". As noted in my statement above, I believe it is reasonable to assume that this is likely to be a copy of the 12 November submission referred to above. As I have explained in relation to that submission, although I was responsible for the drafting, the "analysis" would not truly have been mine alone but rather a collation of the views of my branch and others, on potential issues with the proposals, presented in a coherent way for the benefit of Ministers.
- 4.243. [DHSC0003654\_015] is a minute dated 12 December 1990 from Dr Rejman to me, copied to Dr Pickles and Ronald Powell, which commented on counsel's draft proposals, and reiterated many of his previous criticisms of the Plaintiffs' proposals as set out in his minute of 12 November.
- 4.244. [DHSC0003963\_015] is a minute dated 13 December 1990 from Richard Gutowski (in the MCA litigation unit). I appeared at the very end of a list of copy recipients. The other recipients and copy recipients appear to be predominantly medical and legal professionals. It provided some views on the settlement from the MCA perspective and invited comments from the recipients.
- 4.245. [DHSC0003655\_047] is a minute dated 13 December 1990 from R Provan to me, which provided a suggested amendment to the terms of the settlement.
- 4.246. [DHSC0003655\_021] is a minute dated 18 December 1990 from me to R Provan, which attached a further draft of the settlement terms and drew his

attention to counsel's view on whether to "spell out the extent of the social security disregard" and asked for clarification on some other details in relation to social security disregards.

- 4.247. [DHSC0032267\_082] is a minute dated 8 January 1991 from me to Charles Dobson and Parliamentary Branch. The copy recipients were Ronald Powell, Dr Rejman, and Roger Tyrell in the AIDS Unit. It was stated to attach a suggested reply to a parliamentary question on the proposed settlement of the litigation. The proposed reply is not included in the version provided to me by the Inquiry, but has been shown to me by my advisors [DHSC0032267\_083].
- 4.248. [DHSC0003657\_094] is a minute dated 10 January 1991 from R Provan to me, which provided comments upon the latest version of the draft proposals.
- 4.249. [DHSC0003657\_106] is a minute dated 10 January 1991 from me to Ronald Powell. It was stated to include the latest draft of the agreement "annotated with our comments". The annotated draft has not been included in the version shown to me by the Inquiry, but has been shown to me [DHSC0003657\_107]. I surmise from context that "our" in this context can be taken to mean the comments of policy colleagues, which were being provided to the departmental solicitor so that he could incorporate them into further drafting. It also gave a brief summary of our social security colleagues' views on the heads of agreement. The minute in paragraph above 4.248 set out these views in full.
- 4.250. [DHSC0003657\_022] is a minute dated 30 January 1991 from me to Ronald Powell, copied to Charles Dobson and Dr Rejman. It provided further comments upon the draft terms of settlement and the draft trust deed. It was written using the plural "we" throughout, which I take to mean that it was conveying overall policy views to the departmental solicitor, rather than expressing my own personal views in the singular.

- 4.251. [DHSC0020866\_010] is a minute dated 30 January 1991 from Charles Dobson to me, copied to Ronald Powell, Dr Rejman, and Peter Kendall. It provided an update following a meeting on the subject of settlement of the "medical negligence cases". I consider it likely, although I cannot now be sure, that the main purpose of this minute being directed at me would have been to put me on notice of the fact that (as per paragraph 3) a submission to Ministers, which I may have been tasked with drafting, might be necessary on this issue in short time, and to keep me abreast of developments which may have been included in any such submission.
- 4.252. [DHSC0041438\_009] is a minute dated 30 January 1991 from me to the Parliamentary Branch, with a copy list that included Charles Dobson, Dr Rejman, Ronald Powell, Christine Bendall (another departmental solicitor) and Richard Gutowski. The minute stated that it attached a revised briefing to replace previous briefing, updated to take account of press reports that haemophiliacs were ready to accept the settlement offer.
- 4.253. [DHSC0002432\_092] is a note dated 30 January 1991 titled "Briefing for the leader...HIV/haemophilia-line to take". It is not clear who the author is. I believe that this was probably the note which was stated to be attached to my minute of the same date to Parliamentary Branch outlined above.
- 4.254. [DHSC0003658\_092] is a letter dated 6 February 1991 from John Williams of the Macfarlane Trust, to me, copied to Ronald Powell, in relation to a letter which had been sent to the Plaintiffs by their solicitors. The handwriting on the left of the document is probably mine, but I cannot be sure.
- 4.255. [DHSC0105650\_022] is a minute dated 12 February 1991 from Ronald Powell to me. It set out some issues with the social security disregard and asked that I sought the views of the Department of Social Security.

- 4.256. [DHSC0105650\_021] is a minute dated 14 February 1991 from me to R Provan, copied to Ronald Powell. It was stated to enclose a report of a recent discussion between the Plaintiffs' solicitors and those of the Department on the subject of the social security disregard. The report has not been enclosed with the copy which the Inquiry has provided to me, but it could well be the minute from Ronald Powell on 12 February noted above.
- 4.257. [DHSC0003658\_054] is a minute dated 21 February 1991 from me to Ronald Powell. It recorded that I "discussed with Mr Dobson the outcome of our discussion yesterday with DSS". I have not seen a note of that discussion, but it was evidently about the social security disregard proposed by the DSS, and whether it would be acceptable to the Plaintiffs for the purposes of settlement.
- 4.258. [DHSC0003377\_005] is a minute dated 27 February 1991 from Ronald Powell to David Burrage. Dr Rejman and Charles Dobson are copy recipients. It related to some points arising from a conference with counsel. It recorded that Ronald Powell had asked me "to make some inquiries as to how much leeway we had on the question of costs since no specific figures had been mentioned by the Treasury".
- 4.259. [DHSC0003659\_064] is a minute dated 5 March 1991 from Dr Rejman to Dr Pickles, that provided an update following the court hearing on 1 March 1991. I was a copy recipient along with Charles Dobson, Ronald Powell, Richard Gutowski and David Burrage.
- 4.260. [DHSC0004523\_087] is a minute dated 6 March 1991 from Charles Dobson to Ronald Powell, Dr Rejman, myself and David Burrage, that confirmed action points arising from a discussion held the previous evening.
- 4.261. [DHSC0003659\_042] is a minute dated 7 March 1991 from Ronald Powell to me, copied to Dr Reiman and Charles Dobson. It provided options for the

definition of a "stable relationship" for the purpose of eligibility criteria and gave his view of what formulation he preferred and why.

- 4.262. [DHSC0003659\_043] is a minute dated 7 March 1991 from me to Ronald Powell, with Charles Dobson and Dr Rejman as copy recipients. It related to the terms of an undertaking to be given by non-litigants.
- 4.263. [DHSC0003368\_015] is a minute dated 13 March 1991 from me to Ronald Powell, copied to Charles Dobson and Dr Rejman. It summarised the outcome of a discussion between Charles Dobson and myself on the criteria for judging whether a haemophiliac and their partner were cohabiting in a stable relationship.
- 4.264. [DHSC0003659\_017] is a minute dated 14 March 1991 from Ronald Powell to Charles Dobson, with me as a copy recipient. It related to the question of whether non-plaintiffs should be at liberty to pursue an action against the health authorities after the main settlement.
- 4.265. [DHSC0003660\_040] is a submission dated 22 March 1991 from me to the William Waldegrave, which provided an update on the progress towards settlement of the litigation.
- 4.266. [DHSC0003661\_083] is a minute dated 4 April 1991 from me to Ronald Powell, copied to Charles Dobson and Dr Rejman. It provided comments on a draft letter to counsel. The use of the plural "we" throughout the minute suggests that the comments had come from Charles Dobson, Dr Rejman, and me.
- 4.267. [**DHSC0003661\_061**] is a fax dated 8 April 1991 from Ronald Powell to me. It is a handwritten draft of a briefing for the Secretary of State, which gave lines to take on the progress towards settlement of the litigation.

- 4.268. [DHSC0006473\_049] is a submission dated 8 April 1991 from me to William Waldegrave. It covered briefing giving lines to take on the progress towards settlement of the litigation, which had been derived from the draft provided by Ronald Powell.
- 4.269. [DHSC0041209\_050] is a minute dated 15 April 1991 from Charles Dobson to Parliamentary Branch. It enclosed briefing for the Prime Minister in relation to a Sunday Times article which alleged that the Government was responsible for delays in payments to haemophiliacs. I am one of a number of copy recipients, to be copied "o/r" (on return) suggesting I was not in the office when this briefing was drafted and sent.
- 4.270. [DHSC0105653\_040] is a document entitled "NOTES OF PROPOSED DETAILED TERMS OF SETTLEMENT DATED 16<sup>TH</sup> APRIL 1991". It is not clear who the author was, but it is mostly written in the plural "we", suggesting that it contained comments from more than one person, possibly following a meeting or conference with counsel (as many of the comments appear to come from Justin Fenwick). A comment from me appears on the second page of the document.
- 4.271. [DHSC0003662\_124] is a submission dated 18 April 1991 from Charles Dobson to William Waldegrave, which invited the Secretary of State to give authorisation to officials to make a final offer to the solicitors for the Plaintiffs in the HIV/haemophiliac litigation, and to make payments to individual Plaintiffs upon receipt of a letter of discontinuation. I was one of a number of copy recipients, to be copied "o/r" (on return) suggesting I was not in the office when this briefing was drafted and sent.
- 4.272. [**DHSC0003662\_090**] is a submission dated 19 April 1991 from Charles Dobson to William Waldegrave. It was stated to be a revised version of the submission

dated 18 April 1991. I am one of a number of copy recipients, to be copied "o/r" (on return) suggesting I was not in the office when this briefing was drafted and sent.

- 4.273. [DHSC0003662\_079] is a letter dated 22 April 1991 from William Waldegrave to David Mellor, who was the Chief Secretary to the Treasury, which expressed surprise at the line the Treasury was taking on the costs of the settlement of the litigation. My name, as well as David Burrage's name, were handwritten on the face of the document, which suggests to me that we were provided with copies.
- 4.274. [DHSC0003662\_080] is a minute dated 22 April 1991 from William Waldegrave's Principal Private Secretary to Charles Dobson, which conveyed approval of the proposals set out in the submission on 19 April 1991, and asked for a detailed note on the position of other patients who were "alleged to have been infected by contaminated blood but are not haemophiliacs". I was one of a number of copy recipients.
- 4.275. [DHSC0003662\_076] is a minute dated 23 April 1991 from Ronald Powell to Charles Dobson, summarising a conversation with Justin Fenwick about the draft of the terms of settlement. I was a copy recipient. There is a handwritten note at the top of the minute, which was marked for my attention, and stated "I have spoken to Ron Powell to say I disagree with paras 2 and 6". I believe it to have been written by Charles Dobson.
- 4.276. **[DHSC0006927\_071**] is a minute dated 26 April 1991 to me from Peter Kendall, on the need to inform Parliament of the developments in the settlement, by way of a PQ.
- 4.277. [DHSC0001942] is the main settlement agreement dated 26 April 1991.

- 4.278. [DHSC0003662\_005] is a minute dated 29 April 1991 from Ronald Powell to me. It was stated to include a full copy of the current version of the terms of settlement, although this has not been provided with the copy shown to me by the Inquiry, nor have those advising me been able to locate it. Given the date of the minute, it may well have been the version dated 26 April 1991. There is a handwritten cc list on the document, with a note to indicate that those recipients should send any comments to David Burrage as soon as possible. This suggests to me that on this occasion, David Burrage, rather than myself, took responsibility for collating comments from policy colleagues.
- 4.279. [DHSC0003560\_028] is a minute dated 30 April 1991 from David Burrage to Charles Dobson and Parliamentary Branch. I was a copy recipient along with Ronald Powell and Dr Rejman. The minute attached briefing notes and lines to take on the HIV haemophilia settlement, and HIV infected blood transfusion recipients.
- 4.280. The documents show that decision-making in terms of the settlement was being done at a very high level, with key decisions being referred to the Secretary of State.
- 4.281. The actual drafting of the settlement was undertaken by lawyers. Departmental solicitors, in particular Ronald Powell, took a lead, in concert with the Plaintiffs' solicitors, and both sides' counsel.
- 4.282. From a departmental policy perspective, there would have been a need to ensure that the settlement reflected what Ministers were happy to agree to, and that the settlement agreement would operate as intended. To that end, it would have been necessary to circulate various drafts, as well as other questions and issues arising, amongst policy and medical colleagues, as well as legal colleagues, for their views. The branch in which I worked would have been responsible for such circulation, and the co-ordination of responses, which may

have come from across the Department depending on what specific issue in relation to the settlement was being discussed. These comments and views would then be fed back to the lawyers for incorporation within the drafting.

- 4.283. A good example of this process which can be found in the documents to which the Inquiry has drawn my attention is the minute dated 6 March 1991 from Charles Dobson to Ronald Powell, Dr Rejman, myself and David Burrage, confirming action points arising from a discussion held the previous evening [DHSC0004523\_087]. That minute further stated that if policy issues arose from comments made upon the draft Trust deed, Ronald Powell would revert to me. Although I have no recollection of this specific exchange, I understand that the purpose of him doing so would have been so that I could ensure the views of my branch and any other interested policy colleagues were fed into the drafting process.
- 4.284. Because of this co-ordinating role, I (and others within the branch) would have been very familiar with the various drafts of the settlement agreement at the time they were being circulated, as well as a departmental view, and the policy aims surrounding settlement. It appears on the face of some of the documents to which the Inquiry has drawn my attention I provided a view. For example, in my minute dated 18 December 1990, I provided my thoughts on the extent of the social security disregard in the case of children [DHSC0003655\_021]. Further, in my minute to Ronald Powell dated 7 March 1991, I gave a view on the terms of the undertaking to be given by non-litigants (that I understood that the undertaking would be to refrain from court action against the Central Defendants but would be free to pursue clinical negligence actions against the Health Authorities) [DHSC0003659\_043].
- 4.285. I do not specifically recall any instances of doing this, but it would have been possible, given my involvement in the collation of views, and my knowledge of the underlying policy aims, for me to notice points which I considered worth raising, and in those circumstances I would do so. I was not, however,

responsible for the drafting of, or advising on, the settlement agreement. That was a matter for both sides' legal teams.

#### Q79: Scottish and Northern Irish settlement

- 4.286. I am asked what role, if any, I played in advising on the terms of settlement applicable to the Plaintiffs in Scotland and/or Northern Ireland.
- 4.287. In responding to this question, the Inquiry has asked me to consider a number of documents, which I set out and summarise below.
- 4.288. [DHSC0003664\_173] is a submission dated 14 December 1990 from Strachan Heppell to William Waldegrave. I was a copy recipient along with Charles Dobson, Ronald Powell, and Ramola Christopherson. It updated the Secretary of State on the position with progress towards settlement in Scotland and Northern Ireland. It set out that the Scotlish Home and Health Department and the Northern Ireland Department of Health and Social Services were dealing directly with the Plaintiffs' lawyers. It further set out that the working assumption was that the matter would be settled on a UK basis, and that money would not be released to Scotland or Northern Ireland until the litigants had signed up to the same arrangements as in England and Wales. This submission demonstrates the very high level at which decisions on this issue would have been taken.
- 4.289. [DHSC0003657\_108] is a letter dated 9 January 1991 from myself to Jack Scott, in the Northern Ireland Department of Health and Social Services. It enclosed a draft of the proposed terms of settlement, along with updates about the likely timetable for settlement and potential approaches to non-litigant haemophiliacs.
- 4.290. [DHSC0003657\_026] is a minute dated 25 January 1991 from me to Charles Dobson and William Waldegrave, copying in other Ministers, Sir Christopher

France, Sir Donald Acheson, and others. It enclosed a draft reply to a letter from the Scottish Office [DHSC0003657\_026]. The submission came from me, but the draft would have been created with input from policy and legal colleagues. The distribution list for this submission demonstrates the very high level at which decisions relating to the Scottish (and Northern Irish) settlements were taken and authorised.

- 4.291. [SCGV0000232\_114] is a letter dated 5 February 1991, from George Tucker in the Scottish Home and Health Department to me, which attached a draft of the proposed detailed terms of settlement for the Scottish litigants. It invited comments upon the draft, however the comments sought would not have been my personal comments, but the Department's comments, following circulation to policy and legal colleagues.
- 4.292. [SCGV0000232\_038] is a letter dated 13 February 1991 from George Tucker in the Scottish Home and Health Department to me. It indicated that the Scottish Home and Health Department had received some Ministerial correspondence (which was not attached to the version of this document shown to me), and requested a note on the latest position in respect of the drafting of the proposed settlement, and the timetable for the outstanding steps.
- 4.293. [SCGV0000232\_094] is a letter dated 20 February 1991 from George Tucker to me. It was stated to attach a further draft of the proposed settlement following discussions between Scottish departmental solicitors and the Plaintiffs' solicitors in Scotland. It invited comments upon the further draft, but as with the letter above, my understanding is that what would be sought would be comments from the Department, not comments from me personally.
- 4.294. [DHSC0003660\_074] is a letter dated 21 February 1991 from George Tucker to me. It raised two issues identified by Scottish lawyers that "they consider are policy issues", and asked for views on these. As with the letters above, my view

is that the author of this letter was not seeking my personal view, but a policy view from the Department, which I would have obtained by giving the view of my branch and consulting with colleagues.

- 4.295. [SCGV0000233\_117] is a minute dated 13 March 1991 from Rab Panton to George Tucker, with copy recipients Mr Henderson, Mrs Towers, and Mr Beaton, who are expressed to be in the Solicitor's Office. I was not a copy recipient and I believe this to have been circulated in the Scottish Home and Health Department. The minute summarised a conversation Rab Panton had with me over the telephone where it appears I provided an update on the progress of the settlement of the litigation from the perspective of the Department of Health.
- 4.296. [SCGV0000232\_076] is a letter dated 20 March 1991 from me to George Tucker. It was a response to his letter dated 21 February, above, and explained that departmental solicitors had by that point considered the points raised by the Scottish lawyers and that the latest draft of the Macfarlane Trust deed took them into account.
- 4.297. [SCGV0000503\_030] is the draft final settlement agreement in relation to the proposed detailed terms of settlement of HIV/haemophilia claims in Scotland. It was dated 5 April 1991.
- 4.298. [DHSC0003100\_002] is a minute dated 1 May 1991 from me to Ronald Powell, with Charles Dobson and Dr Rejman as copy recipients. It stated that Ronald Powell should go ahead with making the formal offer to the Plaintiffs. It also spoke about having considered the Keith Park letter of 29 April, and of being persuaded by Simon Pearl's arguments. I have not been shown either the Keith Park letter or Simon Pearl's arguments and so I cannot comment on what relation, if any, they may have had to settlement in Scotland or Northern Ireland.

- 4.299. [DHSC0003664\_165] is a minute dated 20 June 1991 from Robin Feline to me, with a copy list including Charles Dobson, Ronald Powell, and Dr Rejman. It confirmed that "policy and finance people in Scotland and finance in Northern Ireland" did not have any objection to the apportionment of £5 million in respect of Plaintiffs' costs on the basis of the number of Plaintiffs involved.
- 4.300. [DHSC0044584\_103] is a minute dated 11 October 1991 from me to Anthony Merret, with Charles Dobson as a copy recipient. It related to a Scottish proposal to extend the definition of "Category G plaintiff". It suggested that "we" (by which I take to mean policy colleagues within the branch in which I worked) were content with the proposal but sought the views of Anthony Merrett.
- 4.301. Much like with the main settlement agreement, my role in relation to the terms of settlement in Scotland and Northern Ireland would have been largely one of co-ordination, in that my branch would have been the central point of contact through which communications between the various departments and offices would flow.
- 4.302. As can be seen in the documents to which the Inquiry has drawn my attention, I would have kept the other Health Departments updated on the progress of the settlement negotiations. For example, my letter to Jack Scott dated 9 January 1991 provided updates about the likely timetable for settlement and potential approaches to non-litigant haemophiliacs to the Northern Ireland Department of Health and Social Services [DHSC0003657\_108]. Solicitors from the Department of Health would also have kept in touch with the solicitors from the other Health Departments.
- 4.303. As the documents show, it was important to Ministers that the settlement agreements operated in the same manner, and that in that sense the settlement would operate on a UK basis. However, the terms may have needed to be different to reflect differences in the jurisdictions. Close co-ordination was

therefore required between the Department, the Scottish Home and Health Department and the Northern Ireland Department of Health and Social Services.

4.304. If any doubts arose about how the settlement should be interpreted, the Scottish Home and Health Department or the Northern Ireland Department of Health and Social Services would raise this with the Department of Health to avoid any unwanted repercussions. This process can be observed in my letter to George Tucker dated 7 January 1991 where it is apparent that the Plaintiffs' solicitors in Scotland had suggested that the Plaintiffs "should be given six months to accept the settlement offer" and the Scottish Home and Health Department had requested the Department's views on this proposal [DHSC0003657\_115]. The letter was copied to Charles Dobson, Dr Rejman and Ronald Powell, indicating that the response incorporated the views of these colleagues, which were then conveyed in my final letter to George Tucker. A further example can be seen in my minute to Anthony Merrett dated 11 October 1991, where it is clear that the Scottish Home and Health Department had written to the Department with a revised proposal on the definition of "Category G plaintiff" for the Department's consideration and agreement [DHSC0044584 103].

4.305. Most of the substantive amendment and comment on the draft settlements for Scotland and Northern Ireland would have come from legal professionals, both departmental and within the Scottish Home and Health Department and the Northern Ireland Department of Health and Social Services. I did not have specific responsibility for advising on the terms of settlement applicable to the Plaintiffs in Scotland and/or Northern Ireland.

Q80: Waiver

4.306. The Inquiry has asked me to consider the provision within the terms of the settlement that those agreeing to it would be required to waive their right to bring further litigation against the Government in connection with infection with HIV or hepatitis viruses through the use of blood products.

- 4.307. In addressing this question the Inquiry has asked me to consider a number of documents, which I have set out and summarised below.
- 4.308. [DHSC0003654\_032] is a draft of the Terms of Agreement. It was attached to a minute dated 11 December 1990 from Charles Dobson which was sent to me, as well as Dr Rejman, Dr Pickles, and Ronald Powell [DHSC0003654\_036]. As the Inquiry has requested, I have looked in particular at paragraphs 6 and 7 (on pages 7 and 8 of the draft) and these could conceivably be my handwritten notes on this copy. The comments in Charles Dobson's minute dated 11 December 1990 clearly relate to the clinical management cases and not the development of the waiver.
- 4.309. [DHSC0003655\_022] is a draft of the Terms of Settlement which is marked as being "Revised as at 18/12/90 Noon". Paragraphs 5 and 7 of this draft mention the waiver. It appears that this was the draft that I forwarded to R Provan in my minute dated 18 December 1990 [DHSC0003655\_021]. That minute provided comments on the social security disregard and there was not any mention of the waiver.
- 4.310. [**DHSC0003657\_114**] is a draft of the Terms of Settlement dated 7 January 1991. Paragraphs 5 and 8 of this draft mention the waiver.
- 4.311. [DHSC0032267\_082] is a minute dated 8 January 1991 from me to Charles Dobson and Parliamentary Branch, with Ronald Powell, Dr Rejman and Roger Tyrell (AIDS Unit) as copy recipients. That minute is stated to having enclosed a suggested reply to a Parliamentary Question, which has not been included in the copy shown to me by the Inquiry. However, the minute itself makes clear that the contents of that suggested reply related to the fact that settlement discussions were ongoing with the Plaintiffs' lawyers, and the detailed

provisions were not yet finalised. I believe the attachment was likely to be [DHSC0032267\_083].

- 4.312. [DHSC0004523\_091] is a draft of the Terms of Settlement which is dated 21 January 1991. Paragraphs 5 and 8 of this draft mention the waiver.
- 4.313. [DHSC0004766\_068] is a minute dated 22 February 1991 from Dr Rejman to Ronald Powell. I was a copy recipient along with Charles Dobson and Dr Pickles. It set out Dr Rejman's understanding, following a conversation with Dr Peter Kernoff of the Royal Free Hospital, that HIV positive haemophiliacs would have to agree not to raise hepatitis in any further litigation, but that would not stop haemophiliacs not in the scheme from raising hepatitis infection in litigation.
- 4.314. [DHSC0003660\_019] is a draft of the Terms of Settlement dated 22 March 1991. Paragraphs 5 and 8 of this draft mention the waiver.
- 4.315. [DHSC0003661\_021] is a covering letter dated 16 April 1991 from Mark Mildred of Pannone Napier, to Ronald Powell. It attached an amended draft of the Terms of Settlement dated 16 April 1991 [DHSC0003661\_022]. I have looked at paragraphs 5 and 8 in particular, and the marginalia next to it. I am not able to recognise the handwriting.
- 4.316. [SCGV0000233\_040] is a draft of the Terms of Settlement which is dated 22 April 1991. Paragraphs 5 and 8 of this draft mention the waiver.
- 4.317. [SCGV0000233\_038] is a minute dated 24 April 1991 from Justin Fenwick to Ronald Powell. It attached a draft of the Terms of Settlement and set out the changes counsel had made (and his rationale for those changes).

- 4.318. [DHSC0045721\_004] is a draft of the Terms of Settlement which is dated 24 April 1991. Paragraphs 5 and 8 of this draft mention the waiver.
- 4.319. [HSOC0023174] is a letter dated 26 April 1991 from Ronald Powell to the Plaintiffs' solicitors that invited settlement and attached the final settlement agreement of the same date. Paragraphs 5 and 8 included the terms of the waiver.
- 4.320. [MACF0000086\_225] is the undertaking to be given by an individual under the deed of the Macfarlane (Special Payments) (No.2) Trust.
- 4.321. [INQY1000204] is a transcript of Dr Rejman's oral evidence to the Inquiry dated 11 May 2022. In responding to this question, I have looked at pages 1 to 28 in particular. Dr Rejman was clear in his evidence that he was not the "architect" of the waiver, but understood by the time of his minute of 22 February 1991 that it was the intention that such a waiver be included. Dr Rejman was not able to recall how he became aware of such an intention, nor precisely from whom it originated.
- 4.322. [INQY1000213] is a transcript of Justin Fenwick QC's oral evidence to the Inquiry dated 9 June 2022. I have looked in particular, as requested by the Inquiry, at pages 146 to 178 and 193 to 205. It would appear from page 156 of this transcript that it was Mr Fenwick's understanding that the inclusion of hepatitis within the waiver was first expressed by an amendment proposed by the Plaintiffs' solicitors.
- 4.323. The inclusion of the waiver, and its terms, were mainly matters for legal advisors and I have no recollection of being involved in the drawing up of the precise terms of the settlement generally, or the waiver specifically. I am unable to recall

any discussions about the waiver, its existence or how it should be framed. I am unable to assist with the question of how the waiver developed, and from the documents made available to me it does not appear as though I had any involvement in that process at all.

- 4.324. The Inquiry asks the extent to which I consulted with Ministers while developing the waiver provision. I do not recall any such consultation. It is possible I provided briefing about the state of play with regards to the settlement negotiations as they were ongoing, for example my minute of 8 January 1991 to Parliamentary Branch in respect of a Parliamentary Question about the settlement [DHSC0032267\_082]. However, I do not recall any specific consultation that I engaged in with Ministers on the waiver.
- 4.325. I was not aware of any suggestion of a quid pro quo between the waiver provisions extending to claims for hepatitis viruses and the Government disregarding payments under the settlement for the purposes of determining eligibility for social security payments. As I recall, earlier payments for the HIV infected haemophiliacs had been disregarded for social security purposes and if this was not done for the litigation settlement, the value of the settlement would have been reduced.

#### Q81: Issues following finalisation of the settlement agreement

- 4.326. I am asked the extent to which I provided advice on issues arising from the settlement of the litigation, following finalisation of the settlement agreement. I am further asked what the key issues were for Ministers and the Department in making sure the agreement would operate as intended.
- 4.327. In answering this question, the Inquiry has drawn my attention to a number of documents, which I set out and summarise below.

- 4.328. [DHSC0003654\_117] is a document which appears to be dated sometime in November 1990, and sets out some proposed heads of compromise in respect of the litigation. It looks as though it emanated from the Plaintiffs (either their solicitors or counsel) but this is not clear. It evidently pre-dates settlement of the litigation.
- 4.329. [DHSC0003100\_002] is a minute dated 1 May 1991 from me to Ronald Powell, with Charles Dobson and Dr Rejman as copy recipients. It stated that Ronald Powell should go ahead with making the formal offer.
- 4.330. [DHSC0003398\_026] is a submission dated 1 May 1991 from Charles Dobson to William Waldegrave. There is a long copy list which includes Strachan Heppell, Ronald Powell, and Dr Rejman, among others. I appeared towards the end of the copy list. It informed the Secretary of State that the solicitors had been authorised to make the offer to the Plaintiffs via their solicitors, and that it was expected that the new Trust would be set up before the end of that week. It signposted that an inspired Parliamentary Question and press release would be following, along with advice on a reply from the Chief Secretary of the Treasury.
- 4.331. [DHSC0003560\_020] is a minute dated 2 May 1991 from David Burrage to Charles Dobson and Parliamentary Branch. I was a copy recipient along with Ronald Powell, Dr Rejman, Anthony Merrett and Mr Thompson. It attached briefing for the Prime Minister on countering any allegations of delay on the HIV haemophilia litigation settlement and a background note on the issues.
- 4.332. [DHSC0041254\_114] is a minute dated 10 May 1991 from Ronald Powell to me. It provided details of an individual Plaintiff's circumstances. It contained his legal analysis of the position of the Plaintiff in circumstances where there is a question about his entitlement, or the entitlement of his former spouse, under

the terms of the settlement. I was asked whether I agreed with Ronald Powell's view on how to resolve the issue.

- 4.333. [NHBT0000062\_064] is a minute dated 13 May 1991 from me to Charles Dobson and Parliamentary Branch, copying Ronald Powell, Dr Rejman, Anthony Merrett and Mr Thompson. It attached briefing for the Prime Minister on the settlement of the litigation.
- 4.334. [DHSC0004356\_036] is a minute dated 20 May 1991 from me to Ronald Powell and Dr Rejman, with Charles Dobson as a copy recipient. It asked for thoughts on a procedure for dealing with any doubtful cases which may be referred by the Trust to the Secretary of State for decision.
- 4.335. [DHSC0006927\_038] is a minute dated 21 May 1991 from me to a long list of recipients including policy, legal, and medical colleagues, as well as the Northern Ireland Department of Health and Social Security, the Scottish Health and Home Department, and the Welsh Office. It was stated to attach a draft of an inspired Parliamentary Question (which I believe to be [DHSC0006927\_039]) and invited comments from the recipient list. It is clear from the minute that this is not the first draft, and an earlier draft has already been circulated and comments collected and incorporated. Handwritten comments, possibly from Charles Dobson appear on the minute and the draft response.
- 4.336. [DHSC0004356\_027] is a minute dated 22 May 1991 from Dr Rejman to me, in a response to my minute of 20 May. It suggested that in doubtful cases where a medical view was needed, a panel comprised of the Haemophilia Reference Centre Directors would be suitable.
- 4.337. [DHSC0004356\_026] is a minute dated 28 May 1991 from me to Dr Rejman, in response to his minute of 22 May 1991, and which suggested that as a courtesy

he could mention to the Haemophilia Centre Directors that we might seek their advice.

- 4.338. [DHSC0039826] is a minute dated 4 July 1991 from Isolde Doyle, a departmental solicitor to me, copied to Dr Rejman. It dealt with an issue in relation to whether two particular Plaintiffs fell into a particular category. Ms Doyle gave her view, and asked me for mine.
- 4.339. [DHSC0003114\_005] is a submission dated 12 August 1991 from me to William Waldegrave, copied to Strachan Heppell, Charles Dobson, Mike Brownlee and Anthony Merrett. It sought approval to top-up the Macfarlane (Special Payments) (No 2) Trust, and guidance on whether to pursue a bid for additional funding for the original Macfarlane Trust from the Treasury for 1992/1993.
- 4.340. [DHSC0027374] is a minute dated 6 September 1991 from Ronald Powell to Isolde Doyle in relation to a particular Plaintiff and a dispute about whether a young person between the ages of 16 and 18 who is on the "YTS" scheme is to be regarded as in "further education" for the purposes of administration of the settlement. There was a reference within the minute to having discussed the issue with me.
- 4.341. [DHSC0003635\_025] is a collection of documents. There are two letters (dated 26 March 1992 and 9 April 1992) from Ronald Powell to the Macfarlane Trust. There is also a minute dated 7 April 1992 from David Burrage to Ronald Powell, copying myself and Dr Rejman, which gave the departmental view on a particular case of an infected intimate, and how to approach the issue of proof. There is a further minute dated 9 April 1992 from Ronald Powell to David Burrage, which informed him that he would write to the Macfarlane Trust upon the lines of the 7 April minute.

- 4.342. [DHSC0003542\_008] is a collection of documents. It includes minutes which were dated between 1 July 1993 and 16 July 1993, which show a conversation between Martin Cantrell, who was a departmental solicitor, and David Burrage, on the subject of an application upon which the Macfarlane Trust wished to refer to the Secretary of State for a Decision. The letter which requested such a referral and the underlying papers were also included. There is also one minute from David Burrage to Dr Rejman, with me as a copy recipient. I am not copied into any of the other minutes or letters, although it is clear from the contents of the minutes that I had been involved in the discussions relating to this case.
- 4.343. As can be seen from the documents set out above, following finalisation of the settlement agreement, there were occasions when issues arose as to the interpretation of that agreement, in particular issues in respect of what category a specific claim should properly be regarded as falling into.
- 4.344. The collection of documents from July 1993 provides an illustrative snapshot of how this process would have worked. The Macfarlane Trust, upon receiving a claim which they had difficulty categorising, would have forwarded it to departmental solicitors with a covering letter explaining the difficulty. The departmental solicitor would consider the issue and provide details of their view to officials within my branch, for agreement or further comment. I, and others within my branch, would have been well placed to provide such a view as our involvement in obtaining and collating views during the settlement process meant that we were very aware of the policy intention in respect of how the settlement was meant to operate. If a case were particularly contentious, or raised particular difficulty, it would be possible to get authorisation from a more senior official for a proposed course of action. I can see that this was considered in the July 1993 example to which the Inquiry has drawn my attention, but in the end, it was considered unnecessary in this case [DHSC0003542\_008]. I cannot recall any specific examples of when a case was referred to a more senior official.

4.345. In terms of Ministerial priorities, my recollection is that the key issue which was raised with Ministers was the need to get approval to "top-up" the funding of the various Macfarlane Trusts to allow them to meet their ongoing payment commitments.

#### Disclosure and document destruction during the HIV litigation

# Q82: Decision-making, advice and DH processes for document disclosure in the HIV litigation

- 4.346. The Inquiry has asked me to address the extent to which I was involved in decision-making and giving advice about document disclosure in the HIV litigation, and what the Department's process was in making and certifying these decisions.
- 4.347. In answering these questions, the Inquiry has drawn my attention to a number of documents, which I summarise and set out below.
- 4.348. [DHSC0043289] is a minute dated 6 July 1989 from Jayant Desai in the Treasury Solicitor's Department, to Ronald Powell. It requested lists of documents which the Government Defendants were willing to disclose, or unwilling to disclose on the grounds of public interest immunity or otherwise. It is worth pointing out here in my statement that Jayant Desai's request for these lists of documents that the Government Defendants were willing and unwilling to disclose were specifically in relation to the application for pre-action disclosure in the case of GRO-A. These were not lists of documents to be disclosed or withheld in the HIV litigation. This issue is explored further in my statement below.
- 4.349. [DHSC0006401\_087] is a minute dated 14 July 1989 from Charles Dobson to Alan Barton in the AIDS Unit, copied to Ronald Powell, Dr Rejman, Richard

Gutowski and myself. It set out advice from Ronald Powell that the Department should be preparing for disclosure by identifying and listing all the documents likely to be relevant to the HIV litigation, and asked Alan Barton to perform this exercise within the AIDS Unit.

- 4.350. [WITN5292093] is a minute dated 17 July 1989 from Ronald Powell to me, which attached a minute from the Treasury Solicitor's Department with some questions in respect of pre-action disclosure in the GRO-A case. Ronald Powell's covering minute suggested the likely responses to those questions.
- 4.351. [DHSC0006481\_030] is a minute dated 19 July 1989 from me to Ronald Powell. It is a handwritten set of comments on a number of issues that included directions, costs, and discovery. On discovery there were comments that "[from] my own viewpoint the advice to Ministers is something we would certainly want to withhold if this were possible under public interest immunity...There would be no point in trying to withhold items which could not be covered by that immunity".
- 4.352. [DHSC0006481\_020] is a minute dated 21 July 1989 from Dr Rejman to Ronald Powell. I was a copy recipient along with medical and policy colleagues. It was stated to enclose a list of documents which may be relevant for disclosure in the HIV litigation, and included details of some categories of document which he may also have held.
- 4.353. [DHSC0040692] is a minute dated 13 September 1989 from Ronald Powell to me, copying Dr Rejman and Mrs Armstrong (SOLC5 and internal Medicines Division legal adviser). It set out the principles applicable to the disclosure process, and public interest immunity.
- 4.354. [DHSC0014905] is a minute dated 13 December 1989 from Ronald Powell to me, copied to Dr Rejman. It was stated to enclose a copy of a letter from Mr

Conway in the Northern Ireland Solicitor's Office which I believe to be [DHSC0019625], and some statements from my predecessor in post, Roger Moore. It advised that these statements not be provided to Mr Conway, as Roger Moore was unlikely to be called to give evidence.

- 4.355. [DHSC0044876] is a minute dated 18 January 1990 from Dr Rejman to me, copied to Dr Pickles, Ronald Powell, Charles Dobson, and Peter Brand (departmental solicitor). It provided a note on a conference with counsel which occurred on 17 January 1990. Point 3 dealt with discovery and public interest immunity.
- 4.356. [DHSC0014940\_020] is a minute dated 23 January 1990 from Alan Barton (AIDS Unit) to John McCracken (AIDS Unit). I was a copy recipient. It dealt with the expectation that public interest immunity would be claimed over officials' advice to Ministers, and the need to ensure that the identity of individual patients was not revealed.
- 4.357. [**DHSC0043400**] is a minute dated 31 January 1990 from me to Peter Brand, copied to Ronald Powell and Dr Rejman. It was stated to enclose the amended list of documents for discovery (this has not been enclosed with the version provided to me by the Inquiry).
- 4.358. [DHSC0046958\_007] is a minute dated 2 March 1990 from Dr Rejman to Dr Rubery dated 2 March 1990, copied to me and Dr Pickles. It set out the advice that the only set of relevant documents which would fulfil the necessary criteria for public interest immunity in this case would be submissions to Ministers and their responses.
- 4.359. [DHSC0014940\_037] is a letter dated 19 April 1990 from Jayant Desai to me, which enclosed a list of CBLA's documents and suggested that we identify

those in respect of which we wished to claim public interest immunity in the HIV litigation.

- 4.360. [DHSC0038699\_048] is a minute dated 14 May 1990 from Dr Rejman to me, which enclosed a note of a court hearing which occurred on 8 May 1990. It provided a timetable for disclosure.
- 4.361. [DHSC0043223] is a note dated 18 May 1990, that was produced by PGB (who I assume from the attendance list to be Peter Brand). It is stated to be a note of a conference with counsel on 18 May 1990. I am listed as having attended, but I do not have any specific recollection of this conference. The note appears to be in very rough form, with short form sentences and some obvious errors (for example the use of the word "destructed" which I take to mean "destroyed"). I would assume that this note captured the gist of counsel's advice from that conference, but given its form and the errors apparent on its face, it is unclear that it accurately captured what was said in that conference.
- 4.362. [DHSC0044139\_108] is a minute dated 3 July 1990 from Dr Rejman to me, which provided a note of a court hearing which took place on 26 June 1990. It recorded comments made by counsel that "it was not just a discretion to claim [public interest immunity] but that it was a duty".
- 4.363. [DHSC0004360\_072] is an advice from counsel dated 4 July 1990. It dealt with the claim to public interest immunity.
- 4.364. [DHSC0004360\_144] is a submission dated 19 July 1990 from me to Sir Christopher France, copied to legal, medical, and policy colleagues including Strachan Heppell. It asked Sir Christopher France to sign a certificate objecting to the disclosure of certain documents on the grounds of public interest immunity. Permanent Secretary approval was needed (rather than that of a Minister) as the documents spanned two administrations. The submission set

out the reasons that public interest immunity was claimed, which in respect of Departmental papers was to protect the inner workings of government, in particular the formation of policy. In the case of the Licensing Authority and CSM, the public interest to be protected was the voluntary reporting system for reporting adverse reactions.

- 4.365. [DHSC0004360\_006] is a minute dated 17 August 1990 from me to Charles Dobson, copied to Dr Rejman and Peter Brand. It outlined the judge's decision on public interest immunity following a conference with counsel, and gave counsel's advice on how to proceed in the event that the Plaintiffs appealed that decision.
- 4.366. [DHSC0046936\_082] is an advice from counsel dated 1 October 1990. The advice dealt with some additional documents which counsel considered fell within the claim for public interest immunity.
- 4.367. [DHSC0014940\_005] is a minute dated 22 November 1990 from David Burrage to a number of medical, legal, and policy colleagues including myself. It attached an action note on the litigation following an office meeting on 20 November 1990 [DHSC0014940\_006].
- 4.368. In relation to the extent to which I was involved in the decision-making and in giving advice about what documents would be disclosed or withheld by the Central Defendants in the course of the HIV litigation, it is my recollection that David Burrage did most of the work in reviewing the documents for the disclosure process. He would have taken advice on particular documents from departmental solicitors, and I would have also provided input in respect of policy papers. It is also evident from the documents provided to me by the Inquiry that I was involved with liaising with solicitors to provide the lists of documents for discovery in the HIV litigation. For example, on 31 January 1990 I sent such lists to Peter Brand [DHSC0043400].

- 4.369. In determining which documents were relevant and which documents could be withheld, whether on the basis of relevance, legal professional privilege or Public Interest Immunity (PII), the documents provided by the Inquiry indicate that I was reliant on guidance provided to me by departmental solicitors and counsel.
- 4.370. Early on in the document disclosure process before advice had been provided by legal colleagues on the circumstances in which documents could be withheld, it is clear that I awaited this advice. The concepts of withholding documents from disclosure in the HIV litigation on the basis of either relevance, legal professional privilege or PII were legal concepts and I was reliant on guidance from legal colleagues in respect of decisions on the same when working with David Burrage on the discovery process. In my minute to Ronald Powell dated 19 July 1989, I noted that:

"From my own viewpoint the advice to Ministers is something we would certainly wish to withhold if this were possible under public interest immunity. For the others I would like to reserve judgement until I know the scope of public interest immunity. There would be no point in trying to withhold items which could not be covered by that immunity. I think you are going to advise us on this question." [DHSC0006481 030]

- 4.371. As set out above, Ronald Powell, who was a departmental solicitor, then provided some advice at the outset of the process as to the general categories which might qualify for a claim of PII [DHSC0040692].
- 4.372. Further on in the process, counsel was asked for his views on the lists which had been created [DHSC0004360\_072]. Ultimately, while the certificate was to be signed by the Permanent Secretary, the approach to what documents could properly be withheld was principally driven by legal advice. We would have followed that advice in assessing which documents fell within the various subcategories of PII justification as set out in the final lists of documents.

4.373. In this case the finalised list of documents to be withheld in the HIV litigation on PII grounds was put to Sir Christopher France for the signing of the certificate [DHSC0004360\_144] (this document provides the certificate, but not the full lists). As a matter of convention, and to protect the integrity of the policy making and advising process, internal departmental papers produced for a previous administration (i.e. for Ministers in a previous government) are not shown to the current administration. Because some of the documents over which a claim for PII was to be made contained advice given to Ministers in a previous administration, it was not possible in this case to seek a ministerial signature, which is why the Permanent Secretary was asked to sign this certificate.

#### Q83: Ronald Powell's minute of 28 June 1989

- 4.374. On 28 June 1989 Ronald Powell in the solicitor's branch sent a minute to me with the subject header "AIDS LITIGATION: GRO-A" [DHSC0004359\_007]. Dr Rejman and Richard Gutowski were copy recipients. The minute was stated to attach a copy of a minute from Jayant Desai at the Treasury Solicitors with another letter referred to in that minute. Neither of those documents are included with the version shown to me by the Inquiry.
- 4.375. In that minute, Ronald Powell observed that:

"The question of what documents are to be disclosed generally, and what are to be kept back (for whatever reason) is not an easy one. The practical and legal problems involved are substantial."

- 4.376. The Inquiry has asked me what "the practical and legal problems involved" in the disclosure of documents in the litigation were. Any response I am able to give to this question must be caveated by the fairly obvious point that I did not write this minute, and so it is not my comment, but rather a statement which was being made to me, by way of advice from a departmental solicitor.
- 4.377. I have been provided with a copy of a letter from Fisher Meredith solicitors to Jayant Desai dated 5 May 1989, which I believe may be a copy of the letter

referred to in Mr Powell's minute dated 28 June 1989 [DHSC0006401\_079]. This letter indicated that Fisher Meredith solicitors were instructed by an individual haemophiliac. GRO-A in respect of his potential medical negligence claim, having developed HIV after treatment with factor VIII. Fisher Meredith requested pre-action disclosure of certain documents possibly held by the Department, the Licensing Authority and the CSM in order to advise their client on the prospects of success of his claim. Given the subject header of the minute from Ronald Powell to me dated 28 June 1989, I believe it may be this pre-action disclosure that Ronald Powell referred to as involving substantial "practical and legal problems" in his minute dated 28 June 1989, not the disclosure in the HIV litigation.

- 4.378. I think it is likely that the letter from Fisher Meredith solicitors to Jayant Desai dated 5 May 1989 is the document referred to as "the application made in the case of GRO-A (code name Richard Roe)" for pre-action disclosure in Jayant Desai's minute to Ronald Powell dated 6 July 1989 [DHSC0043289].
- 4.379. In relation to the application for pre-action disclosure in the **GRO-A** case, Jayant Desai requested in his minute of 6 July 1989 that Ronald Powell provide:

on behalf of each of the three Government Defendants...lists as follows:-

- (i) Documents which you are willing to disclose voluntarily if any;
- (ii) Documents which you are not prepared to disclose on the grounds of public interest immunity. In respect of these documents objection would be based on class and contents of documents and a certificate signed by the Secretary of State may be necessary;
- (iii) Documents in respect of which objection is going to be taken on grounds other than (2) above. The grounds of objection should be stated."
- 4.380. On 17 July 1989 Ronald Powell sent a further minute to me on this subject [WITN5292093]. This minute attached a copy of a minute from Jayant Desai to Ronald Powell. I have been provided with the unredacted copy of this document, which indicates that the minute from Jayant Desai to Ronald Powell

was dated 13 July 1989 and makes reference to the GRO-A case [WITN7115031]. Jayant Desai's minute to Ronald Powell dated 13 July 1989 referred to the fact that "[in] the GRO-A case there is a Summons for Discovery of documents" and that Jayant Desai's view was "that there should be no voluntary discovery in accordance with the Department's policy and that there should be a Court Order." Jayant Desai requested:

"comments on the categories of documents sought to be discovered based on the following points: inter alia:

- (i) whether the documents listed have been at any time in possession, custody or power.
- (ii) whether there are any documents which any of the Defendants is willing to disclose voluntarily.
- (iii) grounds of objection in respect of each category of documents.
- (iv) categories of documents in respect of which public interest immunity is to be claimed."

#### 4.381. Ronald Powell's minute to me dated 17 July 1989 stated that:

"As regards the numbered paragraphs I assume comments will be something like:-

- (i) Documents of all classes in paragraph 9 of Fisher Meredith's letter of 5<sup>th</sup> May have been in the possession, custody or power of the DoH/SoS,
- (ii) we are not prepared to disclose any documents voluntarily,
- (iii) some documents will be privileged because for example they relate to legal advice or were prepared in connection with the litigation. Precisely what objections to disclosure will be raised can only be given when the documents have been examined,
- (iv) this must await detailed examination of the documents." [WITN5292093]
- 4.382. Ronald Powell's minute to me dated 17 July 1989 therefore likely goes some way to explaining the "practical and legal problems" of pre-action disclosure in the GRO-A case referred to in his minute to me dated 28 June 1989, against the background of the HIV litigation. Given that the documents relevant to both the HIV litigation and the GRO-A case had not yet been properly examined, it appears that the Department would face practical and legal problems with complying Fisher Meredith's application for pre-Action disclosure.

#### Q84: Ronald Powell's minute of 13 September 1989 – order for discovery

- 4.383. On 13 September 1989 Ronald Powell sent a minute to me on the subject of document discovery in the litigation [DHSC0040692]. As set out above, the minute set out some general advice on the principles applicable to the disclosure process and a claim for PII. It asked me whether (in circumstances in which voluntary disclosure had been refused) the Department would be prepared to agree an order for disclosure with the Plaintiffs' solicitors.
- 4.384. My attention has also been drawn to a letter that is referred to in Ronald Powell's minute, which was from the Plaintiffs' solicitors to the Treasury Solicitor dated 11 August 1989 [DHSC0006275\_027]. That letter invited voluntary disclosure (which, as set out, was refused) and was stated to enclose a schedule of documents sought by way of disclosure, which has not been included in the version of this document shown to me by the Inquiry.
- 4.385. I am not able to assist with the response which I provided to Ronald Powell, as I do not recall it and the documents that I have reviewed do not assist. I can say that a decision would have been taken by the Department, informed by legal advice. I may have been responsible for communicating that decision (although without the relevant documents I cannot say), but I would not have been solely responsible for making it.
- 4.386. In relation to who made the decision of whether or not the Department agreed to the order, I am no longer able to recall this information independently. I can see from documents which have been shown to me that it appears that as at 21 September 1989, Ronald Powell, according to a minute addressed to Mike Arthur and copied to Dr Rejman and Charles Dobson (but not to me), that consideration was being given to instructing Justin Fenwick to resist an order for discovery at that stage [DHSC0046937\_071]. The reasoning for that suggestion appears to have been that it would have been preferable to have

waited until after "the preliminary issue has been settled". However, I can also see that on 6 October 1989, Jayant Desai wrote to Ronald Powell and advised of his view that "Mr Justice Ognall would insist that we give full discovery of documents now" [MHRA0019931].

- 4.387. It is not apparent to me what the final decision was on this issue, nor who ultimately made it.
- 4.388. The Department did decline to voluntarily disclose documents, when requested to do so by the Plaintiffs' solicitors. It is clear from Ronald Powell's minute of 13 September 1989 that, by that date, the Treasury Solicitor had replied to Pannone Napier by letter, saying that the Department was not prepared to make voluntary discovery and that an order had to be obtained [DHSC0040692].
- 4.389. A letter from Jayant Desai to Ronald Powell dated 5 September 1989 referred to a telephone conversation between the two lawyers, and recorded the decision that the Plaintiffs would have to obtain a court order for discovery of documents [WITN7115032]. The letter did not record any reasons being given for that decision.
- 4.390. I am unable to assist on why a request for voluntary disclosure was refused. It may be that there was a departmental precedent in place that voluntary disclosure would not be given and the documents available to me indicate that this was the case. Charles Dobson's minute to Alan Barton dated 14 July 1989 stated that "Precedent suggests that we should not volunteer disclosure but wait until a court order is made" [DHSC0006401\_087]. In addition, my handwritten minute to Ronald Powell dated 19 July 1989 provided that "It was agreed on 4 July that we would follow precedent and not disclose documents voluntarily. However we would cooperate fully once a Court Order has been made" [DHSC0006481\_030].

#### Q85: Guidance provided on public interest immunity

- 4.391. On 18 January 1990 Dr Rejman sent a minute to me which provided a note of a conference with counsel which occurred on 17 January 1990 [DHSC0044876]. That note contained, at paragraph 3(ii), a summary of some guidance given by counsel on the types of documents which should be withheld from disclosure on PII grounds. It stated:
  - "(ii) Public Interest Immunity. Mr Fenwick and the MCA Solicitors are to check through their records of the Opren case to determine what will qualify for exclusion under public interest immunity and require certificates from Ministers. In his view briefing to Ministers and replies from Ministers need not be disclosed at this stage. In particular he feels that any documents indicating a line to take in Parliament should not be disclosed whereas those parts that were formally announced in Parliament can be disclosed. There are other aspects which relate particularly to the Licensing Authority and the MSC. Any correspondence between the UK and Foreign and Military Authorities would also be excluded."
- 4.392. In relation to the guidance that was provided to Dr Rejman and me about what should be withheld from disclosure under PII during the HIV litigation, as set out above, Ronald Powell, departmental solicitor, also provided guidance in his minute of 13 September 1989 [DHSC0040692].
- 4.393. Later, on 4 July 1990, counsel provided written advice on PII [DHSC0004360\_072]. As well as dealing with various categories of documents, the substance of that advice was that where a document was protected by PII, the Department or person concerned had no discretion, but was under a duty to claim PII. It would then be a matter for the court to decide whether the balance of competing public interests lay in favour of disclosure. I can also see, although I have no specific recollection of this, that at paragraph 18 of his advice, Justin Fenwick indicated that approval on the Department's approach to PII was to be sought by John Laws, who I believe was First Treasury Counsel at the time.

#### Q86: Alan Barton's minute of 23 January 1990

- 4.394. I have been shown a minute dated 23 January 1990, written by Alan Barton of the AIDS Unit, and addressed to John McCracken (also in the AIDS Unit) [DHSC0014940\_020]. I was one of a number of copy recipients.
- 4.395. I should emphasise that I was not the author of this document, nor its primary intended recipient. Additionally, I have no specific memory of the document, so any comments I am able to make upon it are based upon my reading of it now, some 32 years later.
- 4.396. The document dealt with the AIDS Unit's production of lists of documents which might be relevant to the HIV litigation. It outlined a conversation Alan Barton said that he had with me. He stated:
  - "2. I was very surprised to see documents which appear to constitute officials' advice to Ministers in the list. Such advice is always regarded as confidential and I would expect us to claim public interest immunity against discovery of such documents. I have spoken to Mr Canavan HS1 and he has confirmed that he expects this to be the case. He thinks that it would be difficult to claim such immunity for other documents and has suggested that we provide two lists one advice to Ministers (on which public interest immunity would be claimed, except in the case where the document was clearly innocuous), and the other listing documents we would expect to be subject to discovery. Mr Canavan's section will then consolidate into master lists."
- 4.397. The Inquiry has asked me what I considered to be a "clearly innocuous" document. I cannot be sure that I used that phrase, but it seems clear to me that the Department would hold many documents which did not touch on issues of policy making. I was clear at the time, based upon legal advice on the issue, that only certain limited classes of documents would be covered by PII. Just because a document constituted communication between officials and Ministers did not mean that PII should be claimed over the document. For example, a Ministerial response to an enquiry which had been published, would be "clearly innocuous", as its disclosure and use in court proceedings would not prejudice the public interest in protecting effective policy making and

governmental operations. By a "clearly innocuous" document I therefore likely meant documents that were not in fact policy making advice to Ministers or similar that would not be subject to PII.

4.398. In terms of the process described in Mr Barton's minute where he stated that two lists were to be provided, which my section would then consolidate into "master lists". The lists referred to in that document were specifically lists drawn up by the AIDS Unit of documents they held, and documents they held which they considered might attract PII. The "master lists", which would have contained all of the documents from across the Department of potential relevance to the HIV litigation and in respect of which the Department wished to claim PII, were scrutinised by the departmental solicitors. If there was any uncertainty, counsel would be asked for their views.

#### Q87: Ronald Powell's minute of 31 January 1990

- 4.399. I sent a minute to Ronald Powell on 31 January 1990, with Dr Rejman as a copy recipient [DHSC0046948\_005]. It was stated to enclose a list of documents which had been identified so far for disclosure purposes within the HIV litigation [DHSC0001432].
- 4.400. The minute further stated that work was still being completed on a separate list of Ministerial papers over which a claim for PII would be made. The Inquiry has asked me whether [DHSC0000265] is that list. That document appears to be undated, and so I cannot say whether it was the version of the list which was in existence on 31 January 1990 when my minute to Mr Powell was sent, but I do believe it is a (working) copy of such a list.
- 4.401. My minute to Mr Powell dated 31 January 1990 went on to state that "I think it would look bad if we tried to throw PII over all our documents". Although I do not specifically recall making this comment, I believe that the reasoning for it

can be more readily understood by looking at it in the context in which it appeared in the minute:

"As you know, we have not scrutinised many of the documents which are listed. You were to advise on whether we could put the list forward and subsequently claim PII or whether we had to put in a protective claim for all the documents at this stage. If it is the latter, we should be able to identify some which we needn't cover in this protective claim as I think it would look bad if we tried to throw PII over all our documents." [DHSC0046948 005]

4.402. We were, as I have set out previously in this section of my statement, very aware that PII could only be claimed over limited documents. The reasoning behind this comment appears to me to be that it was important to ensure that at the point that such a claim needed to be made, proper consideration had been given to the individual documents over which PII was to be claimed. It appears that at the point this minute was written, I considered there were likely to be documents within the list that, following careful scrutiny, could be removed from a claim for PII. It would be illogical for the Department to be seen to be making a claim for PII over documents which, when scrutinised, could be shown not to attract such an immunity.

# Q88: Conference between DH officials and DH legal representatives on 18 May 1990

- 4.403. On 10 May 1990, Jayant Desai from the Treasury Solicitor's Department wrote to me, informing me that a conference had been arranged with counsel (Andrew Collins QC) to discuss the question of PII [DHSC0043761]. It was suggested by him that I attended, along with Ronald Powell and/or Peter Brand (departmental solicitors).
- 4.404. I have no specific recollection of this conference, but I understand from documents provided to me by the Inquiry that a note was taken of this conference [DHSC0043223]. As I have set out earlier in this section, that note is in very rough form, and appears to contain some errors (of terminology, at least). I was not the author of the note, and having no recollection of the

conference itself I cannot attest to its accuracy. The note of the conference is signed off with the initials "PGB" which I assume, from the attendance list at the conference, meant that Peter Brand was the author of the note.

- 4.405. I am asked by the Inquiry to provide what assistance I can on two comments which appeared in the note. It is not clear to whom they were attributed and the author of the note appears to have noted down comments made in the conference without making clear who said them or if there was any response from other attendees.
- 4.406. The first is "[we] must stop destruction on the date the litigation comes on". I do not recall this comment being made nor who made it. It is likely to have been a general reminder that documents relevant to the litigation should be preserved as soon as the Department became aware of it (and any routine destruction policies disapplied). The note indicates that several DH officials were in attendance at the conference who were not legally qualified, including myself, and one of counsel or the departmental solicitors in attendance (I cannot say with any certainty who because of the rough nature of the note) was likely reminding us of the duty the Department was under in respect of preserving documents relevant to the litigation.
- 4.407. The second is "Hepatitis virtually nothing. Most of it has already been destructed". Again, I do not recall this comment being made, nor who made it. My general recollection is that there was a dearth of documents available on hepatitis. Much of the reason for that was because the documents stretched back many years, before the litigation began or could have been foreseen. As the conference was on the subject of PII, "[hepatitis] virtually nothing" was likely to be a comment to reflect the fact that there would not have been many documents in the Department's possession on the topic of hepatitis that would have attracted a claim for PII.

- 4.408. "Most of it has already been destructed" was likely a comment related to the fact that, in the circumstances where there were so many of the documents related to hepatitis were historic, potentially relevant documents could well have been destroyed by 1990 in line with the general departmental guidance about the retention and destruction of documents at a time when the litigation was not foreseen by the Department. As previously emphasised the note of the conference on 18 May 1990 provided by the Inquiry is clearly very rough and its contents appear disorderly. It contains some clear errors, such as "[most] of it has already been destructed". It is therefore of limited reliability in respect of providing an accurate record of what was discussed at the conference on 18 May 1990.
- 4.409. The Inquiry has asked me to specify what classes of documents had "already been destructed", by whom and why. Aside from the general comment that there would have been departmental guidance relating to the retention and destruction of documents, I am unable to assist with this question. The general management and organisation of the disclosure exercise in the HIV litigation was carried out by David Burrage, and my involvement would have been limited. As set out above at paragraph 4.61, I managed David Burrage and would have had general oversight of his work, for example making sure deadlines were met. However, I would not necessarily have been sighted on every detail of his work.
- 4.410. Likewise, I would not have known under what authority or policy documents had been destroyed. The Inquiry has phrased its question to suggest that documents were "being destroyed" (at the time of the conference in May 1990), but my reading of the note is that the discussion was focused on things which had been destroyed in the past under departmental guidance on the retention and destruction of documents at that time (before the litigation was contemplated and before my time working in blood services).

- 4.411. I cannot recall whether or not there were retention policies in place specifically for "litigation documentation" as distinct from the generality of record keeping in place at the time of this conference.
- 4.412. I was not aware of any of the Central Defendants intentionally destroying documents for the purpose of ensuring that they were not disclosed as part of the HIV (or other) litigation. Had I been so aware, I would have been very concerned and I would have raised strong objection to any such suggestion or conduct through appropriate channels.
- 4.413. I was also not aware of any of the Central Defendants seeking to abuse the PII process by claiming PII without proper reason in order to avoid disclosure of documents that might harm their case or otherwise cause embarrassment. On the contrary, it is my understanding from reading of counsel's advice dated 4 July 1990, that the opposite was true [DHSC0004360\_072]. Page 8 of that advice, under the heading "DISCUSSION" stated:
  - "4. It is clear from the authorities that where documents are protected by public interest immunity, the department or person concerned has no discretion but is under a duty to claim the privilege. It is then a matter for the court to decide whether the balance of the competing public interests lies in favour of or against disclosure. There is nothing in the documents that I have seen which I would expect to have any significant adverse effects on the case to be put forward on behalf of the Central Defendants in this litigation. Indeed, many of them may be helpful in explaining the careful consideration which was given to various matters at the time. However, that is not the point."
- 4.414. This point was reiterated and made explicit in my submission to Sir Christopher France dated 19 July 1990, which asked him to sign the PII certificate:
  - "Where documents are protected by public interest immunity, Departments have no discretion but are under a duty to claim the privilege. The plaintiffs have the right to challenge the claim and it is then a matter for the Court to decide whether the balance of the competing public interests lies in favour of, or against disclosure.
  - 6. In the view of Counsel our claim is stronger in relation to some documents than others...However, Counsel takes the view there is nothing in any of the documents he has seen that would have any

significant adverse effects on our defence in the litigation. Indeed many of the documents may be helpful in showing the careful consideration given to various matters at the time." [DHSC0004360\_144]

4.415. In other words, it was made clear to the Department and Sir Christopher France that it was not open to the Central Defendants to choose to disclose helpful documents which would otherwise attract a claim of PII. It is also worth emphasising, as stated in my submission dated 19 July 1990, that documents over which PII were claimed were scrutinised by the court to determine whether the balance of competing public interests favoured their disclosure. Any improperly claimed documents would therefore presumably have been swiftly discovered. I am reminded by my legal advisors that the Court of Appeal approved the Department's approach to PII in this litigation, albeit that the Court decided on the application of the balancing exercise that some documents fell to be disclosed.

#### Q89: Miss Wheeler's minute of 23 May 1990 - PES bids and CBLA papers

- 4.416. The Inquiry has provided me with a copy of a minute dated 23 May 1990, from Miss Jane Wheeler (Finance Division) [DHSC0046951\_015]. It is sent to me but is stated to be a response to a request from David Burrage, who was coordinating the disclosure exercise. Miss Lynam and Mr Owen were copy recipients. Public Expenditure Surveys were the annual exercises conducted by Finance to obtain bids for funding from across the Department. Funding might have been relevant to the issue of whether CBLA could achieve self-sufficiency in blood products.
- 4.417. It was stated to enclose a copy of relevant papers from the Finance Division's files that were not already on the list of documents for discovery. It went on to say:
  - "2. What we do not have are copies of PES bids from 1975 to 1986 and the history of their success or otherwise. I understand that many if not all of these papers have been destroyed. However, I should be grateful if Miss Lynam and Mr Owen will consider as a matter of some urgency whether there are any papers available which cast some light on official

and/or Ministerial consideration of funding for CBLA particularly with regard to the funding of the new fractionation plant (Phasel)."

- 4.418. I do not know what reason Jane Wheeler had to believe that the documents in question had been destroyed, although I assume it would have been in line with the general guidance on retention and destruction of papers which may have existed in her section at the time. In these circumstances I would not have pursued the matter further.
- 4.419. I do not recall whether Miss Lynam or Mr Owens were able to supply any further papers and I am not able to assist the Inquiry further on this from the documents made available to me in connection with the preparation of this statement.

# Q90: Ronald Powell's minute of 25 September 1990 – North West Thames RHA papers

- 4.420. On 25 September 1990 Ronald Powell sent a minute to me [**DHSC0012659**]. It dealt specifically with the North West Thames Regional Health Authority and their attempts to find further relevant documents for the litigation. Ronald Powell noted to me that:
  - "2. Peter Brand has spoken very recently to North West Thames Solicitors who at the meeting we had I think in February of this year, said that they would be looking to see whether they had any further documents that might throw any light on the issue of liability."
- 4.421. To the best of my recollection, the searches of the North West Thames Solicitors did not yield any further documents "that might throw...light on the issue of liability", but I cannot now recall.
- 4.422. The Inquiry has asked a number of sub-questions about Ronald Powell's minute dealing with practical matters in relation to the storage of documents. This process would have been managed by David Burrage and I do not believe I would have known the answers to these questions if they had been asked of me at the time and certainly I am unable to assist now.

- 4.423. Mr Powell noted to me in his minute that he was at "Eileen House recently going through some of the documents that were the subject of the public interest immunity claim". I do not know whether all of the documents which were the subject of the PII claim were kept at Eileen House, as opposed to just some. I do not know if documents were stored elsewhere, nor where elsewhere they would have been stored.
- 4.424. I can see that on 8 November 1990, David Burrage advised me and Ronald Powell that copies of the category 4(1) documents were "in the room set aside at New Court" [DHSC0046397] (paragraph 5). I do not now know for what purpose this room was set aside, nor why documents were stored there or for how long. New Court is where the departmental solicitors were based, so it is likely that the reason why these documents were being kept at New Court is because the departmental solicitors needed to access them. David Burrage's minute dated 8 November 1990 does not suggest that New Court was the permanent place of storage of these documents, just that they were presently being kept in a room at New Court.
- 4.425. There may well have been a policy which had to be followed in relation to the storage of documents in the HIV litigation, but as I was not managing the discovery process, I cannot now recall what this was.
- 4.426. I am unable to assist on whether the documents were marked as to be retained for a specified period of time.

#### Q91: "Action note of meeting on 20 November 1990 between DH officials

4.427. I have seen an action note from a meeting held on 20 November 1990, which was attended by departmental officials [DHSC0014940\_006]. It would appear that I attended the meeting as I am listed as a recipient of the action points list

on David Burrage's minute which circulated it dated 22 November 1990 [DHSC0014940\_005]. However, I have no recollection of this meeting.

- 4.428. The action note records that EHF1A, which was the section within which I worked, was "to provide 2 copy sets of discovery and PII documents to SOLB3 for storage/access in room 515A New Court".
- 4.429. I am unable to assist with the question of whether my section did provide two copy sets of discovery and PII documents as described. The task of providing such documents would have fallen to David Burrage as he was managing the disclosure process and presumably he would have provided them as I do not remember any reminders or queries in relation to their non-appearance, which as his manager I would have expected to receive if such a task was not carried out.
- 4.430. Similarly, I am unable to assist with questions in relation to whether there was a specific policy for storage of those documents, or whether the documents would have been marked for retention for a specified period of time.

#### Q92: Destruction of documents by the CBLA/Clifford Chance

4.431. On 12 July 1991, Ronald Powell sent a minute to me, copied to Charles Dobson, Richard Gutowski, and Dr Rejman [DHSC0003664\_190]. It enclosed a letter dated 26 June 1991 from Clifford Chance, who acted for the CBLA [DHSC0006269\_122]. I have no independent recollection of these documents or their contents.

#### 4.432. The letter from Clifford Chance stated:

"Following the final settlement hearing in open Court, I would be grateful if you could confirm whether the following documents should be returned to you, or destroyed by us:-

(i) The discovery of the Department of Health (39 volumes);

- (ii) Discovery of the Committee on Safety of Medicines (1 volume);
- (iii) The documents which were the subject of the Department of Health's application for public health interest immunity privilege, subsequently ordered to be disclosed (8 volumes)." [DHSC0006269 122]
- 4.433. Ronald Powell's minute to me dated 12 July 1991 asked whether I was "content for the CBLA [to] destroy everything and tell us via their solicitors that they have done so?" [DHSC0003664\_190]. It should be noted that the documents held by the CBLA/Clifford Chance were copies of documents which originated within the Department (and, it appears, one volume of CSM material). None of the documents listed by Clifford Chance would have been unique copies (let alone the originals), and destruction of the copies held by the CBLA/Clifford Chance should not be read as destruction of the documents in their original form. Further, it is my understanding, and it appears clearly to have been the understanding of Clifford Chance, that the terms of the settlement required that documentation was either returned or destroyed.
- 4.434. I can see that I responded on the 15 July 1991 and confirmed that I was content for the CBLA to destroy the documents [DHSC0006269\_120]. I also (in the same response) requested to know whether we had any returns/confirmation of destruction from the Plaintiffs' solicitors. Clifford Chance confirmed that they had destroyed the documents on 7 August 1991 [DHSC0003641\_012].
- 4.435. I believe Ronald Powell would have directed the query outlined in his minute of 12 July 1991 on whether the documents held by the CBLA/Clifford Chance could be destroyed because I was the departmental budget holder for the CBLA, and their point of contact within the Department.
- 4.436. I cannot recall whether I consulted anyone else within the Department before communicating the decision for the CBLA/Clifford Chance to destroy the documents they had. I do note that the minute from Ronald Powell of 12 July 1991 is copied to a number of others, including my branch head, Charles

Dobson, so they would have been aware of the proposal. Normally, although I cannot say for certain whether it happened in this case, I would have checked with the CSM about the position in relation to the volume of papers held by the CBLA/Clifford Chance which originated with them.

4.437. The decision to destroy the documents would have been taken in accordance with the undertaking, which I believe was contained within the main settlement agreement. Because none of the documents held by the CBLA/Clifford Chance were originals, and were copies provided for the purposes of the litigation, it would have been clear that there would have been nothing in those files that was not contained in the litigation files already held by the Department. I did not therefore conduct any further checking to ensure that the Department had retained copies.

# Q93: Pannone Napier passing discovery documents to J Keith Park & Co Solicitors – blood transfusion litigation

- 4.438. On 15 October 1991 Ronald Powell sent a minute to me, copied to Dr Rejman [DHSC0002900\_002]. It enclosed a letter dated 23 September 1991 from Pannone Napier Solicitors, where they confirmed to the Department that they had passed the discovery documents from the HIV litigation on to J Keith Park & Co Solicitors to enable them to be used in the blood transfusion litigation [DHSC0002900\_003]. That minute expressed Ronald Powell's view that he considered it likely that Pannone Napier had acted in breach of the agreement to either destroy or return the Department's documents in the main settlement agreement in the HIV litigation, but that any such breach was unlikely to be serious as J Keith Park & Co would already have copies of all the relevant documents, and would hold them subject to the same undertaking.
- 4.439. I can see that I responded on 23 October 1991 [**DHSC0003640\_046**]. It is clear from the first line of the minute that a conversation about this topic took place prior to my writing of this minute. I can see that I stated:

"I am concerned that we should keep firm control over who has access to the haemophilia litigation documents, as provided under the terms of the settlement. Otherwise they may be given an ever widening circulation and eventually some snippets could reach the media. It may be difficult to pinpoint the source but in any case taking action against that party may not undo the damage."

4.440. I am asked by the Inquiry, insofar as I can recall, why I had such concerns. The documents which had been disclosed in the HIV litigation were so provided on the understanding that they would not be shared further or used for any other purpose. Many of the documents disclosed within the HIV litigation would be documents which did not reach the threshold for a claim for PII, but were nonetheless documents which would usually be withheld from public view. If snippets of documents of this type became available to the media, there was a possibility of "mischief making" by the media, or reputational damage, particularly if any such snippets were misunderstood or taken out of context.

# Q94: Dr Rejman's request for preservation of papers in respect of the PII discussions – Lord Justice Scott's Inquiry

- 4.441. On 30 November 1992 Dr Rejman sent a minute to Dr Hangartner [DHSC0017884]. I was not a copy recipient of this minute and it is unclear to me whether I would ever have seen it at the time. The subject matter of the minute appears to be "Lord Justice Scott's Enquiry", which I understand to have been likely to pertain to an Inquiry into arms sales to Iraq. I am informed that the use of PII certificates was one of the issues that was being examined in that Inquiry, particularly (in that context) in relation to certificates signed on the basis of national security.
- 4.442. Dr Rejman set out in that minute that he had an interest (in, I assume, the issue of PII) because in the HIV haemophilia litigation PII certificates were signed (he says in the minute by Ministers, but in fact it was by the Permanent Secretary), "and a procedure was developed between DH and Counsel over what papers should be covered by PII certificates". I assume that by that comment he was referring to the advice that was received and the discussions which were had

on the subject of PII between DH officials and counsel. He further mentioned the fact that the Court of Appeal agreed with the Department's conclusion that Ministers had a duty to sign PII certificates in respect of certain papers.

- 4.443. On 7 December 1992 Dr Hangartner sent a minute to Dr Reed, with Dr Rejman and Mr Schofield as copy recipients [**DHSC0017883**]. I was not a copy recipient of this minute, but it does seem likely I would have seen it at the time, as there is a handwritten note from Dr Rejman to me and Ronald Powell on the bottom of this copy, suggesting it was passed to me following receipt by Dr Rejman.
- 4.444. The minute, and the handwritten note at the top from Dr Hangartner, suggest that it seemed unlikely, but possible, that if Lord Scott's Inquiry was to look at issues of PII in a wide sense, then papers surrounding the PII decision-making process in the HIV haemophilia litigation might be interesting and/or relevant to that investigation, and ought to be preserved "just in case".
- 4.445. The handwritten note to me and Ronald Powell from Dr Rejman asked that we "ensure that any papers we have in respect of the PII discussions are kept secure and not destroyed".
- 4.446. The Inquiry has asked me, to the best of my knowledge, what was the reason for Dr Rejman asking me to do this at the time. I have no specific recollection of this, but it is clear from the papers I have summarised above that it was believed that the thinking which had gone on between the Department and our counsel in respect of PII during the HIV litigation might be of interest to Departmental Officials, and/or Lord Justice Scott, if his Inquiry was going to include an investigation into the use of PII generally. I assume that is because it was a recent use of PII certificates, in high profile litigation, and a lot of complicated thought and work had gone into the process of claiming PII and the use of certificates for the same, the process for which had been approved by the Court of Appeal.

4.447. I cannot recall whether I took any particular steps following this communication to ensure that these papers were not destroyed. My understanding is that file copies would already have been, and were, retained on registered files as a matter of usual practice on policy sections. Dr Hangartners' minute refers to a wider range of papers that Dr Rejman held personally which should be retained, for example extracts from medical publications, that may be relevant to the litigation.

#### Q95: Removal of Hepatitis C files for "discovery"

4.448. The Inquiry has drawn my attention to a file note dated 1 November 2010 [DHSC0003581\_001]. The file note stated:

"This file series has been set up to store rediscovered documents from the 1980s and 1990s on the development of testing for hepatitis C antibody in blood donations.

A number of registered files from those years were found to have been emptied, and a label attached to the front reading "Entire contents of this file removed for 'discovery'". There was litigation on this subject at that time, and these documents appear to have been removed and provided to DH solicitors as part of the legal process."

- 4.449. I am unable to assist with why these documents were no longer available in their files, after having been *"removed for discovery"*.
- 4.450. In terms of the process that was usually followed for the filing and retention of documents which had been removed during the discovery process, my understanding is that normally the documents would be returned to their files after their use for discovery. Originals would not have been given to the Plaintiffs' solicitors but may have been sent elsewhere for review within the Department, for example if they were being scrutinised for a PII claim.

#### Q96: Destruction of papers relating to the HIV litigation

- 4.451. The Inquiry has asked me when I was made aware that papers from the Department relating to the HIV litigation had been destroyed. I have been referred to two documents, which I summarise below.
- 4.452. [WITN4505389] is the Third Written Statement of Charles Lister OBE, provided to this Inquiry and dated 19 May 2022. The passages to which the Inquiry has drawn my attention, paragraphs 3.6 to 3.9, deal with the discovery in the Department that certain papers relating to the HIV litigation had been destroyed. Here Mr Lister states that either in March 2002 or earlier in October 2001 he was told that ministerial submissions relevant to the HIV litigation had been extracted and sent to the Solicitor's Division. It appears that the understanding at that time, or at least by 10 June 2003, was that sometime in the mid-90s, the papers marked for PII during the discovery process in the HIV litigation were destroyed in a "clear out" by departmental solicitors. The passages also deal with Charles Lister's personal recollections of the steps he took at that time to recover the documents.
- 4.453. [DHSC0020720\_081] is the email dated 10 June 2003 from Charles Lister to Zubeda Seedat, which contains the understanding set out in Charles Lister's written statement in relation to what happened to the relevant ministerial submissions, as set out in the preceding paragraph.
- 4.454. As far as I can recall, reading the papers provided by the Inquiry for the purposes of drafting this statement is the first time I became aware that papers from the Department relating to the HIV litigation had been destroyed.
- 4.455. It would appear that the discovery in the Department that the papers from the HIV litigation had been destroyed took place at some time between October 2001 and June 2003, well after I ceased to have any role whatsoever in relation to blood policy. I am therefore unable to assist with what steps were taken by

the Department to discover how and why the Department papers relating to the HIV litigation had been destroyed or who had destroyed them, and I certainly played no role in any investigation that occurred.

#### Q97: Lists of PII documents in the HIV litigation

- 4.456. The Inquiry has drawn my attention to three documents which demonstrate the way that the documents over which the Department claimed PII in the HIV litigation were divided into categories.
- 4.457. [DHSC0002333\_004] is a certificate dated 23 July 1990 signed by Sir Christopher France. The certificate itself indicated (paragraph 3), that there were around 600 documents over which the Department considered a claim for PII needed to be made. It then set out and described the various categories of documents over which the claim was made.
- 4.458. [CBLA000001\_011] is a transcript of a judgment which was given on 31 July 1990 in the chambers of Mr Justice Rougier. It was the initial judgment on the Department's claim PII. It upheld the claim for PII in certain classes, and ordered disclosure in others, albeit with qualifications which would have required further selection of documents from within certain classes.
- 4.459. [RLIT0000657] is the report of the appeal of the above judgment on the question of PII, which was heard by the Court of Appeal on 20 September 1990. The Court of Appeal's judgment emphasised (page 10) that the Department was not claiming PII to put difficulty in the way of the Plaintiffs, but because it had a duty to do so "in support of the public interest in the proper functioning of the public service, that is the executive arm of government". It is further stated that the Plaintiffs acknowledged the validity of the claim to PII, but asked the court to order production notwithstanding the valid claim, as they argued that the public interest in disclosure outweighed the public interest in protecting the documents. Whilst it upheld the approach of the Department to PII, the Court

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of Appeal did order disclosure of documents in wider categories than the judge at first instance.

- 4.460. I have been further referred to a number of lists which are stated by the Inquiry to be lists of documents from each category over which a claim for PII was made.
- 4.461. [BPLL0016040\_011] is a list of documents which were to be the subject of a claim for PII under category 1(1). This was stated to be exchanges between Ministers, either directly or through their private secretaries, relating to policy formation. 162 documents appeared on this list.
- 4.462. [BPLL0016040\_012] is a list of documents which were to be the subject of a claim for PII under category 1(2). This was stated to be exchanges between senior officials of the Civil Service which formed part of the process by which submissions, draft submissions and policy documents were brought into being. 264 documents appeared on this list.
- 4.463. [BPLL0016040\_013] is a list of documents which were to be the subject of a claim for PII under category 2. This was stated to be groups of documents which related principally to papers prepared in the mid-1970s to consider ways and means of expanding the NBTS to achieve self-sufficiency, the majority of which would have required a Ministerial decision in due course if they were to be pursued. 38 documents appeared on this list.
- 4.464. [BPLL0016040\_014] is a list of documents which were to be the subject of a claim for PII under category 3. This was stated to be ministerial briefings and draft parliamentary answers on a variety of topics. 35 documents appeared on this list.

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- 4.465. [CBLA0000042\_038] is a list of documents which were to be the subject of a claim for PII under category 4(1). This was stated to be guidance prepared for Ministers ahead of important meetings (but not including the minutes of those meetings). 20 documents appeared on this list.
- 4.466. [BPLL0016040\_016] is a list of documents which were to be the subject of a claim for PII under category 4(2). This was stated to be draft replies prepared with comments from officials for Ministers on policy and operational matters. 22 documents appeared on this list.
- 4.467. [BPLL0016040\_017] is a list of documents which were to be the subject of a claim for PII under category 5. This was stated to be documents relating to individual cases of hepatitis. The PII certificate signed by Sir Christopher France stated that "[the] interest to be protected is that of our voluntary reporting system for adverse reactions...which depends on the willingness of medical practitioners to provide information about their patients in the cause of the improvement of medical knowledge, in the clear belief that the information provided will be kept in the strictest confidence and will not be passed to third parties in any form by which their patients might be identifiable." [DHSC0002333\_004]
- 4.468. As far as I am able to ascertain, I believe it is highly likely that these lists are a complete list of the documents over which a claim for PII was made. They cover every "category" of document in respect of which a claim was made. However, most of the lists which have been shown to me have been separated from the PII certificate, and are presented as individual undated documents. It is not impossible that some of them might be drafts, to which items were later added or removed. I could therefore not say with absolute certainty that these are the finalised lists, but I believe it is likely that these are the lists which were attached to the signed certificate and put before the Court.

#### **Q98: Lost Macfarlane Trust waivers**

- 4.469. The Inquiry has referred me to a chain of correspondence from April 2007 between DH officials [DHSC5468582]. The email chain indicates that officials in the Department at that time had discovered that certain signed Macfarlane Trust waivers had been lost and possibly inadvertently destroyed. I understand that these were the waivers signed by haemophiliacs when the HIV litigation settled and provided that those accepting settlement would not take legal action against the Department or any other public body in respect of infection with HIV or hepatitis as a result of infected blood products. It appears that DH colleagues were preparing draft responses to Parliamentary Questions from Jennifer Willott MP on issues connected to this in light of the Archer Inquiry [DHSC5468584].
- 4.470. I was not aware that some of the signed Macfarlane Trust waivers had been lost or destroyed in the Department before reviewing the documents provided to me by the Inquiry in connection with the preparation of this statement. Ted Goff's email to Phillip Davison dated 23 April 2007 referred to "earlier PO correspondence last year" which indicated that the Department "could not find the signed waivers because some files were inadvertently destroyed" [DHSC546852]. It appears therefore that it was first discovered in the Department that some of the signed Macfarlane Trust waivers had been lost in 2006, which was a long time after I left the Department. I cannot assist the Inquiry with when, why and by whom the signed waivers were destroyed.

#### Q99: Reflection on how DH handled the HIV litigation documentation

4.471. I am asked to reflect upon how the Department handled the HIV litigation documentation. My view, although I cannot recollect specific issues or lessons which could have been learned from this case, is that there are always lessons to be learned from an exercise of this nature. Many of the officials involved would have been dealing with litigation for the first time. Even for those who were not, litigation comes in many forms with many different complexities, and

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this kind of damages claim was not something those within my branch were likely to have dealt with before. At the time I believe everyone involved within the Department was doing their best, and those on the ground don't always have advantages of hindsight.

### **General questions on the HIV litigation**

### Q100: Behaviour of the Central Defendants in the HIV litigation

4.472. At the time of the HIV litigation, I was not concerned that the Central Defendants were behaving dishonestly, inappropriately or other than in accordance with their duties to the Court. On the contrary, as explained in my statement above, PII was only claimed in circumstances where it was relevant and appropriate, with advice first obtained by departmental solicitors and counsel, and to the best of my knowledge documents were destroyed only in accordance with departmental guidance on the retention of such documents. Prompt responses to requests for comment on draft submissions and other requests for information or decisions indicated to me the seriousness with which the matter was being taken within the Department.

#### Q101: Timing and terms of settlement of the HIV litigation

4.473. Looking back on the HIV litigation, I do not have any particular views on how it was handled by the Central Defendants, in particular on whether it could or should have been settled at an earlier point in time and/or on different terms, which were matters for Ministers to decide. I did not have to weigh the consequences of the costs of early settlement in terms of the funds available for other health activities. These were issues for Ministers.

# Section 5: Funding and Management of the Macfarlane Trust

- 5.1. The Inquiry refers me to the following documents:
  - (1) Unsigned letter dated 6 December 1988 from Dr Roger Moore to The Rev'd A Tanner, which expressed Ministers' concern at press reports which suggested that the Macfarlane Trust had not distributed funds efficiently and announced my takeover as Principal of HS1A from 1 January 1989 [DHSC0003311\_012];
  - (2) Report in the *Sunday Times* dated 9 October 1988 which commented on the same issue about the distribution of funds [**HSOC0013432**];
  - (3) Minute from Dr Moore to Jenny Harper, Private Secretary to the then Minister of State for Health, David Mellor, dated 13 October 1988, in response to the *Sunday Times* article [DHSC0003303\_005]. The minute provided a brief overview of the initial organisation of the Trust and highlighted the fact that priority was given to establishing the Trust, with Department and Haemophilia Society solicitors working together to form the Trust deed. The note detailed the number of applications made to date and the allocation policy. Regular payments were made to those on low income as well as single payments for specific items. The suggested line to take was that the Macfarlane Trust had been established as quickly as practicable and that all applications made had been dealt with in a timely fashion;
  - (4) Minute dated 9 November 1988 from the Private Office of the then Secretary of State, Ken Clarke, to Malcolm Harris (HS1) querying the payment arrangements in place at the time [WITN0758025]. Ken Clarke questioned why only £132,000 had been paid out of the £10 million;

(5) Dr Moore's responses to Ken Clarke's queries, dated 17 November 1988 [DHSC0020286]. The responses were as follows:

"Why has only £132,000 been paid out of £10 million?

1. The Trust was only established in March 1988. The initial priority of the Trustees was to contact all potential beneficiaries to establish a likely level of demand whilst formulating an allocation policy. The amount paid out necessarily began slowly but is now rising rapidly as more applications are received and dealt with. The current amount paid out is £200,000 which will double shortly as backdated payments are made to some beneficiaries. All applications need careful scrutiny, a fair number of fraudulent or unrealistic claims have been received.

#### What plans do the Trust have for the £10 million?

2. The Trustees see the need to support dependents of those who die as a major call on the £10 million. They are investigating ways in which they can help with mortgage payments and life insurance. Meanwhile they are increasing the number of beneficiaries receiving weekly maintenance payments and those being given lump sums for holidays, domestic appliances etc.

#### How long do the Trust expect the sums to last?

- 3. The Trustees do not at present have any definite expectations since they have not yet plumbed the total need. They are concentrating on meeting financial need which they are interpreting as alleviating poverty. They are aware that their responsibility to dependents will remain for many years to come. They are responsibly husbanding their resources since they are aware that the Trust might not get anymore money from Government".
- (6) Minute dated 2 December 1988 from David Mellor's Private Secretary to Dr Moore, which acknowledged Dr Moore's response to Ken Clarke and requested that two monthly reports on the activities of the Macfarlane Trust be provided to the Department [DHSC0003311\_014];
- (7) Periodic reports provided to the Department during the course of 1989:
  - (a) Minute dated 10 March 1989 from Mike Arthur (my HEO) to David Mellor's Private Secretary and me, which attached the first monthly

- report of the Macfarlane Trust and included a breakdown of management costs and a summary of grants made [WITN7068005];
- (b) Minute dated 17 March 1989 from Elaine Webb to David Mellor's Private Secretary and me, enclosing the second of the Trust's bimonthly reports [DHSC0003308\_007]; [DHSC0003308\_001];
- (c) Minute dated 21 July 1989 from Mike Arthur to David Mellor's Private Secretary and me which referred to the Trust grant allocation policy and future spending plans, and attached the third report as of 31 May 1989, drawn up by Rev Tanner and a summary of grants made [DHSC0003319\_012]; [DHSC0003320\_004]; [DHSC0002956\_002];
- (8) Letter dated 26 June 1989 from The Rev'd A Tanner to Strachan Heppell requesting an opportunity to discuss the policies intended by the proposed Trust Deed [DHSC0002955\_009]. The Rev'd A Tanner highlighted that the money proposed would not be sufficient to meet the requirements of the Deed;
- (9) Minute dated 5 September 1989 from Mike Arthur to Strachan Heppell and me which referenced a meeting with the Trust later that month on 7 September 1989 [DHSC0003315\_004] The minute attached a background note [DHSC0003318\_006] and agenda;
- (10)Draft, undated letter addressed to The Rev'd A Tanner and attached to Strachan Heppell's submission of 14 September 1989. The draft letter related to the availability of additional funds for the Macfarlane Trust for people with haemophilia and HIV, and their dependents [DHSC0003317 001];
- (11)Minute dated 22 September 1989 from David Mellor's Private Secretary to Strachan Heppell, which communicated the Ministers agreement to the proposal in Strachan Heppell's submission that an exchange of letters should take place. The minute noted that the Minister was "personally

most sympathetic to the idea of increasing the fund in due course" [DHSC0003511\_066];

- (12)Letter from Strachan Heppell to The Rev'd A Tanner dated 25 September 1989 attaching a draft letter Strachan Heppell intended to send The Rev'd A Tanner in a formal capacity [MACF0000076\_024];
- (13) The Rev'd A Tanner's response to Mr Heppell's letter dated 12 October 1989, thanking Strachan Heppell for the same and requesting that he include a reference to the recent meeting in September 1989 [MACF0000081 060];
- (14) Handwritten minute from me to Strachan Heppell and the DS Policy Group dated 16 October 1989, reporting back on The Rev'd Tanner's response to the draft letter [DHSC0002952\_006]. I specifically raised my concern that the Trust's suggested amendment to the Deed may have led to misinterpretation; and
- (15)Letter from Strachan Heppell to The Rev'd A Tanner dated 20 October 1989 confirming that he was content with the draft reply proposed by The Rev'd A Tanner in his previous letter and making proposals for amendments to the note of a meeting [MACF0000076\_021].

# Q102: My role in developing policy and overseeing the management of the Macfarlane Trust

5.2. I am asked to describe the role that I played in developing policy and overseeing the management of the Macfarlane Trust in the late 1980s and early 1990s. I am reliant upon the documents referred to in paragraph 5.1 above and the material provided to me by my advisers.

- 5.3. I have been reminded that there were three Macfarlane Trusts. The original Trust was set up to make payments on the basis of financial need. The Macfarlane (Special Payments) and the Macfarlane (Special Payments) (No. 2) Trusts were set up latterly in order to pay the lump sums of £20,000 and the litigation settlements.
- 5.4. I liaised with the Macfarlane Trust generally after I took over HS1A in January 1989. This included liaising with Trustees and Department officials about trustee appointments and providing a channel of communication between the Trust and the Department on issues such as additional funding. I was the first point of contact for the Trust over matters such as future funding. I oversaw the Special Payments Trust's (No. 1) disbursement of the *ex-gratia* payments of £20,000. By early 1991, I was liaising with Department officials about the draft deed for the Special Payments (No. 2) Trust and further funding.

#### Q103: DH's role in the work of the Trust

- 5.5. I am asked to describe the Department's role in overseeing, directing or otherwise influencing the work of the Trust.
- 5.6. The original Macfarlane Trust was run by independent Trustees who set payment policies. This structure underpinned the relationship between the Trust and the Department. As was made clear in the draft response to a question from Harry Cohen MP in April 1990, it was the "responsibility of the Trustees to ensure that payments were made in the most effective way, taking into account the differing circumstances of those affected" [DHSC0003322\_015; DHSC0003322\_016]. The Department's role was to provide support to the Trustees and satisfy itself that the Trust was being run properly, rather than to direct the work of the Trust.

- 5.7. The Department's interests lay in ensuring that the Trust's actions met the intentions Ministers originally had in funding it. My attention has been drawn to the original Trust deed [WITN7115033]. From the Department's perspective, the Trust was set up with a wide discretion given to trustees on how the funds should be invested and administered, subject only to the objects of the Trust (clause 4) and the powers provided for in clause 5.
- 5.8. I have been referred to The Rev'd A Tanner's letter to Mr Heppell dated 26 June 1989 [DHSC0002955\_009]. The tone of The Rev'd A Tanner's letter accurately portrays the role of the Department and its involvement with the Trust. In short, the Trust was independent, but the Trustees reported on its progress to the Department and sought guidance where it wished to do so with regards to formal action and explicitly asked for support on issues such as life insurance. The same can be said for another earlier letter from The Rev'd A Tanner to Strachan Heppell dated 25 May 1989 in which The Rev'd A Tanner thanked Strachan Heppell and the Department for their "helpful and flexible approach to what might otherwise have become major problems" [DHSC0046951\_003].
- 5.9. There were concerns about what appeared to be a slow start to distribution of funds by the Trust in 1988. In December 1988, David Mellor asked for bimonthly reports on the activities of the Trust. The purpose of the reports, as set out in Dr Moore's letter of 6 December 1988 to The Rev'd A Tanner, was to obtain a "more complete picture of the need" with a view to providing additional funding in the future [DHSC0003311\_012].
- 5.10. From recollection, the Department became more involved in the work of the Trust from 1991 when, for example, the Department decided who was eligible for payments under the Macfarlane (Special Payments) (No. 2) Trust. If the

Macfarlane Trust had cases of doubt about eligibility for payment or categorisation then they would be referred to us.

#### Q104: Dr Moore's letter to Rev Tanner, 6 December 1988

- 5.11. The Inquiry asks me about Dr Moore's letter to The Rev'd A Tanner dated 6 December 1988, referred to previously above.
- 5.12. As Dr Moore's letter indicates, I assumed responsibility for liaising with the Macfarlane Trust when I took over as Principal of HS1A. I had access to the general files concerning the Trust once I took over as Principal of HS1A but I would not have read Dr Moore's letter at the time. The same goes for the other correspondence listed in paragraph 5.1 above.
- 5.13. I have read the press article [HSOC0013432]. I have also seen Dr Moore's minute dated 13 October 1988 in which he responded to the Sunday Times article [DHSC0003303\_005]. However, I did not become Principal of HS1A until the following year and so I would not have read either of those documents at the time.
- 5.14. I have been referred to the minute from the private office of Ken Clarke to Dr Moore, dated 9 November 1988 [WITN0758025]. I would not have read this minute at the time.
- 5.15. Similarly, whilst I would not have read it at the time, I have been shown that in his response to Ken Clarke's queries, Dr Moore explained how the initial priority of the Trustees was to contact all beneficiaries to establish a likely level of

demand whilst formulating on allocation policy [**DHSC0020286**]. The amount paid out necessarily began slowly but then rose rapidly as more applications were received and dealt with. It appears that Dr Moore expected the amount paid out at the time of writing in November 1988 (approximately £200,000) to double as backdated payments were made to some beneficiaries.

#### Q105: Two-monthly reports provided by the Trust to DH

- 5.16. The press reports about the speed with which the Trust was distributing money led to David Mellor requesting the bi-monthly reports in December 1988 [DHSC0003311\_012].
- 5.17. The reports from the Trust were straightforward in that they set out the numbers and amounts of payments by category, with reference to the relevant policies being followed. By way of illustration, and with reference to the documents referred to by the Inquiry, the Department would analyse the reports in the following way:
  - a) the report would be received by the Department;
  - b) a note would then be sent to Department officials and to the Minister of Health summarising the contents and attaching the report.
- 5.18. I am aware of one occasion in which a meeting with the Trust followed receipt of a report. Mike Arthur minuted me and Strachan Heppell on 5 September 1989 [DHSC0003315\_004]. He attached a briefing ahead of the meeting on 7 September 1989 [DHSC0003318\_006]. The Trust had sought the meeting to determine whether their activities at the time were in line with the Department's expectations and raised some wider issues.

- 5.19. In so far as the speed of distribution of funds was concerned, there was an initial period (1988 early 1989) when the Trust was being established. This included hiring staff, putting administrative systems in place and agreeing various policies. Once this organisation period was over, there was less concern in relation to the efficiency of the Trust in distributing funds.
- 5.20. As such, The Rev'd A Tanner was probably right to be reassured by the absence of any comment or criticism by Department of the Trust following this initial period (during which concerns were raised by David Mellor). Indeed, the Department was content to involve the Trust in setting up the Special Payments Trust and that was well-received by Trustees.
- 5.21. Concerns were raised by the Trustees within the reports, as set out below, but as far as I am aware, the Department had no concerns as to how the Trust was operating. The concerns raised within the reports can be summarised as follows:
  - the fact that people with AIDS and HIV were almost entirely uninsurable and there was apparently very little which could be done in that regard, as raised by the report dated 10 March 1989;
  - b) the issue of mortgages, which generally required at the very least a Mortgage Protection insurance cover; and
  - the general feeling that the funds would run out in the near future. See, for example, the third report dated to 31 May 1989, where Rev Tanner warned that the final accounts for 1988 1989 would show an excess of expenditure over income and that some erosion of capital had begun [DHSC0003320\_004].

5.22. I am asked what The Rev'd A Tanner might have meant by "regular informal contact" between the Administrator of the Trust and the Departmental staff in his letter of 26 June 1989 [DHSC0002955\_009]. As far as I can recall, this contact was generally by phone or the occasional meeting. In other words, we operated on an informal basis and there was no fixed arrangement.

#### Q106: Rev Tanner's request for a meeting with DH, 26 June 1989

- 5.23. The Inquiry has asked me a series of further questions about The Rev'd A Tanner's letter to Strachan Heppell dated 26 June 1989.
- 5.24. First, I am asked to describe my role in advising on the Department's position and communicating with the Trust. I have set out my response above at paragraph 5.4.
- 5.25. I am also asked for my views on whether the Trust was discharging its responsibilities effectively and responsibly in late 1989.
- 5.26. I understand that the view taken by the Charity Commission in late 1989 complicated the setting up of the £20,000 lump sum payments that were to be paid to those entitled to them. Their concerns reflected to some extent the views expressed by the original Macfarlane Trust.
- 5.27. I was copied into a submission from Charles Dobson to Strachan Heppell and the Private Secretary to then Minister of State for Health, Virginia Bottomley, on 29 November 1989 [DHSC0003849\_065]. Charles Dobson outlined the Charity Commission's views:

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

- 5.28. Charles Dobson's submission outlined that "[the] alternative approach is to set up a new discretionary trust to make the lump sum payments." A further submission from Charles Dobson to Virginia Bottomley dated 19 December 1989 indicated that this was the approach agreed to by Ministers and there had been meetings with the Macfarlane Trust to set up the new discretionary trust (to be called the Macfarlane (Special Payments) Trust):
  - "2. Following MS(H)'s agreement to the proposals in my submission of 29 November we have held further discussions with officers of the Macfarlane Trust about the setting up of a new discretionary trust (the "Macfarlane (Special Payments) Trust") to handle the payments. No fundamental difficulties have emerged but solicitors acting for the Trust in drafting the new Deed have been a little slower than all parties would have wished and some legal points have still to be resolved. We are having a meeting this evening with trustee's and officers of the Trust and their legal advisors, at which we hope to settle the remaining details.

However we understand that it is now very unlikely that the 4 people who will be trustees of the new trust will be able to complete the formalities until after the Christmas break even if a final version of the Deed can to be agreed today. The lump sum payments are therefore likely to begin in early January." [DHSC0046948\_040]

- 5.29. A further submission from me to Charles Dobson and Virginia Bottomley dated 29 January 1990 confirmed "that the arrangements were completed today for setting up the Macfarlane (Special Payments) Trust to administer these payments" and that the Macfarlane Trust planned to begin making the lump sum payments on 31 January 1990 [DHSC0002536\_013].
- 5.30. Further, a minute from Strachan Heppell to me dated 30 January 1990 noted:

- "I was very pleased to see that the arrangements have now been completed for setting up the Macfarlane (Special Payments) Trust to administer the new payments.
- 2. I know that there has been a lot of work involved in getting this done, more than was originally anticipated. But the outcome is very satisfactory since we have been able to carry with us the Macfarlane Trust and the Haemophilia Society.
- 3. Congratulations to you, your staff, to legal finance and medical colleagues and to colleagues in DSS for carrying this through." [WITN5289013]
- 5.31. The need to set up the new Macfarlane (Special Payments) Trust contributed to a short period (between announcement of the lump sum payments in November 1989 and the start of those payments being made in January 1990) where the lump sum payments could not yet be paid to those entitled to receive them, but once this practical issue had been resolved, I personally had no concerns as to the day-to-day functioning of the Trust.
- 5.32. The majority of correspondence between the Department and the Trust related to requests from the Trustees for additional funds. As set out in Strachan Heppell's draft letter to The Rev'd A Tanner in September 1989, a key question was whether additional funds would be made available, were the Trust to become exhausted [DHSC0003317\_001]. Indeed, I attended the meeting between the Trust and the Department on 7 September 1989 and have since read the minutes [DHSC0002952\_009]. It is clear that the dominant issue was funding.
- 5.33. In the early years of the Trust, the Department's advice to the Trust was that, as made clear by Tony Newton upon announcing the Trust, the initial £10 million was adequate based on the case presented to the Department. However, changes could be made at a later stage. As suggested by Strachan Heppell in the draft letter, that later stage would most likely be when Trust funds were sufficient to meet commitments for a further two to three years only.

- 5.34. I note that David Mellor agreed to Strachan Heppell's draft letter and added "I am personally most sympathetic to the idea of increasing the fund in due course" [DHSC0003511\_066]. I think the Department recognised that the funds would need to be increased at some point, and this was no doubt informed by the fact that the Trust were reporting regularly to the Department as to its activities and spending. See, for example, the first report dated 10 March 1989, in which the Trustees recorded their concern that the existing fund could have been totally committed within a few months [WITN7068005]. See also the second report of the Trust where Trustees forecast that they would exceed £1 million by the end of March 1989 [DHSC0003308\_001].
- 5.35. Thirdly, I am also asked for my views on the relationship between the Trust and the Department. When he handed over the role of Principal of HS1A to me in December 1988, Dr Moore thanked The Rev'd A Tanner for "the open and productive way we have been able to work together over the last three years" [DHSC0003311\_012]. I tried to continue that relationship during my time in post.
- 5.36. The provision of the bi-monthly reports strengthened communication between the two bodies and, as demonstrated in the correspondence between Strachan Heppell and The Rev'd A Tanner, with regards to proposed drafts of the letter about Trust funds, Trustees and officials worked well together and did so in an attempt to make sure the Trust was a success. The Department managed to strike a balance between observing the independence of the Trust and providing support and guidance where needed. This is demonstrated in the briefing note provided ahead of the 7 September 1989 meeting, and in Mr Heppell's letter to Mr Davey of 14 September 1989 following the meeting in which he noted "[...] *Ministers supported the Trust in its work and were*

generally content with the progress that had been made so far" [DHSC0003318\_006]; [DHSC0003511\_067].

- 5.37. The issue of additional funding could have caused issues with the working relationship but in my experience, it did not. As one can see from Mike Arthur's note dated 5 September 1989 to Strachan Heppell and me, there is mention of the Haemophilia Society describing the previous £10 million sum as inadequate and those views were most likely shared by some [DHSC0003315 004]. However, as far as the Department was concerned, there was a clear distinction between the Trust fund and the out-of-court settlement the Haemophilia Society sought. Whilst that distinction was not necessarily borne out in the media, there was a fundamental operational difference and generally speaking, it is therefore my view that the Department had a successful and productive working relationship with the Trust.
- 5.38. I am asked to comment on the strengths and weaknesses of the way in which the Trust was organised. As set out in paragraph 5.26, the issue of setting up the Macfarlane (Special Payments) Trust (No. 1) in order to make the additional lump sum payments was resolved relatively quickly.
- 5.39. I believe the introduction of the bi-monthly reports established strong channels of communication between the Trust and the Department and effectively informed the planning for future funding arrangements.
- 5.40. Finally, I am asked if I know whether a final exchange of signed letters between the Trust and the Department ever took place. I cannot recall and have not seen anything in the documents to suggest it did.

### Section 6: Other issues

# Q107: Prosecutions in France of ministers and blood transfusion service officials

- 6.1. The Inquiry asks me to set out my knowledge of what was known or discussed either at meetings or in internal communications or informal discussions between ministers and officials regarding prosecutions in France of ministers and blood transfusion officials.
- 6.2. The Inquiry refers me to certain documents. My advisers have also referred me to some additional documents. These are as follows:
  - a) My minute to Miss McKenzie, International Relations Unit, dated 8 November 1991 [DHSC0002435\_079]. The minute concerned the UK's line on press reports about delays in France in introduction of HIV screening on donated blood and heat treated plasma for fractionated products. I attached a briefing which set out what we knew of the situation in France.
  - b) My advisers have referred me to a fax from Dr Roger Moore (Deputy Director, NBTS) to John Rutherford dated 22 June 1992, which attached a letter of the same date from Dr Moore to all Regional Transfusion Directors [WITN7115034]. The letter advised recipients to make "no comment" to media enquiries about the French court action. The fax was copied to me, Dr Rejman and Jenny Moseley (Press Office).
  - C) Minute from Dr Rejman to me, dated 13 October 1992 [DHSC0042274\_021]. Dr Rejman had been in contact with Dr O'Brien of the East Anglia RHA. The RHA (and the University of Cambridge) felt Professor Allain had been "extremely hard done by". They would set up a panel to consider the evidence, but would not suspend him. They had prepared a statement that they intended to use to brief ministers. Dr

- Rejman said, "I stressed to Dr O'Brien our anxiety regarding donor and patient confidence in the NBTS, particularly if a guilty verdict resulted."
- d) Minute from Dr Rejman to Mr Paton (CA-IU), dated 15 October 1992 (copied widely, including to me). [DHSC0042274\_020] The minute said that Dr Rejman had discussed East Anglia RHA's draft statement with me. Dr Rejman said that the statement contained inaccuracies (e.g. about date of knowledge of risk of HIV infection). He said it was difficult to advise on a line until it was known what the RHA would do, but Ministers would need to be informed.
- e) Minute from Dr Rejman to Mr Paton dated 20 October 1992 [WITN7115035]. The East Anglia RHA confirmed it was not their intention to make public the statement sent previously to Mr Paton.
- f) Minute to me from Melanie Harper, Private Secretary to Tom Sackville, dated 28 July 1993 [DHSC0004237\_032]. She asked me to write to Lord Marlesford on behalf of Tom Sackville setting out the RHA's decision on Professor Allain.
- g) Joint press statement dated 28 July 1993 [DHSC0004237\_023] issued by Cambridge University and East Anglia RHA about Professor Allain. It said he was unavailable to conduct his duties as Regional Transfusion Director and this would be reviewed later.
- h) Minute from Iain Martin (CAIU) dated 29 July 1993 [DHSC0004237\_022] (not copied to me). Mr Martin flagged that a problem might arise if Professor Allain was granted leave to appeal and the University and the RHA sought to reemploy him.
- i) Minute from John Rutherford to Tom Sackville's Private Secretary, dated 30 July 1993 [DHSC0004152\_019] which attached a letter I had sent to Lord Marlesford. As requested, the letter provided an update on Professor Allain [DHSC0004152\_020].

### FIRST WRITTEN STATEMENT OF JOHN CANAVAN Other issues

- 6.3. I understand that Professor Allain was Professor of Transfusion Medicine at Cambridge University and Director of the East Anglia blood transfusion centre He also held roles in the French blood transfusion service.
- 6.4. I understand that In November 1991, Professor Allain was charged by the French authorities with alleged offences relating to events in the French blood service between 1983 and 1985. Following his trial, he was found guilty on allegations relating to his treatment of haemophilia patients in France.
- 6.5. During this period, I was working in CA-OPU. I was copied into correspondence and discussions around the issue of Professor Allain continuing his duties with Cambridge University and East Anglia RHA given the ongoing criminal proceedings. I do not remember the details of the case. However, I recall there were several press reports about him and the Department was concerned about the any potential reputational effect on the UK blood transfusion service. The DH was kept informed by the RHA, but the matter was handled by them. I am not able to recall any informal discussions between ministers and officials around this issue.

#### Q108: Any others matters of relevance

6.6. I do not have anything further to add.

#### Statement of Truth

I believe th	at the fa	acts stated	in this wi	tness state	ment are true.
			GRO-C		
Signed			s <del>Samuella</del>		
Dated		6 Sep	tomb	es 202	2