Witness Name: Professor Sir Kenneth Calman
Statement No.: WITN3430001
Exhibits: WITN3430002 - WITN3430098
Dated: 12/10/2022

INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF PROFESSOR SIR KENNETH CALMAN

Contents

Preface

0.1. My full name is Professor Sir Kenneth Charles Calman. My date of birth and home address are known to the Inquiry.

0.2. I am providing this statement in response to a request from the Inquiry dated 10 November 2020; it follows the provision of a draft statement to the Inquiry on 4 February 2022.

The Limitations of this Statement

0.3. It is now over 20 years since I left my role as Chief Medical Officer ("CMO") England, in the autumn of 1998, and more than 30 years since I began it. Given the passage of time, I have difficulty recalling my involvement in the specific issues raised by the Inquiry. I believe that I have read the key documents provided to me by the Inquiry.[1] My legal advisers have also directed my reading towards a selection of additional documents which show direct and personal involvement on my part; the references to these are given in this statement. I have also referred to material that I wrote, such as some of the books which I wrote or edited. In my statement, I have sought to reflect upon these sets of documents to answer the questions insofar as I am able to do so. In doing so I must stress that what I say is based on the documentary record that has been made available to me and not, unless made clear expressly, from my own recollection.

0.4. To assist the Inquiry, I attach to my statement an Annex (split into separate sections, each section relating to individual questions) setting out further material that is relevant to my involvement. The Annex does not attempt to provide an exhaustive account of a particular issue, but rather provides background and context to my involvement in the issues I discuss in my statement. This has often been because, as CMO, I saw only a part of the

[1] There are a limited number of documents which are either duplicates or drafts of documents that I am unlikely to have seen at the time, which are not referenced in this personal statement. I understand that some of these will have been explained and referenced in the Annex.

work that was being carried on in relation to an issue. The Annex has been drafted by my legal advisers following their review of the underlying material. I emphasise that although I have read the Annex carefully, I have not read the underlying documents referred to therein. This has been necessary to keep the task of preparing this statement, and reflecting on the documents that I have seen, to a manageable one.

0.5. I have used the Annex to try to refresh my memory about certain issues. My statement also uses the material in the Annex as a point of reference for explaining my involvement. My statement and the Annex reflect this where they cross-refer to each other.

0.6. I have been specifically asked by the Inquiry to avoid providing comment on the contents of the Annex, because I have not personally read the underlying documents. One effect is that, at times, this limits the help that the statement can provide the Inquiry, which I regret; but I have nevertheless complied with the request.

0.7. My statement, and the Annex, mention the names of various other individuals who were involved in the issues raised by the Inquiry. I have included their names, and, where available from the documents, their division, to assist the Inquiry to decide whether the questions could be better directed to another witness.

0.8. The Inquiry has asked me detailed questions about Scotland, the Scottish government, the Scottish Home and Health Department ("SHHD") and the Scottish National Blood Transfusion Service ("SNBTS") during my time as CMO Scotland (1989 to 1991). The Inquiry has acknowledged that I have not been provided with the documentation that will assist me in answering those questions. The Inquiry has therefore directed me to disregard any question or part of a question that relates to those issues. I would of course be willing to consider questions relating to Scotland if the relevant documents are available.

Reflections

0.9. I would like to begin my witness statement by making a few brief opening comments on its contents.

0.10. This statement covers a wide range of issues, reflecting some of the multiple challenges faced by the NHS and the Department of Health whilst I was in office. It still covers only a small part of those challenges (albeit an important one); the wider picture would be apparent from the CMO's Annual Reports. As a result, it is difficult to draw themes together. However, I believe that in the body of this statement I have referred to:

- My belief in the importance of patient and public participation in healthcare, which was something that I learnt and emphasised from my early experience as an oncologist (see paragraph 2.03 below, as well as the further details of the patients' groups I set up contained in my autobiography).
- My continuing interest in the ethics of healthcare, including the importance of the relationship between doctors and patients, and the importance of patients' consent to treatment.
- The importance of ensuring that proper information was made available to the public, on major public health challenges such as BSE and vCJD. This was of major importance to me. I believe that some useful steps were taken towards greater openness and better communication, for example by enabling the publication of summaries of advice from Advisory Committees such as that on Spongiform Encephalopathy, SEAC; or the programme of work on the public communication of risk in 1996 – 1997. I also tried to improve communication with the medical profession, by the introduction of the "CMO's Update" and the Public Health Link system, supplementing existing methods of communication.
- The challenge faced in determining how new treatments should be made available to patients. Thus, Section 8 of this Statement, which

addresses the topic of treatment and support for HCV patients, reflects on the lengthy process involved in considering, with clinicians, the science behind a new treatment; the judgments upon information for patients as this evolved; and the challenge of securing funding for new treatments. This last point also engaged the issue of whether judgments should be made centrally or locally. The establishment of NICE and the development by it of a process to produce national clinical guidance, after I had left office, represented a major step forward in this area.

- The reality of finite resources and constant pressures on budgets, which was experienced throughout.

0.11. Finally, throughout the process of drafting this statement, I have been very conscious of those who were infected with viruses transmitted by blood or blood products, and their families, carers and friends who were affected by this. I hope that the Inquiry is able to answer some of the questions to which they seek answers.

Section 1: Introduction

1.1. I have been asked to provide a summary of my professional qualifications and employment history with dates and a brief summary of the roles and responsibilities of the various posts I have held. I have provided a brief curriculum vitae at Appendix 1 to this statement to outline my background, experience and qualifications. I have limited my CV to matters likely to be of greater relevance to the Inquiry.

Q.2 Employment History

2.1. I graduated in medicine and science from the University of Glasgow in 1967. I became a lecturer in Surgery in 1969. My main interests were vascular and transplant surgery and I worked as a surgeon in this field for seven years. During this time, I was awarded an M.D and a Ph.D. and became a Fellow of the Royal College of Surgeons in Glasgow. While I dealt with the issue of HIV while working as a surgeon, I was not an expert on haemophilia and never dealt with blood products during my clinical career.

2.2. In 1972 I was awarded a Medical Research Council Fellowship for one year at the Chester Beatty Research Institute associated with the Royal Marsden Hospital. I met a number of oncologists at this time, together with Dame Cicely Saunders, a specialist in Palliative care.

2.3. In 1974, I was appointed Professor of Oncology at the University of Glasgow. This was the first such post in Scotland. Two aspects of my career at this time may be of relevance to the Inquiry. First, I recognised how much patients and their families knew about cancer from their experience of the disease. I encouraged them to use their experience to help others; patient involvement was critical. Secondly, I led the teaching of Medical Ethics with the Professor of Moral Philosophy. This developed my interest in this subject. I subsequently became involved in a number of organisations and professional groups in this subject area. I also published in this field, most notably the book

that I co-authored with Professor RS Downie published in early 1987, "Healthy Respect: Ethics in Health Care".

2.4. In 1984, I became Dean of Postgraduate Medical Education at the University of Glasgow. I was involved in improving the training of doctors across the west of Scotland. This reflected my interest in medical education and its relevance to preparing doctors for their career ahead.

2.5. I was then invited to apply for the post of Chief Medical Officer ("CMO") for Scotland. I was CMO for Scotland between 1 January 1989 and 13 September 1991. I then became CMO for England on 17 September 1991 and held the role until 18 September 1998.

2.6. In September 1998, I became Vice Chancellor and Warden of Durham University and continued in that role until 2007. I served as Chancellor of the University of Glasgow from 2006 to 2020. I was also Chair of the National Library of Scotland from 2016 to 2020.

Q.3 and Q.4 The role of the Chief Medical Officer

3.1. As detailed in paragraph 2.5 above, I confirm that the dates referred to by the Inquiry are correct as to when I held the CMO roles for Scotland and England.

4.1. I have been asked about my role and the responsibilities involved in the role of CMO for Scotland and for England.

4.2. Regarding my role as CMO England, the Inquiry has referred me to the English CMO's Annual Reports "On the State of the Public Health" [See DHSC0007013, DHSC0007014, DHSC0007015, DHSC0007016, DHSC0007017, DHSC0007018 and DHSC0007019]. I have tried to make reference below to some of the key matters relevant to the subject of this Inquiry contained in the introductions to those Reports. More generally, they provide an indication of the breadth of the issues which the CMO was asked to consider and advise upon. The CMO has been described as "the nation's

doctor", the one person responsible for looking after the health of the whole population (see the book setting out a history of the role entitled "The Nation's Doctor", written by Sally Sheard and Sir Liam Donaldson in 2006).

4.3. In my own short autobiography, I wrote:

> *"There's hardly any health job with a wider remit. To work out how wide, just look at the news headlines. Each week there will be some new issue on which the CMO might be expected to either comment or to help direct government policy … the CMO is effectively at the head of a medical intelligence operation and in theory should be relied upon to have his or her finger on the pulse of new developments. In practice, this isn't always possible."*

4.4. I noted that it is generally accepted that there are five, often interrelated determinants of a nation's health – social and economic factors, lifestyle, environment, the quality of the health service, and the extent of our knowledge of genetics and the basic biological mechanisms of disease. Matters related to all these issues might cross my desk on a daily basis: i.e., public health challenges as well as issues related more directly to the delivery of any aspect of healthcare services. The broad canvas of the job meant that, in practice, any CMO has to work closely with his or her team of advisors both to understand the issues coming up, to advise government and assist in developing solutions, and when the implementation of any initiatives was under discussion.

4.5. I am reminded I told the Bristol Inquiry in my oral evidence that maintaining and developing links with others in the medical profession is *"one of the most important functions of the Chief Medical Officer"* [WITN3430002]. These lines of communication gave me a sense of how doctors would likely react to particular situations and problems as they arose, which allowed me to better advise the Secretary of State.

4.6. I was supported in my role by the Deputy Chief Medical Officers ("DCMOs"). The DCMOs I worked with during my time as CMO England were Dr Diana Walford (in post until December 1992), Dr Michael Abrams (in post until 1993) and Dr Jeremy Metters, with whom I worked for my entire period in office. Thus, when I started, there were three DCMOs; by 1994, the structure was such that there was a single DCMO. I recall that when we went down to one DCMO things felt even busier.

4.7. The Annex gives further detail on the role of CMO England (at paragraph 4.1 onwards).

Q.5 WHO role between 1998 and 1999

5.1. The CMO Reports serve as a reminder of my roles in and attendance at the WHO. The World Health Assembly is the annual meeting of WHO Member States that takes place in Geneva in May. I have been referred to the parts of the CMO Reports that show I was part of the UK's delegation to the World Health Assembly for the years 1992 to 1996 and led the UK delegation in 1993 and 1996 (ministers led the delegation in other years). I gave speeches on major health problems facing the world, such as malaria, tuberculosis and AIDS.

5.2. The European Regional Committee of the WHO takes place in a European city in September. I led the UK delegation every year between 1992 and 1997, except for 1993 when the UK delegation was led by Dr Metters.

5.3. The WHO has an Executive Board to give effect to the decisions and policies of the Health Assembly. The Board meets twice per year, with an annual meeting in January and a shorter meeting in May, as a follow up to the Health Assembly. From May 1992, the UK again became eligible to put forward a member to serve on the Board. I attended the Board as the UK's designated representative from 1992 until 1996.

5.4. The 1996 CMO Report notes that in May of that year, I was elected to a three year term of office on the WHO Executive Board.

5.5. I chaired the WHO Executive Board for one year starting in May 1998, which was the normal period of office. I completed my time as Chair after I left my post as CMO England. I see from a document contained in my personal collection of papers that an important development occurred during this year. The Secretariat's Report dated 11 December 1998 refers to the establishment of "An Expert Advisory Panel on Blood Transfusion Medicine" to respond to world-wide concern for blood safety [WITN3430003]. As Chair, I was responsible for the establishment of the Panel. I do not have any further information about the Panel's work as I left the WHO shortly after.

5.6. I do not now have any independent recollection of any discussions or decisions relevant to the Terms of Reference. I would have thought any notable policy decisions would be recorded in the reports of the Executive Board, which I understand are publicly available online.

Q.6 Involvement in Other Inquiries or Litigation

6.1. I have been involved in a number of inquiries or reviews over the years (Cancer Services in England and Wales, the Commission on Scottish Devolution, a review of the Education of Medical Trainees). In 1999, I gave evidence to the Public Inquiry into children's heart surgery at Bristol Royal Infirmary 1984-1995 ("the Bristol Inquiry"). I deal with this further below and in Section 9.

6.2. As far as I can recall, with the exception of the two inquiries referred to in the following paragraphs, I do not believe that I have been involved in any inquiries, investigations or litigation relevant to the terms of reference of this Inquiry.

Q.7 Evidence to the Penrose Inquiry

7.1. I have been referred to my evidence to the Penrose Inquiry [PRSE0000406]. As far as I am aware, its contents are true and accurate. I have not been provided with any further material which would lead me to doubt its contents, and it was signed at a point rather closer in time to the events in question. But it is apparent that I was not provided with documents in relation to, in particular, events in England and so could not comment on them; this statement therefore addresses events in England in more detail than was then possible.

Q.8 Evidence to the BSE Inquiry in 1998

8.1. I have been referred to my evidence to the BSE Inquiry in 1998 [BSEI0000007; BSEI0000008; BSEI0000009; BSEI0000010; and BSEI0000011]. Again, I confirm that to the best of my knowledge and belief, the information given to the BSE Inquiry was true and complete.

Section 2: Structural and Organisational Matters

Q.9 Involvement in Committees, Working Parties or Relevant Associations

9.1. I have been asked to set out my membership of, or regular attendance at, any committees or similar bodies which are relevant to the Inquiry's Terms of Reference.

9.2. I have already mentioned the WHO Executive Board above and I address the Expert Advisory Group on AIDS ("EAGA") below.

9.3. At this remove, unless my recollection is jogged by paperwork relating to the committee or body, it is difficult to remember any other committees (etc) that I attended regularly that are relevant to the Inquiry's Terms of Reference.

9.4. I do not, at present, have access to SHHD papers, but my statement to the Penrose Inquiry does not suggest direct involvement in any such committees, and nor does the review of the English papers carried for this Inquiry, save for the EAGA.

9.5. Clearly, at this time there were a large number of expert Advisory Groups or Committees whose role it was to provide expert advice, and in this context expert clinical advice, to government. Examples relating to the events discussed in this statement include the Advisory Committee on the Virological Safety of Blood (the "ACVSB"), which in early 1993 was replaced by the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (the "MSBT"); it was chaired by Dr Metters (DCMO). I refer to the Annex (paragraph 9.1) which gives some general information about the role of expert committees.

9.6. I should add that, as CMO, I sat on the NHS Policy Board, along with ministers and NHS Executives. I do not now recall any specific issues of blood policy or related matters from my involvement with the Policy Board.

Q.10 The Expert Advisory Group on AIDS

10.1. The EAGA had been set up in late 1984/early 1985 (the first meeting was held on 29 January 1985) under Sir Donald Acheson, as a source of expert advice to the UK CMOs and thus the Government on HIV/AIDS, and the response to that pandemic. Its initial membership can be seen in the press release at [WITN4461005]. (20 February 1985); it contained experts on all aspects of the disease. It was usually chaired by a CMO (Sir Donald Acheson when in office) or by a Deputy CMO (Dr Abrams).

10.2. I have been referred to the minutes of a few of the meetings of the EAGA, which I see that I attended as CMO of Scotland (Minutes of 28/2/89 [NHBT0008413], 3/10/1989 [NHBT0008219_002] and then as the English CMO (Minutes of 8/10/91 [NHBT0008406_002], when I am recorded as saying I would attend whenever possible, and as recognising the continuing important role of EAGA in advising the UK CMOs). The breadth of the issues raised by the AIDS pandemic and its public health response are evident from the minutes of the meetings.

Q.11 Senior Colleagues in the SHHD and the Department of Health

11.1. I have been asked to identify, first, senior colleagues at the SHHD involved in decisions about blood and blood products, during the time that I worked there. I do not have access to papers relating to this period at the SHHD, which would assist in reminding me of the names of senior colleagues.

11.2. By reference to the Civil Service Yearbooks, my legal advisers have reminded me of the names of the most senior figures in Scotland. Malcolm Rifkind MP was Secretary of State for Scotland when I was appointed CMO at the Scottish Office in 1989. Ian Lang MP succeeded Malcolm Rifkind in 1990. Michael Forsyth MP was health minister for Scotland throughout my time. Sir William Reid was the head of the SHHD when I arrived and was succeeded by Sir Graham Hart in 1990. My Deputy Chief Medical Officer was Dr Graham Scott until 1989 and thereafter Dr Andrew Young. Dr Archie McIntyre was the

Principal Medical Officer for Communicable Disease and Environmental Health. These names are all familiar to me and are the appropriate names, so far as I can recollect.

11.3. I understand Dr Iain Macdonald, my predecessor as CMO for Scotland, gave a statement to the Penrose Inquiry on HCV testing in the course of which he provided an outline of the medical staff in SHHD.

11.4. In England, a number of medical advisors played a part, including:

a) Dr Metters, my DCMO and now sadly deceased.

b) Dr Diana Walford, also a DCMO.

c) Dr Abrams, also a DCMO. He chaired the EAGA.

d) Dr Elizabeth Smales, Dr Hugh Nicholas, Dr Michael (Mike) McGovern, Dr Felicity Harvey and Dr Susan Shepherd; my Private Secretaries.

e) At a more junior level, there would have been a number of Medical Officers involved, as well as various other officials from the medical and administrative branches of DH. I no longer have any independent recollection of the names of others involved. I therefore refer the Inquiry to those names I mention elsewhere in this statement in connection with specific issues. I understand the Civil Service Yearbooks are a useful source for the names of Medical Officers by year.

11.5. Dr Metters was a key figure on blood policy. I worked closely with him. He was a high profile figure within the Department and good at getting things done. I note from some of the documents I have seen that Dr Metters took the lead on certain policy areas, and often did so in relation to blood issues. While he would have no doubt consulted me on key issues and decisions, he also had a high degree of autonomy in how he went about his work. I would not

have expected him to come to me on every issue and indeed given the wide portfolio of my role it was obviously necessary to delegate certain responsibilities to my team.

11.6. My Private Office received a large volume of correspondence, papers and submissions. It would not have been possible for me to read everything received by my Private Office. I worked very closely with my Private Secretaries, who were very skilled at judging what material I needed to see and become involved with myself and what could be dealt with by the Private Office or by others in the Department.

Q.12 Organisation of the Department of Health, with regards to the safety of blood and blood products

12.1. The long-standing arrangement of the Department of Health, when I came into the office in 1991, was to have parallel medical and administrative hierarchies, the former reporting upwards to the CMO, the latter to the Permanent Secretary.

12.2. As mentioned in the Annex (at paragraphs 12.1-12.3), the Banks Report recommended the abolition of twin/paired medical and administrative hierarchies. I see I told the Bristol Inquiry that my role and responsibilities changed around 1995:

> *"Following the Banks Report, the medical staff, apart from half a dozen or so of secretarial staff, reported either to the Permanent Secretary or to the Chief Executive of the NHS and the Chief Medical Officer therefore had no direct reporting medical staff."*

12.3. There was nevertheless still a professional reporting line from the medical staff in DH to me as CMO. I do not now recall that the change of line management caused any particular issue with how we worked; I was able to work with the medical and administrative staff regardless of who they reported to.

12.4. I have been referred by the Inquiry to a note from Dr Rejman [DHSC0032052_176] about his role arising out of the changes brought about by the Banks report; the Inquiry may need to pursue matters of detail with him.

12.5. There were regular meetings and links with other departments in Whitehall, notably MAFF. There were a range of specialist advisers who provided expert advice when required. There was a Press office and I regularly appeared in the newspapers and on the radio and TV. My autobiography mentions that on days heavy with health news, I would often find myself doing between seven and ten interviews on the same subject on the same day.

12.6. I had quarterly meetings with the CMOs of the other UK nations and regular meetings with EU staff and WHO. I had meetings with the Health Select Committee.

12.7. It was important to have good lines of communication between my office and the medical profession in England. In 1994, the Public Health Link system was set up. This was an *"urgent communications cascade"* used by my office *"to provide rapid information to doctors about important health information"* [CMO Update 4] [WITN3430004]. This system also had a role in responding to public health incidents. Information that was not urgent was communicated through CMO Letters (specific CMO Letters relevant to Infected Blood are referred to elsewhere in the statement) or through "CMO's Update".

12.8. CMO's Update was a series of bulletins produced by my office to highlight major issues in health. The updates started in January 1994 *"to improve routes of communication between the CMO and doctors in England"* and was intended to reduce the number of individual CMO Letters sent out on individual topics [CMO Update 19] [WITN3430005]. These communications with the medical profession were very useful.

12.9. I have not re-read the CMO Updates for the purpose of this statement, but my legal advisers have drawn my attention to those few passages which touched

on issues related to Infected Blood. The January 1994 Update discussed new guidelines issued by the NHS Management Executive on protecting health care workers and patients from Hepatitis B (HSG(93)40) [CMO Update 1] [WITN3430006]. The March 1995 and February 1997 Updates gave details on HIV surveillance [HSG(95)5; HSG(97)13] [WITN3430007; WITN3430008]. In response to widespread interest about vCJD, from July 1996 onwards the Updates provided figures for deaths from CJD, including vCJD [CMO Update 11] [WITN3430009].

12.10. I was also involved in the production of a series of CMO Fact Sheets, which covered a range of health-related topics, from smoking to nutrition. These were intended for internal use within the Department only. I produced a CMO Fact Sheet on HIV and AIDS in November 1993. This is mentioned further in Question 67 below.

Summary of CMO Reports – Scotland

12.11. As CMO Scotland an annual report – "Health in Scotland" – was produced. This was around 150 pages long and covered a wide range of issues. I authored the introduction section to reports for the years 1988 to 1990 (although with input from other colleagues). The reports were addressed to the Secretary of State for Scotland (Malcolm Rifkind for the years 1988 and 1989 and Ian Lang for 1990).

12.12. While I have access to the Scottish CMO Reports, I do not have access to other papers relating to my time as CMO Scotland. I would be willing to revisit the CMO Scotland reports further when other papers are made available.

Summary of CMO Reports – England

12.13. As CMO England an annual report – "On the State of the Public Health" – was produced which covered as many issues as possible and was around 300 pages long. This provided an opportunity to raise key issues to the wider public. It covered issues related to Infected Blood. A glance at the contents of

a CMO's report underlines the wide remit of the role and the range of issues covered.

12.14. The CMO Reports were produced by the Medical Editorial Unit at DH (see the thanks I offered in the introduction to the 1997 report). I believe I was largely responsible for drafting the introductions (albeit with assistance from staff). I cannot recall the extent of my involvement in drafting the executive summaries (when introduced from the 1992 report onwards) but believe I would have been involved. The substantive chapters of the report were, I believe, drafted by the editorial team, although I would have been consulted about what to include and would have provided input.

12.15. For the purpose of this statement, I have re-read the introductions and executive summaries of the Reports only and not the main body (save where expressly indicated below). Some of the key matters relevant to the subject of this Inquiry contained in the introductory sections are summarised below. The Annex refers to further issues of relevance contained in the main body of the Reports.

CMO's Report of 1991: "On the State of the Public Health" [DHSC0007013] (published September 1992)

12.16. This was the first report to which I contributed and was addressed to the Secretary of State for Health, Virginia Bottomley.

12.17. The introduction and the chapter contents list give an idea of the scale of the activities of the Department of Health at that time. The introduction refers to the Green Paper, "The Health of the Nation", published in June 1991. That had been followed by a White Paper in July 1992, which led to targets for health improvement being set in key areas, including: coronary heart disease and stroke, cancers, accidents, HIV infection and AIDS and sexual health, and mental illness. The "Health of the Nation" strategy was at the heart of much of what I did in these years as CMO England.

12.18. On HIV/AIDS, the introduction noted that in early 1992, I had asked the director of the Public Health Laboratory Service ("PHLS") to convene an expert working group to provide further forecasts of the prevalence of HIV disease in England.

12.19. The subject of hepatitis C in blood donations was mentioned briefly in the introduction:

> *"Screening of blood donations for hepatitis C virus commenced in September 1991 to exclude the major cause of non-A non-B transmitted by blood donation. As the first test kits available produced a high number of false-positive reactions, screening was introduced only when validated supplementary tests became available."*

12.20. I have been referred to a passage from Chapter 5, which addressed the subject of Communicable Diseases, namely (a) HIV infection and AIDS; (b) other STDs; (c) Immunisation; and (d) hepatitis C in blood donations. The section on hepatitis C in blood donations summarised the matter thus:

> *"Routine screening of blood donations for anti-HCV (hepatitis C virus) commenced on 1 September 1991. Hepatitis C is believed to be the main cause of non-A non-B hepatitis transmitted by blood donation. The screening test kits give a large number of false-positive results, and the three available screening tests differ in this respect. Supplementary testing by recombinant immunoblot assay (RIBA) it is necessary to indicate probable infectivity. Confirmation requires testing by polymerase chain reaction (PCR). Since both RIBA and PCR are time-consuming, the data so far available are incomplete.*
>
> *UK figures from 1 September 1991 to 31 January 1992 show an average repeat reactive screening positivity of 0.39%, but of 0.5% among new donors. RIBA supplementary testing gave positive results in 17.6% of these and indeterminate results in 26.1% (i.e. 0.07% and 0.1% overall respectively). So far, it has been shown that 90% of RIBA*

positives are PCR positive, although it is not known how many RIBA indeterminates are infective. PCR testing will help to resolve this question. Screening and supplementary tests are continually being improved, and it is hoped that future reports will give a more accurate picture."

CMO's Report 1992 [DHSC0007014] (published September 1993)

12.21. The report said the format of the introduction had been revised to also include an Executive Summary of the whole report.

12.22. The introduction noted that 1992 saw considerable activity to disseminate the messages of the "The Health of the Nation" White Paper. Reference was made to the fact I chaired one of the three committees (the Health of the Nation Working Group) charged with implementation and monitoring of the strategy.

12.23. The introduction mentioned briefly that screening and supplementary tests for hepatitis C in blood donations continued to be refined.

CMO's Report 1993 [DHSC0007015] (published September 1994)

12.24. In the Executive Summary, the report noted:

"HIV infection and AIDS

Data reported for HIV infection and AIDS showed a similar pattern to previous years. In 1993, they were combined with data from unlinked anonymous surveillance as a basis for a new report on projections for infection in England and Wales up to 1997. Publication of the new report was accompanied by a statement on Government strategy on HIV/AIDS, which reaffirms commitment to this area."

12.25. The Executive Summary noted the publication of new guidelines:

"Hepatitis B guidelines

New guidelines for protecting health care workers and patients from hepatitis B were issued by the NHS Management Executive." (These were the Guidelines "*Protecting Health Care Workers and Patients from Hepatitis B*", HSG((93)40) [DHSC0002561_096].

12.26. The Executive Summary noted the creation of the National Blood Agency ("NBA") in April 1993; the NBA took over the roles of the Central Blood Laboratories Authority (which managed the Bio-Products Laboratory ("BPL") and the International Blood Group Reference Laboratory), and the National Directorate of the National Blood Transfusion Service. Further detail is given in Section 3, below.

CMO's Report 1994 [DHSC0007016] (published September 1995)

12.27. This report was addressed to Stephen Dorrell, now Secretary of State for Health.

12.28. Within the Introduction, when highlighting new issues identified during 1994, I raised the increasing importance of ethical dimensions to health and health care. I noted that the issues raised – including in such areas as confidentiality and resource allocation – needed wide discussion. The debate was necessary to clarify thinking and to assist in making decisions about patients in which there was (and is) real uncertainty and for which there was no 'right' answer. Judgement was difficult, I noted. I highlighted a number of further themes, including the distinction between equity and equality.

CMO's Report 1995 [DHSC0007017] (published September 1996)

12.29. The Report contains information on the nation's health, but as always I also highlighted areas for particular attention. These included a broader understanding of the language of risk.

12.30. The Introduction noted that a major theme that developed in the early part of 1996 was the identification by the UK National Creutzfeldt-Jakob disease (CJD) Surveillance Unit (set up in 1990), of a novel variant of CJD. This appeared to have a younger median age at death. The report noted that whilst regular statistics were published to inform clinicians, it remained impossible at that stage to predict the likely trends for the reports of the new variant, or indeed CJD as a whole.

12.31. The theme of understanding the language of risk was discussed at some length at pp8-13, and attempted to put forward a classification of risk, in an attempt to answer the public's questions as to what might be safe. It considered how best to communicate the level of risk associated with a particular health or health care issue to the public. The preliminary classification offered was accompanied by an emphasis on the *"importance of ensuring that the public are full partners in the process of risk assessment and management"* and noted that *"it is only with such involvement that progress can be made."* (p12).

CMO's Report 1996 [DHSC0007018] (published September 1997)

12.32. This report was addressed to Frank Dobson, now Secretary of State for Health.

12.33. I identified consent as one of the four key issues for attention during the coming year. The report explores this in more detail at pp21–23, albeit with a focus on capacity and consent. Reference was made to 1996 DH guidance "*Protection and use of patient information*" HSG(96)18, which emphasised the importance of informing patients about the essential uses of their personal health information (p22).

12.34. The Introduction noted research into the nature and possible causes of the new variant of Creutzfeldt-Jakob disease ("nvCJD"), identified in 1996, remained a priority. The possibility of a link with BSE was noted, but the

evidence to date did not constitute formal proof of a causal link and further data was required (p3).

12.35. The topic of the communication of risk was further addressed (p10–p12) with guidelines on risk communication for use throughout the Department being developed. The report described an extensive programme of research, workshops, case study seminars and other means to further the development of good practice on risk communication.

12.36. At p13, there was discussion of the recent introduction of combination antiretroviral therapy in treatment of HIV. Evidence suggested these treatments were beneficial and may delay the onset of AIDS. Public health measures aimed at prevention of infection would remain central to containing HIV.

CMO's Report 1997 [DHSC0007019] (published September 1998)

12.37. This was the final CMO's Report to which I contributed.

12.38. The introduction noted the publication in February 1998 of the "Our Healthier Nation" Green Paper. Publication of the White Paper was planned for later in the year.

12.39. Research in October 1997 had shown a convincing link between BSE and vCJD (p13). The mechanism of infection was still not well understood, so there was a need to maintain a precautionary approach. Although the evidence did not show transmission through blood or blood products, the importance of confidence of the public in safety of blood was such that further precautionary measures had been announced in February 1998 (p13). In May 1998, the CSM advised manufactured blood products should not be sourced from UK plasma and use of leucodepletion for blood destined for transfusion was being explored.

12.40. Following on from what was said in the two previous reports, the theme of risk communication and the language of risk was discussed at pp21–22.

12.41. The report noted that a new, UK-wide, National Screening Committee had been set up in 1996 to advise on new and existing screening programmes (pp28-29). In its first year it recommended, amongst others, screening antenatally for Hepatitis B susceptibility.

Q.13 & Q.14 SHHD relationships with the SNBTS and the PFC

13.1. I have been asked about the working relationship between the SHHD and the Scottish National Blood Transfusion Service, with a series of detailed questions set out. Similar questions have been asked with regards to the Scottish Protein Fractionation Centre ("PFC").

14.1. I do not now have any real recollection of any particular dealings with the SNBTS or PFC when in office as CMO in Scotland and I do not have access to SHHD papers. I understand that the IBI does not expect an answer, without those SHHD papers being available. I can remember that Professor Cash, the head of the SNBTS, wrote to me occasionally, and we also met now and then (see Question 28 below), but I cannot remember any details.

14.2. The CMO Scotland's Annual Reports, which are public documents, would carry information on public health and specifically HIV, Hepatitis and blood transfusion.

Q.15 SHHD relationships with the UKHCDO

15.1. I have been asked to describe the working relationship between the SHHD and the UK Haemophilia Centre Doctors Organisation ("UKHCDO"; I believe, from the Minutes of the time, that it was actually the UK Haemophilia Centre Directors' Organisation).

15.2. Its minutes would reveal whether representatives of SHHD attended its meetings. I do not now have any recollection of any particular dealings with

the UKHCDO when in office as CMO in Scotland and I do not have access to SHHD papers. I do not think that I can comment on this issue.

Q.16 SHHD relationships with commercial pharmaceutical organisations

16.1. I have been asked to describe the relationships between the SHHD and pharmaceutical companies involved in the manufacture, importation and/or supply of blood products. This is not something that I remember being involved in and I do not think I can comment further.

Q.17 DH relationships with the NBTS

17.1. I have been asked a series of detailed questions about the working relationship between the DH and the National Blood Transfusion Service. I can see from the papers that the main point of contact between its Director, Dr Robinson and the Department of Health was Dr Metters. The NBTS was replaced by the National Blood Authority (the "NBA") in April 1993; this is a topic covered in more detail in the Statement below, although it was not a matter in which I had any real personal involvement.

Q.18 DH relationships with the BPL

18.1. I have been asked about the working relationship between the DH and BPL (by this time known as the Bio-Products Laboratory). I had no involvement in the management of the BPL, which at that time was managed as a part of the Central Blood Laboratory Authority ("CBLA"). There is considerable detail about those management arrangements included in the section about the creation of the NBA, below. But I do not think that I had any particular link to the NBA or BPL.

18.2. I have also been shown a letter dated 5 February 1993 that I wrote to Professor Stewart, the Chief Scientific Advisor and Head of the Office of Science Technology [DHSC0006792_019]. He had apparently asked for the Department's view on the privatisation of the laboratory. My response noted

that up until late in 1992, BPL had not been "for sale" as this would have led to major political difficulties. But *"given that BPL is a classic non-core activity of the NHS and the fact that attitudes within Government to involvement with the private sector are changing fast, Ministers have decided that now is the time to review the position".* The topic was to be examined by the new National Blood Authority. I would suggest that papers relating to the NBA would be the best source of information on this topic. Also relevant is the fact that the CMO speaks publicly only with the authority of Ministers (see further below). My comments will have reflected Ministerial policy, as can be seen from the letter.

Q.19 DH relationships with the UKHCDO

19.1. I am asked to describe the working relationship between DH and the UKHCDO (again, I think this was the Directors' Organisation). I should emphasise at the outset that I cannot now recall having either any personal involvement with UKHCDO or any involvement in managing the DH's relationship with UKHCDO. I understand the Inquiry has possession of UKHCDO meetings minutes. I expect those documents would provide further insight into the relationship.

19.2. I am not aware the relationship between DH and UKHCDO was ever put on a formal footing or that there was any formalised internal structure within DH for managing the relationship with UKHCDO. UKHCDO clinicians were leaders in the field of haemophilia care and it would be of obvious benefit to the Department to be kept informed of developments in research, treatment protocols and developments in the field, as well as to be able to inform the UKHCDO of any issues from the DH perspective. I cannot speak for what were the UKHCDO's policy objectives.

19.3. The sharing of information between the two organisations was not, to my knowledge, formalised. The lines of communication between UKHCDO and DH mainly took the form of: (i) ad hoc correspondence sent to me, and others

in the Department, from either the Chair of UKHCDO or clinicians affiliated with UKHCDO (I have referred to some of the more significant items of correspondence elsewhere in this statement); and (ii) attendance of a DH observer at some, although not necessarily all, UKHCDO meetings. During the period when I was CMO, it seems that there might not be DH attendance at every UKHCDO meeting, but when there was, it was most often Dr Rejman who attended.

19.4. I am not aware that the DH was, in general terms or as a matter of day-to-day policy, in a position to *"ensure that the UKHCDO was informed and kept up to date about the risk of infection from blood and blood products,"* as has been suggested by Inquiry questions to me. Generally, the members of the UKHCDO as expert clinicians would have been well-informed on these matters and the DH would have looked to leading clinicians amongst them to participate in, and advise the DOH through, the mechanism of Advisory Committees or Expert Groups (the EAGA is an example, albeit with a focus on AIDS rather than blood or blood products per se). To the extent that risks arose from blood products manufactured by BPL or from blood transfusions, I would have expected that such risks would be communicated partly through product information sheets or similar mechanisms, and via the NBTS.

19.5. In relation to communication to Ministers of information received from the UKHCDO, I do not expect that this would have been dealt with differently to any other information which needed to be made known to Ministers. Officials would brief new Ministers on key issues on coming into the Department and other developments would be communicated to Ministers by way of ministerial submissions or other briefings, as the need arose.

Q.20 DH relationships with individual clinicians

20.1. I have been asked about the working relationship between the DH and individual clinicians. I hope that I have made it plain that the DH maintained links or was in communication with professionals and their medical

associations in numerous different ways, virtually on a constant basis. Relationships would be formal (e.g., via committees or formal consultation) or might be informal (e.g., attending or speaking at professional conferences and the informal discussions that these would lead to). Plainly the relationships, their strength and their warmth, varied, depending on issues and personalities.

20.2. In my first statement to the Bristol Royal Infirmary (paragraph 5), I wrote that I had always maintained a close relationship with the medical profession, with regular formal and informal meetings with all relevant bodies. This included regular visits to the Colleges, the BMA and GMC. I commented generally on the interaction of the DH and its officials with the profession. I spent a great deal of time meeting people. Keeping in touch with clinicians in various specialisms and feeding back comments from them was an important part of my role. I facilitated discussions with not only clinicians but bodies such as the Royal Colleges or the GMC that Ministers could not meet so regularly.

20.3. I have been asked how frequently I was approached by individual clinicians on issues relating to blood and blood products. When correspondence on issues relating to matters relevant to the Terms of Reference to this Inquiry has been shown to me now, I have tried to refer to it in this Statement. But to take one source of statistics, as mentioned above the Banks Report (p32: see Chapter 8 of "*It Started in a Cupboard*") set out how in 1993 alone *"*[DOH] *as a whole answered 25,560 letters from MPs* [and] *58,600 letters from members of the public"* (as well as providing speeches and briefings for more than 130 Parliamentary debates and answering an average 28 Parliamentary Questions each sitting day). I do not think that I can reliably state how many letters, of the 58,600 or so annual letters from members of the public would have been from clinicians, on the topic of blood policy, or how many of those would have been addressed to me personally within the Department. Even if addressed to me personally, that does not mean that I would necessarily have answered it personally or have seen it; many items were handled by staff without reference to me.

20.4. The two items of correspondence referred to by the IBI as part of this question have been addressed elsewhere in my statement.

Q.21 DH relationships with commercial pharmaceutical organisations

21.1. I have been asked about the relationships between the DH and pharmaceutical companies involved in the manufacture, importation and/or supply of blood products. I have referred to the organisational chart contained in the Banks Report, which shows the pharmaceutical division of the DH and also refers to the role of the Medicines Control Agency.

21.2. I did not have personal contact with pharmaceutical companies as CMO. It would not have been appropriate. I do not think that I can assist the Inquiry further on this matter and suggest that those who were directly involved in these aspects of the DH's work may have more to offer.

Section 3: Relationships between officials and ministers

Introductory remarks

22.1. In general terms, I had regular meetings with Ministers whilst CMO. The Secretaries of State while I was CMO for England were, in sequence: William Waldegrave, Virginia Bottomley, Stephen Dorrell and Frank Dobson. The Permanent Secretary throughout this period was Sir Graham Hart.

22.2. Wider meetings of Civil Service groups across Whitehall were helpful and I used them to raise special issues, such as BSE and its implications. Ministers were an essential part of the wish to move health and health care forwards. Some major developments came from such meetings, including a key review of cancer services.

22.3. 'Health of the Nation' was a major health project initiated by John Major and developed further as 'Our Healthier Nation' by the incoming Labour Government in 1997. I have discussed some of these initiatives, in very broad terms, in my summary of the CMO's reports, in Section 2.

Q.22 Decision-making Structures and Processes

22.4. I have been asked to describe the decision-making structures and processes that were in place in both SHHD and DOH to ensure the assessment of risk, and information sharing etc regarding blood and blood products.

22.5. I have not addressed the SHHD, in the absence of documents.

22.6. In relation to the DH, there were a number of ways in which issues about the safety of blood and blood products were considered.

a) Blood products were regulated under the Medicine Act 1968 and issues relating to regulated products were handled by the Medicines Division;

b) The safety of blood collected from donors was a matter for the Blood Transfusion Service and the Regional Transfusion Centres, as well as the National Blood Authority created in 1993;

c) The CBLA managed the BPL;

d) Specialist advisory committees existed to support decision-making. On the issues that the IBI is concerned with, the Advisory Committee on the Virological Safety of Blood (the ACVSB) was one such Committee (replaced in October 1993 by the MSBT). Other expert Committees included, for example, the EAGA and the Hepatitis Advisory Committee. Such bodies might be chaired by a DH medical officer (eg Dr Metters), but typically had a DH-provided secretariat, both administrative and clinical, which could ensure the dissemination of information and decisions from the Committees;

e) Advisory committees could be assisted either by sub-committees or ad-hoc groups as needed, such as the Working Party which made the practical arrangements for the Lookback in 1995. Or independent advisory groups might be put together as needed: see my account of "Mad Cows" in Chapter 9 of my autobiography, where I referred to the expert advisory group under Sir Richard Southwood – its recommendations led in turn to the creation of a standing committee, the Spongiform Encephalopathy Advisory Committee ("SEAC");

f) External units with particular expertise might be established: for example, the National CJD Surveillance Unit (based in a hospital in Edinburgh) was founded in 1990, again after the Southwood Committee recommended that CJD should be monitored in the UK;

g) Generally, the Department of Health received information from individual clinicians, clinical interest groups such as the UKHCDO or more formal bodies such as the Royal Colleges. Groups of clinical leaders, together with organisations from the voluntary sector, might also be involved in initiatives supported by the DH, such as the

development of guidelines for the use of Alpha Interferon (see Section 8 below, on this);

h) DH Medical Officers, as well as other civil servants, would seek to keep abreast of clinical developments both by study of journals but also by liaison with clinical interest groups such as those mentioned above.

22.7. This is such a wide question, and such a wide set of issues, that it is difficult to be comprehensive. Essentially, the use that was made of information from these sources, and the nature of the consideration of any risks involved, would vary according to the issues being considered. The nature of the issue would determine which Ministers were involved and who I had contact with; for example, BSE was handled by MAFF to a large extent and I had to liaise with MAFF. Liaison was more complicated in England than when in the smaller SHHD; in Scotland, everyone was based in one building and it was easier to make contact and links with those involved in different policy areas.

Q.23 Procedures for Securing Information about Risks

23.1. I have been asked who was responsible, and what was the procedure in the Department of Health for ensuring the Department was kept informed of risks, for briefing Ministers and keeping them informed of changes to risks.

23.2. Again, it is difficult to generalise. Civil servants were organised into teams with policy responsibility for specific areas; broadly, they were expected to track developments in those areas, e.g. by their role in attending or supporting specialist committees. Ministers were informed of issues as and when it was considered that there were issues that needed their attention. That might be because the Department had identified an issue or the need for policy developments or change. It might, equally, be because Ministers took the initiative in asking for information about an issue that had been raised by a public campaign, a constituent or fellow members of Parliament.

23.3. The general method of informing Ministers about issues were written briefings or submissions, drafted by the civil servants with policy responsibility for the areas in question. They would be supplemented by meetings or other discussions with the Ministers in question. There are numerous examples of this process set out in the statement.

23.4. I have also described how I would regularly meet with Ministers and other policy officials. The CMO, together with other senior staff including the DCMO, played a leading role in how to present risks to Ministers, in key areas such as HIV, BSE and then vCJD. Part of my discussions with Ministers and others would be about how to present risks to the public.

23.5. Information to Ministers is linked to the issue of the CMO's communication with the public. The issue of risk and communication of risks to the public has been an important issue for me throughout my career. Together with Peter Bennett, I edited a book about it after retiring as CMO: "*Risk Communication and Public Health*" (OUP, first published in 1999). Other publications are listed in my autobiography, but whilst CMO, the Department published "*Communicating about Risks to Public Health*" (Department of Health, November 1997). This was a part of a substantial programme of work to develop understanding of, and to improve practice in relation to, the communication of risks to the public. I have set out further details in the answer to Question 91.

23.6. In my autobiography, I set out the four principles that informed my handling of the BSE/vCJD crisis. The last was:

> *"Keep the public informed at all times about the disease, health risks and relevant research."*

23.7. I also stated that "*I cannot stress enough how important openness is in the field of public health …. Provided patient confidentiality is protected, transparency is vital in dealing with risks to public health. I have always believed this and cannot think of any occasion where I didn't present relevant*

evidence during a health crisis as soon as it became available. But that doesn't mean that I feel I should tack on doubts, gut feelings, suppositions and suspicions to any health advice I gave when none of them had yet been cleared by science." My autobiography (Chapter 9) discusses these issues in more detail, as do the publications I have referred to. I also explained (Chapter 7) that *"Officially, according to the guidance from the Permanent Secretary in the Department of Health, the CMO 'speaks publicly only with Ministerial authority'. On issues such as smoking, where I had strong views, this posed problems, but perseverance eventually won the day."*

Q.24 Civil Service candour with Ministers

24.1. I have been asked to what extent officials were forthright with Ministers about what was known and understood about the risks of infection associated with blood and blood products.

24.2. I was personally open and forthright with Ministers. In meetings where other civil servants took the lead (e.g., due to their specialist knowledge, see below) they would be equally so. We had briefing meetings beforehand and we would agree what needed to said. In my autobiography, when talking about information to be given about BSE risks, I wrote:

> *"I have always believed in utter transparency in matters such as this; only by pointing out potential health risks where they are known and proven to exist can we avoid the appearance of subterfuge and cover-up even when (as here) it doesn't exist. In a memo to Ministers to explain what had been found at the abattoirs, I was keen to flag up the potential health risk to human health this revealed".*

I continued, explaining the process by which the text was finally agreed:

> *"To the MAFF officials this was a 'step too far'; instead they wanted to highlight that there was still not a single case in which specified bovine offal had entered the human food chain. In the end, the agreed text did mention that what had been uncovered in the unannounced abattoir*

inspection was a potential health risk but added that there was still no evidence that the human food chain had actually been compromised."

Q.25 Ministerial and CMO roles

25.1. I have been asked what kinds of decisions, relating either to the risks arising from blood and blood products or the response to such risks, would be taken personally by either Ministers or the Chief Medical Officer.

25.2. The primary role of the CMO was to offer medical advice to Ministers (including Ministers outside of the DH) and to the public where appropriate, rather than to personally make decisions about the response to risks. That might include giving information about risk, again to the public as well as Ministers; but such assessments and statements would have been informed by specialist advice in the areas in question. This was certainly the case with regards to issues relating to blood and blood products. I have set out my professional background in Section 1; it was not in these areas. Even if it had been, I would have taken specialist advice to ensure that the information I had was up to date. If I was meeting Ministers but there was a medical officer with more specialist knowledge, I might well agree in the pre-meeting briefing that they would take the lead. This was to ensure that the best advice was given, and also make sure that the officer's personal expertise was recognised by the Minister.

25.3. Although Medical advisors gave advice to Ministers in order to ensure that Ministers were briefed upon, and took decisions upon, key issues, equally (to generalise) Ministers were respectful of clinical advice and would follow it. Again, these matters are best explored by examples, such as the introduction of HCV 'Lookback' in 1995 where Ministerial decision-making was based on advice from the MSBT.

Q.26 Ministerial Engagement

26.1. I have been asked to identify those Ministers with whom I had dealings in relation to the areas/issues covered in the Statement Request. I served as CMO for England under four Secretaries of State. Those Secretaries of State might have had some involvement with any of the major policy decisions or issues attracting public comment and question, during their terms of office.

26.2. Mr Waldegrave was Secretary of State from 2 November 1990 to 10 April 1992. Mrs Bottomley was Minister of State for Health and Baroness Hooper was the Parliamentary Under-Secretary with blood policy in her portfolio.

26.3. Baroness Bottomley was Secretary of State from 10 April 1992 to 5 July 1995. Tom Sackville was the relevant Parliamentary Under-Secretary.

26.4. Stephen Dorell was Secretary of State from 5 July 1995 to 2 May 1997. Mr Sackville, and later John Horam, were the relevant Parliamentary Under-Secretaries.

26.5. Following the 1997 election, Frank Dobson was Secretary of State. Tessa Jowell was in the newly created role of Minister of State for Public Health (followed by John Hutton, but after I had left my post). Baroness Jay also had some involvement in blood policy matters.

26.6. The involvement of individuals has been noted, where relevant to the matters that I can speak of, in this Statement. I note that there is at times more detail in the Annex.

Q.27 "Party-political positions" and the decision-making process

27.1. I think that this may be a question for Ministers to respond to. But political parties do, quite properly, have stances on issues of public health or the funding and organisation of the NHS, for example. It is the job of the Civil Service to implement those democratic choices and that may involve getting on with the job in a slightly different way. For example, there were shifts in

approach when Mr Dobson came into post in 1997. The CMO needs to be part of a team, working with Ministers. However, I cannot now remember any pledges that had particular relevance to the IBI's work, and none have been drawn to my attention by the IBI.

Q.28 Restructuring of blood services and creation of the National Blood Authority

28.1. The Inquiry has asked me about my knowledge of, and involvement in, the decision to restructure blood services and the creation of the National Blood Authority ("NBA").

28.2. The significant structural change that occurred fairly early in my tenure as CMO for England was the creation of the NBA on 1 April 1993. This was followed a year later by the NBA taking over direct management responsibility for the Regional Transfusion Centres ("RTCs").

28.3. As would be expected for this kind of major structural change, the advice and co-ordination of the reform was led principally by the administrative side of the Department of Health. Accordingly, save for a very few instances to which I refer below, I do not believe that I had significant direct involvement in the restructuring.

28.4. At the time that I was appointed to the role of CMO for England, Dr Metters as DCMO was keen to ensure that any changes to blood services did not conflict with the role of the Advisory Committee on the Virological Safety of Blood (ACVSB) in giving advice to the Department and Ministers. Once I was in post, that was a view I would have shared and supported. While medical officers and/or the DCMOs in the Department were kept informed of developments, it was administrative Civil Servants who took the lead in the reforms in this area. The Annex (at paragraphs 28.2 and 28.3) gives further details of the individuals involved with the restructuring of blood services both within the Civil Service and at a Ministerial level.

28.5. As CMO for England, I did not have any specific role (formal or otherwise) with the NBA nor was I part of any committees or working parties particularly looking at the reform and the NBA's creation.

28.6. By the time I took up the post as CMO for England, Ministers were going out to consultation on the proposal for the NBA and were already minded to accept that there needed to be such a central body. As noted above, this was not a reform in which I was significantly directly involved. My involvement was limited to the minor occurrences highlighted below.

28.7. I note that on 22 October 1991 the late Professor Cash wrote to me on the NBA proposals, sending his letter to my home address in Scotland [DHSC0006858_051, SBTS0000640_166]. I do not recall receiving Professor Cash's letter. However I can see from the documentation made available to me that he stated as follows,

> *"I have now been contacted by the majority of the NBTS Regional Transfusion Centre Directors and there can be no doubt the proposals do not enjoy their support. We have had an opportunity to see the proposals and the report (by Ernst Young) and whilst we welcome the moves to enhance the co-ordination of the management process in England and Wales we believe, from our experience, that the option selected will not work at the operational level.*
>
> *I am conscious of the occasion when we first met - in my room - and of your subsequent contribution to the longevity of the SNBTS Protein Fractionation Centre. The fruits of your efforts are now very apparent to us (see enclosed)* [A press release on the opening of the new £4.4 million PFC at Edinburgh was enclosed]*. It occurs to me that your timely intervention in the affairs of the NBTS may now be appropriate and much needed.*

Should you wish to discuss the matter, in the strictest confidence, I would be delighted to meet you in London or Glasgow."

28.8. Although I do not specifically now recall this exchange, using a draft reply provided by Dr Rejman, I can see that I responded to Professor Cash on 28 November 1991 setting out the recent steps in the consultation exercise [SBTS0000030_053]. The Annex (at paragraph 28.7) gives further details on the reasons for the decision not to meet with Professor Cash.

28.9. As is conventional, in advance of the April 1992 election, briefing needed to be prepared for potential new Ministers in the event of a change of Government. Part of this, in DH, was a CMO's briefing. On 23 March 1992, Dr Rejman provided a short contribution on the NBA for my briefing to incoming Ministers. This gave a brief summary of the position reached in the following terms:

"National Blood Authority. This Authority would involve the merger of the NBTS Directorate and the Central Blood Laboratories Authority. The first meeting of the Technical Working Group to consider operational aspects is due to take place on 3 April. Contracts form a major part of the considerations, and so the proposal may need revision in the light of views of incoming Ministers." [DHSC0003591_081].

28.10. The formal announcement of the decision to create the NBA was made on 27 November 1992 in answer to an inspired Parliamentary Question, with an associated press release [DHSC0006579_103; NHBT0006432]. The NBA was to come into being on 1 April 1993 and replaced the existing Central Blood Laboratories Authority ("CBLA") and National Blood Transfusion Service ("NBTS"), and would then assume responsibility for managing the RTCs at the earliest opportunity.

28.11. From the announcement of the NBA on 27 November 1992 to the NBA's 'live-date' of 1 April 1993, there was then a significant amount of work required on,

amongst other things, appointments to the NBA (John Adey was in due course appointed Chief Executive and members of the NBA board were also appointed); the legal instruments for its creation and management; its budget; and planning its work so that it could start effectively upon its launch. Again, these are matters with which, for the most part, I was not directly involved (nor would I have been expected to be).

28.12. The Annex gives further detail of discussions in respect of the status of the Bio Products Laboratory (BPL) prior to the launch of the NBA. I was largely not involved in the consideration given to the status of the BPL, however I did receive a request from Sir William Stewart, the Chief Scientific Adviser and Head of the Office of Science and Technology, for the Department of Health's view on the privatisation of BPL. On 5 February 1993, I wrote a short reply to Sir William in line with a draft that had been prepared for my consideration [DHSC0006792_019; DHSC0006792_023]. Reflecting the Ministerial indications given by Mr Sackville, I explained that:

> *"Up to late last year, BPL has not been 'for sale' as there would have been major political difficulties in selling. This was the position put to Medeva last November when the Chairman met Mr Sackville. However, given that BPL is a classic non-core activity of the NHS and the fact that attitudes within Government to involvement with the private sector are changing fast, Ministers have decided that now is the time to review the position. Our National Blood Authority, which will be established in April, is to examine possible options as a matter of urgency. Mr Sackville has recently told Medeva to put any proposals for purchase or other forms of collaboration with BPL to the Chairman designate of the new Authority in the first instance."*

28.13. The establishment of the NBA required a range of secondary legislation and Ministerial directions; again, these did not involve me and are a matter of record.

28.14. The NBA was launched on 1 April 1993, and Mr Sackville issued a press release that day [NHBT0003960].

28.15. The Annex (at paragraph 28.4 onwards) provides a chronological outline from the documentary records of the position on the restructuring of blood services from when I took up the post of CMO for England until the launch of the NBA on 1 April 1993.

28.16. In terms of my opinion on the advantages and disadvantages of the NBA over the previous arrangements, I cannot recall what I considered the advantages and disadvantages of moving from RTCs into the NBA at the time of this structural change. The wider Department would have considered the pros and cons to ensure that patients were not negatively impacted by this transition.

Q.29 Differences in organisations and structures responsible for blood in Scotland and England

29.1. It is difficult to generalise on this topic now, especially as I have explained the limits of any review of my SHHD involvement above. Looking across my statement, I would say that Scottish policy could be different from English policy, and Scotland maintained its own way of doing things. So, there is at least one example in my statement of a time when Scottish policy diverged: in late 1994/95, Scotland was pressing more quickly towards the introduction of an HCV "Lookback" exercise. However, I wonder whether that was due to differences in the structure or organisation in the two countries, or simply reflected the fact that the Scottish blood service and Scottish policy-making had some degree of autonomy. However, this autonomy also existed within the two countries: for example, I have noted how Dr Gillon introduced a Lookback Exercise in Southeast Scotland at a time when that was not happening within Scotland generally (see Section 7, Question 38). In England, it seems that Newcastle sought to introduce HCV screening for donations earlier than the rest of the UK (see paragraph 31.349 of Lord Penrose's report [PRSE0007002]), referring to a meeting on 30 April 1991:

> *"On 30 April there was an SNBTS/NBTS Liaison Committee meeting. [500] It was suggested that a commencement date of 1 September would be appropriate. Dr Gunson reported that the general manager at the Newcastle Transfusion Centre, Dr Huw Lloyd, had commenced testing in the last week. There was no confirmatory testing being carried out and it was not clear whether positive donors were being counselled. Mr McIntosh immediately informed SHHD officials about these events. Dr Gunson had already advised the DoH of the same and 'advice was awaited'…"*

29.2. My experience was that local divergences in approach were generally tolerated as there was awareness that if they worked, then they would benefit patients. Financial issues were created by autonomy, but decision-makers were also conscious that local experiments or differences could benefit people. The geography is different in Scotland, with more scattered rural communities, so this posed different management challenges; but otherwise, I think that the two services were not so different. Links between clinicians were strong, and so too was information-sharing.

Section 4: Anonymous HIV Sero-surveillance

Q.30 Anonymous HIV Sero-surveillance

30.1. I have been asked to describe my involvement in discussions regarding anonymous HIV testing in 1989 (Question 30). I do not now have any real recollection of this issue when in office as CMO in Scotland and I do not have access to SHHD papers. I understand that the IBI does not expect an answer, without those SHHD papers being available.

Section 5: Knowledge of, and response to, risk of viruses from blood products

Q.31, Q.32 and Q.33 Knowledge of, and response to, risk of hepatitis

31.1. I have been asked a series of questions (Questions 31–33) about my knowledge and understanding of the risk of infection, including hepatitis, associated with blood and blood products when I took up my post as CMO in Scotland and later. Again, I understand that the IBI does not expect an answer without the SHHD papers being available.

Q.34 Knowledge of, and response to, risk of blood borne infections

34.1. I have also been asked to provide a detailed, chronological account of my understanding of the risk of infection associated with blood and blood products, whilst CMO (Question 34). I am also asked to give an account of any steps taken by DH to reduce the risk of infection in consequence of treatment with blood and blood products, at least to the extent that I was personally involved.

34.2. Given the passage of time and the breadth of this question, it is very difficult for me to provide a chronological account of what I knew and when. The detail set out elsewhere in this statement (on, for example, HCV and nvCJD) is the best account I am now able to give regarding my knowledge and involvement in the issues relevant to the Inquiry's Terms of Reference.

Section 6: Screening for Hepatitis C

Q.35 and Q.36 Screening for Hepatitis C

35.1. I have been asked to provide an account of any steps taken by SHHD, during my time as CMO Scotland, to reduce the risk of Hepatitis C infection (Question 35). I am also asked to describe my knowledge of, and involvement with regard to, the decisions, actions or policies of the SHHD regarding HCV testing and/or screening donors for HCV (Question 36). I do not now have any real recollection of this issue when in office as CMO in Scotland and I do not have access to SHHD papers. I understand that the IBI does not expect an answer, without those SHHD papers being available.

Section 7: HCV Lookback

Q.37 'Lookback' and the introduction of HCV screening of blood donations, from 1 September 1991

37.1. I have been asked why a 'lookback' exercise was not introduced as part of, or as an accompaniment to the introduction of HCV screening of blood donations, from 1 September 1991.

37.2. The documents that I have had access to, to date, relate to a period before I joined the Department of Health as CMO. Access to previous SHHD documents, where I was in office, has not been given to me to date.

37.3. From the documents summarised in the Annex (which I can see may not be complete), it seems that the issue was considered as part of the planning in England, Wales and Scotland that took place for the introduction of screening tests, but a decision was taken not to introduce this element.

37.4. I have not identified any personal involvement on my part from reading through the account set out in the Annex. I do not now have any personal recollection of this issue.

37.5. I can see that reasons for not introducing 'Lookback' in 1991 have been given by a number of individuals:

a) In a paper written by Professor Cash in 1994 entitled "Recommendations of the Standing Advisory Committee on Transfusion-Transmitted Infection [SACTTI] to the Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation (the MSBT) concerning the merits of adopting an HCV "look-back" policy":

> *"When anti-HCV screening of blood donations was introduced in September 1991, a look-back programme was not recommended. Doubts about the long-term effects of hepatitis*

C infection, coupled with the lack of an effective therapy for individuals so affected, appear to be the main reasons behind this recommendation. Furthermore, secondary infection of HCV to sexual partners and offspring appears to occur rarely. This is in contrast to HIV, where secondary transmission is more likely and effective counselling can reduce the likelihood of such transmission" [PRSE0001236].

b) By Dr Young, DCMO at the SSHD, to the Penrose Inquiry: "*The reasons why the lookback exercise was not launched at the same time as anti-HCV testing was because there were gaps in the scientific and medical knowledge; for example the natural history of the disease was not fully known; there was no cure available; and no feasibility study had been completed*" [PRSE0002894].

c) 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].

37.6. There are further explanations set out in the Annex.

Q.38 Consideration of lookback - September 1991 to December 1994

38.1. I have been asked what consideration of a Lookback Exercise took place from September 1991 (when screening of blood donations for Hepatitis C was introduced), to December 1994.

38.2. Summary Position: the information summarised in the Annex is mostly derived from the Penrose Report, as far as I can see. This suggests that the major initiative during this period was taken by Dr Gillon in Southeast Scotland. Dr Gillon led a targeted lookback exercise from September 1991 – February 1992 which was not widely known about, although a report was published in a scientific journal in July 1994. However, the topic was put on the agenda of a Medical and Scientific Committee in November 1993, and it appears to have gained further prominence thereafter. But this issue appears to have been considered at the level of specialist sub-committees in which I as the CMO had no direct involvement. The first submission traced to date that was sent to my Private Office was in November 1994 and I do not remember any issue on this being referred to me before that date. This submission has been considered in my answer to Question 40, below.

Q.39 Screening for women who had received Anti-D immunoglobulin

39.1. I have been asked about my knowledge of and involvement in the UK's response to the Irish Department of Health decision in March 1994 to establish a screening programme for women who had received Anti-D immunoglobulin.

39.2. The background to the Irish government's decision to establish a screening programme is set out in the Annex.

39.3. I am aware that Anti-D immunoglobulin ("Anti-D") is a blood product administered to Rhesus ("Rh") negative women pregnant with Rh positive children to protect the child from haemolytic disease. Anti-D immunoglobulin is usually given intramuscularly rather than intravenously. However, in the

Irish Republic, anti-D was given intravenously. In Ireland, a problem with hepatitis C infection as a result of contaminated batches occurred in 1977. I understand this became known around 1993 to 1994 [WITN3430010].

39.4. In a letter dated 22 February 1994, Dr Tierney, Irish CMO, wrote to me. He said this possible link, plus the recent availability of a standard screening test for Hepatitis C, was the reason for the establishment of a screening programme by the Irish Blood Transfusion Service Board [WITN3430011]. I have no recollection of having received this letter, but I accept it is likely that I would have received and considered it.

The DH's response

39.5. As noted in the Annex (at paragraph 39.3), Dr Rejman was tasked with producing a background note for me. The final version of Dr Rejman's Note was sent to my Private Office on 25 February 1994 [DHSC0003970_034; DHSC0003970_035]. It was copied to several others including Dr Metters. Again, whilst I have no recollection of receiving it, it is likely that I would have seen it or at least discussed its contents with Dr McGovern or Dr Metters.

39.6. As regards the issue of Anti-D use in Ireland, Dr Rejman's Note said as follows (albeit paragraph 3.3 was said to be provisional):

> *"3.1 The Irish Blood Transfusion Board issued a lengthy press release on 21 February 1994 stating that they intended testing Rhesus negative women who had received intravenous anti-D immunoglobulin following pregnancies in the Irish Republic. There were 6 cases reported of NANBH occurring in 1977, and 2 of these women have been re-tested, 1 being positive for hepatitis C the other negative.*
>
> *3.2 The Irish anti-D immunoglobulin is intravenous, unlike anti-D given in the UK, which is intramuscular. This difference is crucial. The MCA has no records suggestive of hepatitis associated with intramuscular anti-D immunoglobulin on the adverse reaction database. With*

reference to viral transmission intramuscular immunoglobulins have a good safety record.

3.3 The Irish Blood Transfusion Board has contacted the PHLS to ask them to screen for hepatitis C any Rhesus negative women who received anti-D after pregnancies in Eire, and to complete a questionnaire. PHLS has been in touch with DH and have been advised that completion of the questionnaire should not be pursued and that testing could have potential problems.

(i) passing of confidential patient information to another country.

(ii) publicity causing unnecessary anxiety in people not at risk, particularly women who had pregnancies in the UK,

(iii) costs incurred in testing - particularly expensive confirmatory testing and counselling for any positive patients and possible need for counselling before testing.

(iv) suspicion of drug abuse in patients found positive of hepatitis C but on subsequent questioning found not to be linked to the Irish anti-D.

The benefit of knowing if a positive result may prompt the need for expensive interferon treatment which in some cases may help and the prevention of the risk of sexual transmission as against anxiety and problems of obtaining life insurance etc.

3.4 We also understand that a very small number of patients in the UK were given Irish intravenous anti-D for reasons unconnected with pregnancy. This would have been given on a named patient basis."

Publicising the issue to Rh negative women who gave birth in Ireland

39.7. On 25 February 1994, Dr Nicholas provided comments to Dr Rejman. Dr Nicholas identified an ethical issue as to whether the matter ought to have

been given similar publicity to that in Ireland so that more of those exposed would be given the chance to come forward. His minute of 25 February indicated that this could only be done if a CMO letter were sent to the profession [DHSC0003550_085].

39.8. I do not specifically recall the possibility of such a letter being canvassed with me and have not seen any notes relating to any such discussion. I am unsure as to what the concluded position was on publicising the issue more widely, or the reasons for it. Within the contemporaneous documents made available to me, I note the article within The Lancet dated 5 March 1995 which indicated that a blood alert had gone out for Irish women living in England who may have received Anti-D while living in Ireland [WITN3430012], although this appears to refer to an alert issued by the Irish authorities.

Additional matters

39.9. Within the contemporaneous documents, I note a minute dated 10 March 1994 addressed to my Private Secretary, Dr McGovern, from Dr Nicholas. The letter indicated that Public Health doctors in Nottingham had analysed their database of cases of Hepatitis C identified by blood transfusion donations in Trent which had shown an excess in Rh negative women. The suggestion being made was that these women could have all had Anti-D in Trent [DHSC0002547_173]. I understand that these doctors were keen to corroborate their findings with reference to the BTS and seek publication of their findings. I have no knowledge of how this investigation progressed nor concluded.

Summary of UK's response

39.10. The matters set out above and in the Annex indicate that the DH's response was two-fold. Firstly, the UK assessed its own risk for Hepatitis C infection arising from the administration of Anti-D. It measured this risk as being

relatively low in light of its use of intramuscular Anti-D having no material history of posing a risk of infection.

39.11. Secondly, it was decided GPs would be advised to reassure women who had received intramuscular Anti-D that they were unlikely to be amongst the women affected. Further, advice was issued to PHLS that it would be reasonable to test those women who gave birth in Ireland in the past 15 years and who are Rh negative and think they may have received Anti-D. It seems that a decision was taken that a more general CMO letter to GPs was not needed.

Q.40 Initiation of the Look Back Exercise in 1994

40.1. I have been asked about the start of the UK Look-Back Exercise in 1994, and the relevance of the Panorama Programme "Bad Blood" to this decision.

40.2. As far as I am aware or can remember now, I did not have any personal involvement in this matter until November 1994, when a submission on this topic was sent to my Private Office. However, it is possible that I was kept informed of developments by Dr Metters at an earlier date.

40.3. **Summary Position**. From the contents of the Annex, I can see that discussions of a lookback exercise had started well in advance of November 1994. Decision-making can be traced, in particular, through the minutes of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (the "MSBT") which replaced the ACVSB in October 1993. Both were chaired by the Deputy Chief Medical Officer, Dr Metters. From a medical perspective, key factors in driving decision-making appear to have been:

a) A so-called 'pilot' lookback exercise carried out in Scotland by Dr Gillon's team and the subsequent decision in Scotland, by the end of 1994, that the SNBTS would anticipate developing a LBE for 1995;

b) Further information on transmissibility to sexual partners;

c) Licensing of the drug Alpha Interferon in the UK, in November 1994, for treatment of Hepatitis C;

d) Reflecting these developments, the formal recommendation of the MSBT that a lookback exercise should be carried out, made on 15 December 1994.

40.4. The first material that appears to have been sent to my office was on 16 November 1994. A general briefing on Hepatitis C was sent to the Secretary of State (Mrs Virginia Bottomley) and was copied to my Private Office [DHSC0041152_216; DHSC0041152_217; DHSC0041152_218; DHSC0002548_159]. The submission set out background information on matters such as the current call for financial support or compensation for HCV sufferers. It noted the introduction of routine screening of donated blood for the presence of Hepatitis C, from 1 September 1991. Discussing the numbers of those possibly infected, it noted that the MSBT had asked a small group of its members to examine claims made by the Independent newspaper on 16 November 1994 and to report back. "*This will enable a view to be established on the viability and desirability of a 'look back' exercise to trace, treat and counsel those who may be affected."* There was no request for Ministerial action.

40.5. On 6 December 1994, Dr Nicholas sent a note about a programme which Panorama was preparing on the topic of Hepatitis C. He was not clear whether a LBE would be covered by the programme. His minute was sent to my office, as well as to others, for information [DHSC0003550_109].

40.6. It is apparent from the fact that I attended the MSBT meeting on 15 December (below) that I must have discussed these developments with Dr Metters and had been kept informed.

40.7. On 15 December 1994, the MSBT recommended to Ministers that there should be a Look-Back exercise for blood transfusion recipients infected with HCV prior to September 1991. Although I do not remember this meeting, it is

clear from the minutes that I attended the discussions on the Look-Back, or at least part of them [MHRA0020247].

40.8. The minutes note that the feasibility of a LBE had been demonstrated by a study in Scotland (East of Scotland Blood Transfusion Service) and Alpha-Interferon was now licenced in the UK. A Working-Party should be set up, to determine the processes to be followed. A duty of care was owed to those infected through NHS treatment, so procedures should be put in place to identify those at risk. Whatever was done should be done equally and uniformly throughout the UK. There was a debate on the practicalities, but the minutes record me as intervening to say: "*The CMO said that in the public interest an urgent decision on a UK wide basis was needed on the matters of principle. The detail was important, but less urgent".*

40.9. A submission was then sent to the relevant Minister with responsibility for blood policy (Mr Sackville, the Parliamentary Under Secretary of State) on 22 December 1994, recommending that a LBE should be undertaken. It was copied to my office. See Question 41, below for further details.

40.10. I have been asked about the place of the Panorama Programme in this history. It seems to me that the programme was not responsible for the initiation of the LBE, but it did push the timing of the exercise and specifically its public announcement, forward. In particular, there was a public announcement of the exercise in January 1995, before the practical details of the exercise had been sorted out.

Q.41 The establishment of the HCV lookback exercise

41.1. The Inquiry has asked for a chronological account of how the HCV lookback exercise was established, from the decision to undertake the exercise in December 1994 to the announcement on 11 January 1995. Each individual decision maker involved should be identified, it is said.

41.2. There are many documents showing a flurry of activity in late December 1994 – January 1995. Please see the details in the Annex. It is apparent that the medical leadership within the Department of Health was provided by Dr Metters. My office (ie Dr Harvey, my Private Secretary) was copied into certain key documents, including:

a) Comments from Dr Metters on the draft Ministerial submission on 21 December 1994 [DHSC0032203_154].

b) Ministerial Submission dated 22 December 1994, recommending to Mr Sackville that a LBE should be undertaken [DHSC0032203_153 (submission and copy list); DHSC0002501_116 (Annex A); DHSC0003555_228 (Annex B); DHSC0032208_161 (Annex C)].

c) Minute from Mr Scofield to PS(H)'s Private Office [DHSC0003555_084], misdated 1994. Mr Scofield noted his understanding that PS(H) had agreed to the submission on the LBE and there was therefore no question of any delay by the DH or any justification for the Scots 'going it alone'.

d) Minute from Mr Sackville's Private Office to Mr Mogford, PS to the Secretary of State (Mrs Bottomley), informing the Secretary of State that PS(H) had agreed that there should be a LBE as recommended in Mr Scofield's submission, and detailing practical arrangements that would be made. At that point the proposal was that I would front a press conference. [DHSC0032203_133 and also DHSC0003555_197].

41.3. The announcement of the LBE was made via an inspired Parliamentary Question on 11 January 1995 [NHBT0005796]. This noted that the planning for the process was in hand; the actual exercise would follow once that was completed.

41.4. The PQ was immediately followed by a Press Conference with a wide list of invitees [DHSC0002502_016], held by Dr Metters (DCMO) and Dr Robinson

(Medical Director NBA). The papers show that Dr Metters was sent (see [DHSC0002551_002]) a series of documents including:

a) A copy of the Press Release [NHBT0005792];

b) The "Lines to Take" [DHSC0003555_130] and notes for supplementary questions [NHBT0005855];

c) Note on the administrative arrangements [DHSC0003555_003];

d) There is a copy of the additional information for GPs at [DHSC0003555_014] and the script for the Helpline at [DHSC0002502_007];

e) A draft of the Opening Statement from Dr Metters [NHBT0005856].

41.5. An announcement of the decision was then sent to all Directors of Public Health by Dr Rejman, from the CMO's Office (with a letter from Dr Metters, Additional Information for GPs and Helpline Questions and Answers), with a request for widespread circulation within the NHS [HHFT0000002_002].

41.6. I can see from the papers that I was in Geneva at the time on WHO business but agreed that the announcement should go ahead in my absence, bearing in mind the fact that it would not have been appropriate to have the policy first announced through the medium of a Panorama programme. I am said to have approved the arrangements made to provide information to GPs, hospital doctors and the public, but I have no memory of the process now.

Q.42 My Involvement in the Lookback Exercise

42.1. I have been asked, with reference to the 11 January 1995 letter from the CMO's office announcing that a lookback exercise would be conducted, what involvement I had personally in designing the LBE and what information I was provided with, as well as being asked to comment on aspects of its design.

42.2. The Annex provides summaries of documents, particularly on issues where I appear to have had no real involvement.

Leadership Roles – the Look Back Exercise

42.3. As set out above, the documents that I have summarised above show that the primary senior medical decision-maker within the Department of Health was Dr Metters, who as the Chair of the MSBT had been heavily involved in the recommendation that the LBE should be undertaken, and then became the Chair of the Working Party that determined the detailed arrangements. He also managed, together with Dr Robinson, the Press Conference of 11 January 1995, as I was abroad. However, the documentary record also makes it clear that I was copied into key documents when finalised for release, including submissions to Ministers and the final arrangements for the announcements of 11 January. I expect that I would have discussed them with Dr Metters, but I have no real memory of any details now. I later signed the CMO letter that was the product of the Working Party's discussions and was issued on 3 April 1995.

42.4. More broadly, Dr Metters was assisted by the members of the Working Party ("the WP"). The membership is set out at [DHSC0003555_013] and included Dr Robinson (Medical Director of the NBA), and medical experts, including from the devolved administrations. Overall approval of the decisions lay with the Parliamentary Under Secretary of State, which was Mr Sackville until 29 November 1995, and then Mr John (later Lord) Horam. Officials involved with the planning included Mr Roger Scofield and Dr Rejman, with input at times from Dr Nicholas.

Publicising the Look Back Exercise

42.5. I have been asked what consideration was given to ensuring that the information was disseminated to the most suitable audience. Again, I was not directly involved in this decision-making. But I can see that:-

a. The original announcements were to Parliament, in the form of a PQ, and to the press. As well as being announced to the media, the briefing from

Dr Metters, together with supplementary information, was sent out from the CMO's Office via the Directors of Public Health to recipients throughout the NHS including GPs and relevant consultants [HHFT0000002_002];

b. A Helpline was set up, via the NBA, for members of the public who were concerned. The Helpline was aimed at ensuring that the public had access to information, including as a result of the Panorama programme. There is reference in LBE WP minutes to the Helpline receiving in excess of 12,000 calls in the first weeks after the announcement and/or the broadcast of the Panorama programme, which ultimately took place on 23 January 1995;

c. The minutes of the Working Party show that attention was given to the provision of detailed guidance to RTCs, consultants and GPs. There was co-ordination with the Devolved Administrations.

Counselling and Testing Arrangements

42.6. I have been asked about the consideration of counselling and testing arrangements. I can see that some initial information for GPs and others contacted by patients as a result of the announcement of the LBE and/or the Panorama programme was included in the information sent out on 11 January 1995.

42.7. Counselling and testing arrangement were then considered in detail by the LBE Working Party and were ultimately set out in the guidance sent out on 3 April 1995 in the "*Dear Doctor*" or CMO letter (PL CMO(95)1 [NHBT0002796_002]). Annex A contained the Guidance on Look Back Procedures and Annex B contained guidance on counselling and treatment. The second document noted that patients might need several consultations to come to terms with their situation and that independent support networks

might be helpful; there was reference to the role of the British Liver Trust. It is apparent that the precise form of the counselling and follow-up would be a matter for the specialist centre to which the patient was to be referred. See further Section 8 below.

The Wording of the Parliamentary Question, 11 January 1995

42.8. The Inquiry has asked about the wording of the Inspired PQ of 11 January 1995, which ultimately read:

> *"The Government has accepted the recommendation of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation with a look back exercise should be undertaken with a view to tracing, counselling and treating those who may have inadvertently been infected with Hepatitis C through blood transfusions given in this country …"* [DHSC0003555_024]

42.9. I do not remember having any involvement in the drafting of this and I have not been referred to any record of such involvement. As a result, I do not feel that I can comment further on the choice of words.

42.10. An explanation of the scope of the LBE was included in my CMO's letter of April 1995, which stated that *"For patients transfused prior to September 1991, it may only be possible to provide full reassurance by offering to test them for antibodies to HCV"*. This was a limitation in the design or scope of the LBE, although it is apparent that during this period, further tests were carried out as a result of patient concerns, outside of the LBE itself.

Information for Patients and Members of the Public

42.11. I have been asked about the position of patients and members of the public.

a. There was scope for members of the public to be worried, as they would not know whether blood that they had received was potentially infected,

or whether an infected donor returned to give blood after September 1991.

b. As set out above, arrangements were made to provide information to concerned members of public, whether via the Helpline or by ensuring that GPs were equipped to answer questions about the LBE.

c. Patients were advised to wait until contacted, for the reasons set out in the script for the Helpline, which stated that the risk of infection was very small: see [DHSC0002502_007]. However, it is apparent that during this period, further tests were carried out as a result of patient concerns, outside of the LBE itself.

d. The fact that the LBE would not succeed in tracing all patients who had been exposed to an infected transfusion was recognised in its design (see above). The problem of donors who had given blood before that date but not afterwards was further considered by the Working Party: see at Question 47 below.

Design of the LBE

42.12. I have been asked whether in retrospect, a different approach might have been taken to either the LBE itself or the announcement of the LBE and the information provided to doctors about it.

Ethical Issues – Information to Patients

42.13. I have been further asked about the ethics of the draft answers at F1 in the Supplementaries for the Dr Metters and Dr Robinson Press briefing of 11 January [NHBT0005855]. There are handwritten notes on it, making it difficult to know what, if anything, might actually have been said about this topic in the press conference (the issue might not have been raised).

42.14. Again, I had no involvement in the drafting of this Guidance, but the relevant parts state:

- *"It will be for their GP or consultant to decide if, and when to inform someone who is found to be at risk.*

- *In most cases the medical practitioner will make known the situation to his patient but in some cases where it is judged that there is no benefit in so doing and the patient would be unnecessarily distressed, the information may be kept for medical purposes only."*

42.15. The handwritten notes on the righthand side are difficult to decipher, but they seem to raise the case of the patient whose underlying disease is such that HCV infection would not cause (or raise) symptoms in their lifetime. It is not possible to be confident that this what the note says but if these suggestions are accurate, my view is that a clinician might – depending on the circumstances - regard it as unnecessary or inappropriate to inform the patient of a potential HCV infection. It was regarded as a matter for individual clinical judgement.

42.16. The Annex to this Statement notes how ethical concerns were held by, for example, the members of the MSBT Sub-Committee which met to discuss a LBE on 3 November 1994. Whilst I cannot comment on the authorship of the "Supplementaries", it seems to me likely that the passage which has been highlighted by the IBI arises out of such ethical concerns, and, ultimately, the concern that the LBE should not cause harm to patients.

42.17. The final guidance attached to the "*Dear Doctor*" CMO's letter of April 1995 (PL CMO(95)1 [NHBT0002796_002]), stated that:

a. <u>In the actions for RTCs</u>: Whilst generally it would be assumed that all blood taken from donors identified as HCV positive would be infected and archived blood samples would not be tested to confirm this

assumption, "*An exception could be made where individual patient circumstances make it desirable to know whether or not they were put at risk, i.e., in individual patients where it would be preferable not to inform them that they had been put at risk unless the presence of an HCV infection would alter their management*".

b. General Principles of the Look Back: this repeated the wording of the draft put to the LBE: "*The presumption will be that each identified recipient would be tested and counselled. However in exceptional circumstances such as severe psychiatric illness or terminal physical illness the consultant or GP may feel it inappropriate to add to the patient's distress.*"

42.18. Finally, I note that the minutes of the last meeting of the LBE WP (13 October 1995) stated that the NBA had been asked to advise on *"whether the next-of-kin should be informed when infected cases were identified but the individual was thought not suitable for counselling (eg because of their age). The NBA's legal advisors considered that their* [sic] *was no medical or legal obligation to take such action, unless a "need to know" existed."*

42.19. I would comment now that these were all difficult ethical questions, in which the relationship between individual clinician and patient is genuinely important. It is of central importance that the clinician is truthful with his or her patient. But there may also be sensitivities about the manner and timing of communicating information, depending on the individual patient and their circumstances. The Inquiry may wish to note that I had discussed these sorts of issues in my book *"Healthy Respect: Ethics in health care*" (first published 1987), written with Professor RS Downie. I have exhibited Chapter 11, pages 144 – 155, which discuss both truth-telling and paternalism [WITN3430013]. We (Professor Downie and I) rejected the latter, but we also noted that truth-telling is complex, and that it may be appropriate to take time to explain all the features and implications of a diagnosis to a patient and their family.

The Numbers of Potentially Infected Patients.

42.20. I have been asked where the figure of 3000 potentially infected patients derives from. Please see the Annex for information; the paper from Dr Gillon's work in South East Scotland, published in 1994, seems to be the ultimate source for this estimate.

Q.43 Concerns raised after the announcement of the lookback exercise

43.1. I have been asked what concerns were raised with the DOH about the LBE, and what steps were taken to address them.

43.2. From the papers, it does not appear that I had any day-to-day involvement in the LBE until the issue of the CMO's letter on 3 April 1995. As a result, it seems to me that the information available on this topic is most appropriately set out in the Annex to this statement.

43.3. I can see that some correspondence was sent to me. For example, on 6 April 1995, I was sent a letter from Dr GD Bell, a Consultant Gastroenterologist, who asked who was responsible for paying for the treatment advised as a result of being identified as HCV positive. [DHSC0003595_023]. However, the reply to this was sent on 6 June 1995 by Dr Nicholas. He replied that prescribing of interferon was not envisaged as being a matter for GPs; it would be prescribed by a specialist hospital centre, "*with the costs falling to the health authority or the GP funding holder as appropriate presumably through the necessary contract or ECR*" [extra-contractual referral] [DHSC0003595_024].

Q.44 Tracing donors who did not return to a Transfusion Centre

44.1. I have been asked what consideration was given to tracing the recipients of blood from a donor who had given blood prior to September 1991 but had not come back to a Transfusion Centre since that date.

44.2. The limits of the scope of the LBE are set out in, for example, the letters sent to Consultant Microbiologists as part of the processes developed by the Working Party. See the draft letter at [NHBT0005834_002] which stated:

> *"It is not part of the current look back exercise to examine recipients of blood products or fractions that have come from donors whose Hepatitis C status is not known, but it remains relevant to notify the Blood Transfusion Service of patients who have received blood prior to 1991 and believe that their documented Hepatitis C infection may have been transmitted to them by transfusion. It is also not part of the current look-back exercise to examine recipients of tissues, organs, or semen prior to the introduction of testing for Hepatitis C. Recipients of semen are thought to be at very low risk of infection. Consideration should be given to the origins of any Hepatitis C infection detected in organ and tissue transplantation as it may be advisable to trace other recipients from the same donor."*

44.3. The Guidance on Counselling included with the CMO letter of 3 April again noted that not all patients would be identified by the LBE and stated: *"For patients transfused prior to September 1991, it may only be possible to provide full reassurance by offering to test them for antibodies to HCV"* [BMAL0000022_003].

44.4. Testing of patients was therefore a step that could be taken if those patients approached practitioners with concerns.

44.5. It is apparent from the documents that the LBE Working Party considered the wider issue raised by donors who had not returned to give blood after 1 September 1991 on a number of occasions. The information is set out in the Annex and relates to whether it would be practical or proportionate to test stored samples of blood, being the only way of identifying donors who had not returned after HCV screening had been introduced.

44.6. In particular, I can see that the matter was reconsidered in the last meeting of the WP, held on 13 October 1995, where the minutes [WITN3430014] state:

> "*Testing of stored samples.*
>
> *6.1 Research in Scotland on testing of stored samples not included in the look-back had shown that the number still alive after five years is small [NB see here para 4.4 of the minutes: "During discussion of the number of recipients still alive, the Chairman noted that it was anecdotally reported that 50% of blood recipients die within one to two years after receiving blood, of their underlying disease, but good data on post transfusion survival was not available".] which suggests that it is not worth attempting to do.*
>
> *6.2 Professor Thomas considered this to be an unique opportunity to see if all patients who are exposed become infected.*
>
> *6.3 Dr Gillon confirmed that the Scottish experience had shown that if the donation is infected then 100 per cent of recipients become infected.*
>
> *6.4 The Chairman said that he had asked lawyers for advice and was awaiting their reply.*"

44.7. The "*conclusion of the [LBE] exercise*" minutes at the end of this meeting stated that the Chair (Dr Metters) stated that officials would be sending a report to Ministers. "*They would recommend that stored samples which did not relate to previous donations of donors found to be positive since 1991 should not be included.…It would be more important to underline the continued availability of tests to those who asked for one.*" (See also paragraph 3.6 of the minutes, where the Chair summed up "*that test[s] were available to anyone who requested them, particularly where there had been multiple transfusions. The group did not advocate extending the look back exercise beyond its original remit.*").

44.8. A report was made to Ministers (PS(H)) on 5 February 1996 from Dr Metters. It was copied to my Private Office. No action was said to be required, although Ministers might wish to meet with officials to discuss the report. Relevantly, it stated:

> "*3.2 It was agreed that the look-back exercise should be concentrated in the first instance upon donors who had given blood prior to September 1991 and had been found to be Hepatitis C antibody positive after the introduction of testing in September 1991. The services would not try to trace donors who had not come back to a Transfusion Centre since then. The work involved in doing so would be disproportionate to the benefit. The Working Party considered the testing of serum samples stored from before September 1991 and agreed the Ministers should be advised that the testing of such samples would also be disproportionate, although a legal view on this should be obtained and the subject would be considered again following the results of the current Look Back. However, where an individual who had been given blood requested a test this should be made available, particularly where there had been multiple transfusions. The Working Party also advised that the lookback should not be extended to other blood products.*" [DHSC0004469_013, & Annex at DHSC0003533_023].

44.9. It seems to me, looking at this now, that this emphasis on what was proportionate reflects the reality of resource constraints in the NHS. It is difficult, indeed not possible, to provide the ideal services that you would like to provide. Resources used for one exercise means that they are not available for another. The constraints relate not only to money, but the availability of trained staff and equipment.

Q.45 & Q.46 Meeting of the Health Select Committee in February 1995

45.1. I have been referred to a record of a briefing note for an informal meeting with the Health Select Committee on 15 February 1995 [DHSC0041441_109] and asked if the briefing is an accurate representation of my views at the time. It is apparent that the briefing note is an internal one, probably from a member or members of the medical staff (see the statement at the end *"Mr Luxton … would be happy to brief CMO further if necessary"*). As such, it does not set out my views, although I have no reason to doubt its accuracy.

46.1. This Note in turn refers to a separate briefing on the LBE being provided. I have been provided with a copy of a short briefing note sent to my Private Office by Dr Rejman on 27 January 1995 [WITN3430015]. An updated briefing was sent by Dr Rejman on 3 February 1995 [DHSC0003512_120 and DHSC0003512_121]. Both appended documents that were available at that date.

46.2. I have been asked what my understanding of the purpose and extent of the LBE Exercise was. I would expect that I would have studied the documents that were attached to the two briefing documents I have referred to. But ultimately, the answer to that should be apparent from the CMO's letter of 3 April 1995, when the scheme had been more fully developed.

46.3. It may be worth noting that this briefing was only one of a range of briefings for this meeting with the Select Committee, and also that Dr Metters and Dr Winyard were also probably in attendance. See, for example, the minute from Mr Pink to Dr Winyard dated 23 January 1995 and my minute dated 20 February 1995 thanking officials for their work in preparation for the Health Select Committee meeting [WITN3430016]. It is not clear to me now how much information was sought by the Select Committee on Lookback. No record of the meeting has, I am told, been found to date, although the Inquiry may be able to make further inquiries of the House of Commons Authorities.

Q.47 The erroneous National Blood Service letter of 21 March 1995.

47.1. I have been asked to say what measures were in place to ensure that Blood Transfusion Centres sent out appropriate information to blood donors who were identified as HCV positive. In particular, the IBI has drawn my attention to a letter to a donor dated 21 March 1995 [NHBT0017239], from a Dr Gorman (Consultant Haematologist) of the National Blood Service, Brentwood. The letter advised the donor that he had been infected with Hepatitis C, and gave advice on the severity of the illness which, it can be seen, downplayed the potential infection risks associated with the condition. As Dr Nicholas commented on 31 August 1995 in his subsequent letter to Dr Metters [DHSC0002549_054], "*the third indent of para three is extraordinarily complacent in playing down transmission risks in the face of knowledge at that time*."

47.2. It seems that the case was drawn to the attention of Dr Metters by Alison Rogers, the Director of the British Liver Trust, in their meeting on 16 June 1995. She followed an oral discussion by sending a copy of the letter to the patient (whose name and address had been blanked out, see [WITN3430017]), as well as a newspaper article referencing the case [DHSC0002549_057] to Dr Metters on 21 August 1995. This suggests that the patient's wife received an infected donation in a transfusion in 1988 and was given a positive diagnosis for HCV after screening of blood donations commenced in September 1991. Her husband was told that he too was infected in April 1995.

47.3. It also appears that the patient concerned wrote directly to myself as CMO. However, the letter(s) have not been traced to date – only Dr Nicholas' reply. Dr Nicholas replied to the patient on 1 August 1995 on my behalf, giving information along the lines of the Working Party's guidelines / CMO letter (see letter of 1 August 1995 at [DHSC0002549_055]. As can be seen from the letter of 31 August 1995, he also subsequently brought the matter to the attention of Dr Metters who asked Dr Rejman to look into the matter (see the

handwritten note on the top of the letter from Dr Nicholas). However, I am told that searches for any further documents have not been successful.

47.4. There is a further letter from Dr Nicholas on the topic to Dr Rejman dated 14 December 1995 [DHSC0002550_094], in response to a minute from Dr Rejman dated 27 November, commenting on a defensive letter from Dr Hewitt of the NBS. He commented that the NBS was explaining the difficulties of counselling individuals, but these were not issues that the DH had been critical of. "*Our point is that what information the NHS provide should, as far as is possible, be accurate, in line with current knowledge and with the advice given by other competent authorities. Dr Robinson would have been well aware of current opinion regarding sexual transmission because it was discussed at the Ad Hoc Working Group earlier in the year, and drafts of the various materials going into the CMO letter had been discussed and circulated for comment well before Dr Gorman's letter was sent out."* Since the CMO letter had since gone out, and presumably read by those who worked in the NBS, there was no more to do, *"but it would be nice to be re-assured that all parts of the NBS were offering similar advice about hepatitis C."*

47.5. As far as is apparent from these documents none of these letters were sent to me at the time, with the exception of the letters from the patient to which Dr Nicholas replied. I do not recollect having any involvement in this matter. I am not able to say what follow-up action was taken by Dr Metters or others.

47.6. Generally, the information sent out by the National Blood Service was a matter for it and not for the DH. However, accurate information to patients is very important and I would have expected consultation with DH. The information sent out by its consultants or staff was the Blood Service's responsibility, but it should have been discussed with DH.

Q.48 Issue of the CMO Letter of 3 April 1995

48.1. On 3 April, a CMO's letter was issued by me, supported by a Health Service Guidance circular. The CMO letter consisted of:

(a) "Dear Doctor" Letter, PL CMO (95)1 [NHBT0002796_002];

(b) Annex A: Procedural Guidance, outlining steps to be taken by the Regional Transfusion Centres in particular and attaching an "algorithm" setting out the steps to be taken [as above];

(c) Annex B: Guidelines for Counselling Patients identified as hepatitis C positive [BMAL0000022_003].

48.2. The Health Service Guidance circular HSG(95)23 issued by the NHS Executive [NHBT0002737_005] supported the CMO letter by asking Trusts to make all the necessary arrangements for action, particularly with regards to tracing records, and by bringing the matter to the attention of all appropriate staff.

48.3. I have been asked what work was done to issue this guidance. As set out above, the key work was done through the group of experts convened as an ad-hoc Working Party, chaired by Dr Metters. The minutes of their meetings record the primary tasks undertaken: see the minutes of:

(a) 20 January 1995: [NHBT0009715];

(b) February 1995: [WITN3430018];

(c) 14 March 1995: [DHSC0003595_030].

Q.49 The provision of psychological support

49.1. I have been asked about the provision of psychological support to patients.

49.2. Counselling has been addressed above and has again been picked up in response to Section 8, below. As noted in the Submission from Mr Pudlo

dated 11 July 1995, discussed at Question 59 below, the question of what counselling services were provided by specialist centres, and whether they included psychological input, was primarily a decision for local health services and its form or source might vary as a result. Although there was explicit reference to the need for counselling of those who were identified as at risk through the LBE, counselling had to be provided to all those facing a diagnosis of HCV infection, regardless of the route of infection. I have commented more extensively on counselling in Section 8 (Question 59, Question 60). In general, I do not think that the picture in respect of counselling for a hepatitis diagnosis differed from that which would be found if other serious clinical conditions were examined. Furthermore, resources – people as well as money – were always an issue in the health service.

Q.50 Infected recipients living outside of the United Kingdom

50.1. I have been asked whether consideration was given to how to trace the recipients of infected blood who lived outside of the UK. From the documents, it appears that I played no personal role in considering this issue. Please see the Annex for further details. It appears that advice was given that clinicians abroad should be notified of any known infectious units of blood sent.

Q.51 Letter of May 1995 from Kenneth Clarke to Virginia Bottomley

51.1. I have been asked about a letter sent by Mr Kenneth Clarke MP on behalf of his constituent, a Dr Bywater.

51.2. I do not believe, from the documents supplied, that I had any personal involvement in this matter or in drafting the correspondence referred to. Please see the Annex for further details. The documents show that Dr Bywater was concerned about those who might have been infected before 1989, as he erroneously thought that the LBE was limited to those transfused from 1989 onwards. He did not appear to have received the CMO's letter, perhaps because he was retired. He was reassured about this. But the broader aspect of this question again relates to the issue of how infected

donors who gave blood prior to the introduction of screening but had not returned after September 1991 could be traced. I have addressed this issue in answer to Question 44 above.

Q.52 Correspondence about transfusion numbers

52.1. I have been asked about figures for the numbers of those potentially infected with HCV as a result of transfusions that were substantially in excess of the figure of 3,000 used as a working estimate in the LBE.

52.2. I have been referred to a paper published in May 1995, entitled "Hepatitis C virus Infection: Public Health Research Priorities" [DHSC0002556_039]. In this, Dr Adrian Renton of the Academic Department of Public Health, St Mary's Hospital School London, gave an *"estimate that there may be some 40,000 transfusion associated cases and perhaps comparable numbers of injecting-drug-use acquired cases currently in the UK population. In addition there may be several thousand community acquired cases".* The figures were given in the context of proposals for follow-up studies linked to the LBE.

52.3. I can see from the information summarised in the Annex that this estimate of 40,000 was sent to Dr Metters and discussed within the DH. However, I do not have any recollection of this discussion, which does not seem to have involved me.

52.4. The undated note by an unknown author at [WITN3430019, WITN3430020, WITN3430021] seems to have set out the conclusions reached after some discussion (see Appendix 2, WITN3430021):

> *"The figure of 40,000 for prevalence among recipients of blood transfusions has gained some currency. In Dr Renton's model such an estimate is based on an annual mortality of about 10%. However, we know that half of transfusion recipients are dead within one to two years. This implies an annual mortality rate of 25% – 50%, a good way above the upper end of Dr Renton's range. The prevalence estimate is very sensitive to the annual mortality rate. A rate of 25%-50% leads to a prevalence estimate below 10,000. With these mortality rates and*

> *indeed with Dr Renton's rates of 10% and 20% prevalence at [sic] the starting data [sic] of 1975 is irrelevant because the vast majority will be long dead. The lookback figures may give a better starting point for an estimate than the apparently promising "crude actuarial model" approach followed by Dr Renton."*

52.5. I have been asked whether in the light of "*this revised figure*" (of 40,000), what steps were taken to identify the substantially higher number of recipients, and whether the guidance to GPs was amended. However, given the note I have reproduced above, it is not apparent that the figure of 40,000 was accepted, or that the estimates of those who might reasonably be picked up by the LBE were altered.

52.6. The wider question of prevalence was again considered by Dr Metters on 6 November 1995 [DHSC0002550_137], when he wrote to Drs Nicholas and Rejman expressing the opinion that the only conclusion he could draw was that "*we really have no certainty*" about the numbers of patients with HCV "*as a result of transfusion or perhaps more importantly, the total numbers in the population who are HCV positive.*" *"We could give all the data to the mathematical modellers and ask them to come up with better estimates, but given the numerous uncertainties about transmission via different groups during the last six 5-year periods, I doubt they will be able to give us any more robust figures!"* His view was that, rather than "*arguing*" over mathematical modelling etc, HP Division and CA-OPU2 should decide what additional information about prevalence was needed for policy purposes and build on this.

52.7. In my view, this is a good example of the problem of uncertainty or decision-making with limited information. It was often not possible to have all the data that would ideally be at hand to decide a policy response, and the decisions had to be made on imperfect information. If the figure had been 40,000, it plainly would have had important implications, but the LBE was based on the best estimate available.

52.8. The issue of the further research work needed as a result of (or linked to) the LBE was one of the topics being considered by the MSBT/LBE WP. More generally, issues of prevalence, identification (including by way of screening programmes) and what that meant for treatment responses were amongst the topics considered in relation to HCV infections more generally, across the course of 1996. Please see Section 8, below.

Compensation for HCV Infection

52.9. Under the heading of this question, the Inquiry has also drawn my attention to a letter from a GP dated 5 May 1995, although it concerns the rather separate issue of financial support or compensation. The GP refers to the case of a patient who appears to have been infected with HCV as a result of a transfusion received 5 years following a bowel operation. The GP asked for my views on the issue of compensation for such patients.

52.10. I can see that a letter was sent in return by Mr Levy on my behalf, setting out the position taken by the Department of Health. It outlined the history of the introduction of HCV screening and steps being taken to help those infected, including the LBE. It continued:

> *"The Government does not accept, however, that there has been any negligence and they have no plans to make payments to such patients. On the more general issue of compensation, the Government has never accepted the case for a no fault scheme of compensation for medical accidents. It is unfair to others and still requires proof of causation which is often difficult to establish. Every individual case where a medical accident has occurred is a personal tragedy for both the individual concerned and their family. If the NHS is proved negligent in a Court, it accepts its liability to pay damages.*
>
> *It is the Government's view that the most effective use of resources is to seek to improve the understanding, management and treatment of the condition ….*" [WITN3430022].

Q.53 Public health campaigns to raise awareness of HCV

53.1. I have been asked whether any consideration was given to a public health campaign to raise awareness of Hepatitis C, particularly amongst those who might not be identified by the LBE. I cannot now recall what consideration was given to this topic, and it does not appear to be a matter in which I was personally involved.

Q.54 Letter of 16 June 1995 from Dr Rejman to Dr Robinson

54.1. I have been asked questions about the ethics of a draft reply from Dr Rejman to Dr Robinson, in response to Dr Robinson's detailed letter of 6 June 1995 [NHBT0092067_015]. This is not correspondence that I would have seen at the relevant time and I had no personal involvement in it.

54.2. I would comment generally that I had considered and written about medical ethics in healthcare before becoming CMO; I have already referred to my book from 1987. The issue of how doctors speak to patients has evolved and changed over time. So for context, it may be worth noting that in 1995, the GMC's Guidance "Good Medical Practice" did not include any clear statement about what to do in the event that harm to a patient was discovered, although under the heading of "working with colleagues", it did include advice that *"You must not make any patient doubt a colleague's knowledge or skills by making unnecessary or unsustainable comments about them"* [WITN3430023].

54.3. In July 1998, that advice was withdrawn and the GMC updated its Guidance with a new section, "If things go wrong". This stated that "*If a patient under your care has suffered serious harm, through misadventure or for any other reason, you should act immediately to put matters right, if that is possible. You should explain fully to the patient what has happened and the likely long- and short-term effects. When appropriate you should offer an apology."*

Q.55 GP Knowledge of the CMO Letter

55.1. I have been asked about the contents of a briefing from Mr Pudlo to Mr Hollebon (Private Secretary to the Parliamentary Secretary for Health) dated 11 July 1995 [DHSC0003552_115]. It followed a request for a briefing on a pamphlet published by the British Liver Trust "C-Positive".

55.2. Details of this material are set out in the Annex. I was not copied into any of this material at the time and I have no personal knowledge of it.

55.3. The general issue is the extent of knowledge amongst GPs of my CMO letter of 3 April 1995, particularly in the light of an NBA *"straw poll"* of GPs in the "South West zone" which suggested that the Counselling Guidelines had not been digested and none could recall the CMO's letter on Look-Back.

55.4. Information about the announcement of the LBE on 11 January 1995 was sent to GPs. The Guidance sent out on 3 April 1995 was then deliberately sent out as CMO letter as that would mean that it was sent directly to all registered medical practitioners (about 90,000), both in private practice as well as the NHS. It was regarded as a means of assuring the Department that "*no group of doctors which needed to be included would be left out of this important exercise*" (see the minute from Mr Burrage dated 13 March 1995 [WITN4486092]). The letter contained detailed guidance for GPs.

55.5. Although GPs are busy practitioners, it is difficult to know what more the DOH could reasonably have done. The "C-positive" newsletter carried an article from a Clinical Nurse Specialist which made the point that there was a general problem of a lack of awareness of HCV amongst healthcare workers, GPs, hospital doctors, nurses, etc.

55.6. There was a lot of interaction between the Department at and the British Liver Trust in 1995. See Question 59 below, where this is discussed in more detail.

Q.56 Interim Report on Lookback

56.1. I have been asked about a draft report on the LBE exercise produced in September 1995 and its report on progress. The Interim Report produced by John Nash on 4 September 1995 [DHSC0002557_157] was an early draft.

There is nothing to show on the documents that I would have received it at the time. Furthermore, it contains only a little information about progress. Although the questions ask me about a statement in it about progress being slower than expected, this does not appear in this report, as far as I can see. The report went through various iterations before, ultimately, an updating submission went from Dr Metters to Ministers in early February 1996 [DHSC0004469_013]. That report was addressed to the Private Office of the Parliamentary Under-Secretary of State for Health, the Minister responsible and was copied to my Private Office.

56.2. Before that report went to Ministers (and my Office), the progress of the LBE and options for more speedy progress had been discussed in a series of meetings or reports. I have seen summaries of the relevant minutes, as set out in the Annex. I do not think, from the documentary record, that I had any involvement in these discussions at the time.

56.3. The Ministerial submission sent 5 February 1996 [DHSC0004469_013] set out the history of the LBE and the numbers identified up to that point. On this: some 1727 donors for Hepatitis C who had given blood prior to 1991. 9048 donations had been identified, with 2808 recipients identified of whom 1631 had already died of unrelated causes (see Annex E at [DHSC0004469_025]). *"These figures suggest that the original estimate of identifying approximately 3000 recipients who are alive was realistic".*

56.4. The submission explained that the exercise had taken longer than expected. The bottlenecks were: (i) tracing medical records for recipients identified by hospital blood banks; and (ii) a shortage of counsellors to see patients prior to and after testing. But if these bottlenecks were overcome, hepatology services and, where appropriate, commencement of treatment, *"would probably not be able to cope*". The recommendation to Ministers (following the advice of the MSBT) was to continue 'as is', as slower identification of those affected across the rest of 1996 was unlikely to damage patients and risked creating subsequent bottlenecks.

56.5. Annex F [DHSC0004469_027] set out the alternative approaches to continuing as planned - including abandoning the LBE and offering Hepatitis C tests to anyone who had been transfused. There should be communications between the BTS and hospital where particular problems were identified, to enquire as to progress etc. Annex F stated that the options of abandoning the Look-Back entirely and offering hepatitis C tests to anyone who has been transfused should not be followed, as the LBE *"had been carefully designed to identify and offer counselling and treatment to recipients of blood transfusion units implicated in the Look-Back in a structured way that would maximise benefits to them. At the same time the Look-Back would obtain important information about the rate of transmission and natural history of Hepatitis C when acquired from transfusion that was currently not available."* It was said (relevantly to the possible offer of assistance to overcome bottlenecks) that *"a delay in the identification process that might be extended for the rest of 1996 would not disadvantage patients as the evidence was of a 20-30 year time frame for significant liver damage to occur".*

56.6. Overall, the Minister was asked to note progress, with a meeting with officials for any further details to be discussed.

56.7. I have been asked why the options in Annex F were not pursued. I do not have any personal knowledge of this matter, but I can see that the options were discussed with members of the MSBT and the submission to Ministers (and my Office) reflected the advice of that Committee. The issues identified represented a dilemma that was not uncommon. That is, it might be known what the ideal solution would be (i.e., faster progress), but the resources to adopt it were not there (the progress had to match the ability of the system to cope).

56.8. Mr Horam responded briefly on 12 February noting the progress and actions to date [DHSC0002533_119]. Further detail was provided on 4 March 1996, when his Private Secretary wrote on his behalf:

> "*… PS(H) has clarified his views. He agrees that central exhortation to speed up the Look-Back exercise would be unlikely to achieve much. He is content with the preferred option of continuing the current strategy, whilst improving communication between the BTS and hospitals where there are particular problems and offering assistance to overcome the bottlenecks.*
>
> *PS(H) does not feel that a meeting at this stage is necessary but looks forward to receiving a further report in the next 6 – 9 months.*" [DHSC0002533_152]

56.9. My attention has been drawn to other correspondence which shows the pressures related to the potential wider demand for treatment for HCV and interferon in particular. See the letter from Dr Nicholas dated 16 January 1996 [DHSC0004469_052] to Ms Phillips and Ms Marsden, speaking about the difficulties of managing the potential demand from other groups. *"Such patients could compete with those infected by blood transfusion as available resources allocated to the treatment of hepatitis C by Health Authorities is likely to be limited."* The issue of access to treatment is considered more fully in Section 8.

56.10. I can see from the Annex that further discussions about progress continued.

Q.57 The Hepatitis Seminar of 1998

57.1. I have been asked about a seminar that I held for M(PH) and MS(L) (Ms Jowell and Baroness Jay) on hepatitis in early May 1998, by reference to [DHSC0038649_079]. This is a minute written on 3 December 1998, after I had stood down as CMO; it is addressed to my successor.

57.2. Documents relevant to the seminar are summarised in the Annex. I do not have any memory of this seminar and no note of it has been found. Given that the minute of 3 December did not attach a note of the seminar, one may well not exist. That minute suggests that there was no particular outcome, in terms of concrete decisions: "*The outcome was that Ministers asked for a further meeting some time in the autumn to consider in a more focused*

manner possible ways forward on a number of issues. This further meeting had has to be postponed …"

57.3. I do not think that I can add to this now.

Section 8: Treatment and support for Hepatitis C positive patients

Q.58 Counselling and Support, 1992

58.1. I have been asked about correspondence sent to me in February 1992.

58.2. On 4 February, Dr Mehtar, Chair of the North East Thames Microbiology Advisory Committee, wrote to me requesting a separate allocation of funding to investigate and deal with the overall prevalence of HCV carriers and to advise them via "social support systems" [DHSC0002501_019]. He noted that three centres tested for Hepatitis C as a screening service, and also *"provide specialised supplemental and reference facilities for sero-positive individuals".* He argued that factors such as the numbers of those being diagnosed and the serious consequences of infection meant that there needed to be a separate allocation of funding to enable advice *"to HCV carriers via social support systems – much the same as HIV positive patients and Hepatitis B positive patients."*

58.3. The process of drafting a reply is dealt with in the Annex. I cannot now remember any discussion of this letter and I do not know whether or not Dr Metters or anyone else discussed it or any reply with me. Generally, the process of dealing with letters received as CMO was that I would see letters addressed to me (unless they were short acknowledging ones or similar) but then they would usually be passed to medical colleagues with specialist knowledge or involvement in the policy area for reply. Many would result in a reply from (e.g.) the DCMO, rather than myself. My Private Secretaries were all medically qualified, were excellent and were good at handling these decisions.

58.4. The context of the letter from Dr Mehtar appears to be the general issue of HCV prevalence in the population (rather than the more specific topic of those infected by the blood transfusion route). The issue of counselling has been discussed further below, in Questions 59, 60 and 63 in particular. The general DH view was that this was an issue for the purchasers of services; this would have included advice to drug misusers about testing, etc.

Q.59 The views of the British Liver Trust, 1995

59.1. I have been referred to a short briefing that was drafted by Paul Pudlo, CA-OPU2 to Andrew Hollebon, the Private Secretary of the PS(H), Mr Sackville [DHSC0003552_115]. In it, Mr Pudlo noted that the British Liver Trust were critical of the lack of counselling for new HCV patients and poor GP awareness of the disease.

59.2. I have already noted above in response to Question 55 (Section 7), the criticisms made by the BLT of the counselling available for those diagnosed with HCV and about poor GP awareness of the disease. I have been asked what awareness I had of these counselling issues. The submission from Mr Pudlo of 11 July 1995 was sent to the Private Secretary of the Parliamentary Secretary for Health and, as far as I am aware, was not copied to me. I have no personal knowledge of this material.

59.3. The focus of the questions from the IBI is upon the provision of "psychological" counselling. The term has not been defined, but it appears that the Inquiry is interested in whether there was more than "clinical" information about a diagnosis, its potential effects and treatment options offered. The Inquiry appears to be interested in whether more long-term support for those infected was offered. This, however, could potentially be offered by a range of healthcare workers and it would not necessarily have been seen as requiring the expertise of psychologists or those with psychological training.

59.4. This is consistent with the practice and policy in other areas of care, including cancer services (with which I am most familiar, since that was my specialist area of practice). Patients and their families needed information and support, including practical support, to cope with diagnosis, treatment and living with a disease. These could be provided by a range of healthcare workers, as well as social workers too. Also very important and useful was support from other patients. In my autobiography, I talk about how when practising as an oncologist, I set about involving patients in the specialist oncology service of which I was part. We set up a patient support group called "Tak Tent" ("Take

Care"), at a time when there was nothing like this in the UK. Patients were involved in, for example, writing leaflets to share information about experience of living with cancer. At that time (the 1980s) cancer still had a stigma attached to it. These are all aspects of providing counselling and support to patients.

59.5. Thinking about this topic now, it seems to me that the counselling that was referred at the time might not be psychological counselling (although equally, on occasion, it might be). The decision would be one for the specialised services concerned, and the provision would probably not be uniform across the UK but would depend on specialist advice as well as available funding. I have explained above how broad the sources of potential support could properly be.

59.6. I note that the Minute from Mr Pudlo also referred to the fact that the DOH was funding, though a s64 grant, a Haemophilia Society study into patients' needs in terms of counselling, and that officials took the view that more work had to be done to identify those needs.

59.7. I have been asked about my involvement in decisions about counselling, in responding to the BLT. I cannot remember any personal involvement in this issue. As will be plain from this Statement in general, HCV-related issues were generally dealt with by Dr Metters or those reporting to him, although he would have discussed issues or progress with me from time to time.

59.8. The issues dealt with by Dr Metters included responding to the BLT. When a letter was sent by Dr Rogers of the BLT to me on 20 April, suggesting a meeting (the letter is reported in a minute at [WITN3430024]), an internal response from Mr Scofield [WITN3430025], records that I was not keen to meet with the BLT myself, no doubt because Dr Metters had been leading on this area of policy. The suggestion was that Dr Metters should meet them with those involved in the LBE WP. I understand, from reading the Annex, that Dr Metters subsequently met with the BLT in June 1996.

59.9. As for my involvement in increasing GP awareness of the disease, my CMO's letter of 3 April 1995 about the Lookback Exercise included general

information about Hepatitis, its effects and treatment. This was sent to all GPs.

59.10. Generally, the DH funded the Health Education Authority to produce information for the public about health issues, and to support national and local health-related events. This produced information on Hepatitis C, amongst other issues (see Question 64 below).

Q.60 Meeting with the Haemophilia Society, August 1995

60.1. In August 1995 a meeting was held between Mr Parker of the Haemophilia Society and Mr Pudlo of the DH [DHSC0002467_049] in which concerns about counselling were again raised. I have been asked what steps were taken to address these concerns.

60.2. In the minute following this meeting dated 9 August 1995 [DHSC0002467_049]. Mr Pudlo reported back on a range of issues that had been discussed. The minute was addressed to Dr Rejman but was copied to my Private Secretary, Dr Harvey, amongst others.

60.3. In relation to the topic of counselling, the Haemophilia Society was told that the prospect of ring-fencing funding for counselling initiatives (amongst others) was "*remote. However we are funding through s64 a Society Study into patient needs in terms of counselling.*" Mr Barker had told Mr Pudlo that the Society was beginning to get results from its research and to identify areas for further work. He was urged by Mr Pudlo to liaise closely with groups like the British Liver Trust and Mainliners to avoid duplicating efforts or arriving at inconsistent solutions.

60.4. On 2 October 1995, a lengthy paper on HCV treatment [DHSC0003552_018 DHSC0002467_049] was written by Mrs Phillips (HCD-SCS(A)2) with input from Drs Nicholas, Doyle and Mrs McIntyre. The topic of counselling was addressed thus:

> *"Another resource question that will have to be addressed is the question of who is to counsel the different categories of patients who are found to have HCV. BLT wish to undertake the work themselves*

given appropriate funding. This is not a practicable option and counselling is currently being undertaken by a variety of healthcare professionals. Guidance issued to the NHS in April (CMO letter) said that patients confirmed to be anti-HCV positive should be counselled on the implications of the test result and referred for a specialist opinion. We are under some pressure to provide additional resource is specifically for this."

60.5. Please see Question 63 for further information about this topic.

Q.61 Access to Alpha Interferon Treatment

Access by Haemophiliacs infected with HCV

61.1. The issue of access to interferon treatment was raised in an adjournment debate on 11 July 1995. Mr Sackville promised that the Department of Health would look into allegations of problems with the provision of Alpha Interferon for treatment of haemophiliacs infected with HCV [HSOC0026481_010 DHSC0002467_049].

61.2. I have already noted that on 9 August 1995, a meeting was held between Mr Pudlo (NHS Executive) and Mr Barker of the Haemophilia Society. The agenda for the meeting was set by a letter from Mr Barker to Mr Pudlo dated 18 July 1995 [DHSC0002474_007; DHSC0002467_049], in which he raised a number of issues including requests for specific, centralised funding for counselling, the PCR test for HCV and treatment with alpha interferon. He suggested that the Society had "*examples of haemophilia centres wishing to prescribe interferon but being told that they cannot because of lack of funds. This is unacceptable".*

61.3. The nature of the discussion and the issues raised are apparent from Mr Pudlo's subsequent minute to Dr Rejman, which was copied to my Private Office [DHSC0020838_160; DHSC0002467_049]. From this, it seems that Mr Barker stated that there were difficulties experienced by haemophiliacs in getting access to Interferon treatment.

61.4. In his Minute about the meeting, Mr Pudlo reported that the Society had only anecdotal evidence of treatment being withheld on financial grounds. Mr Pudlo had explained the difficulties which DOH had in responding without hard data on the nature and extent of the problem. He had agreed that the UKHCDO would be asked for further information. Mr Pudlo asked if Dr Rejman would contact Haemophilia Centre Directors to seek agreement in principle for a survey to be conducted. Dr Rejman agreed [DHSC0003534_087], saying that he would ask that the matter be discussed at the next meeting of the Regional Haemophilia Centre Directors on 4 September.

61.5. The follow-up investigation proposed by Mr Pudlo is addressed in the Annex. It is not apparent that I was asked to become personally involved in this or that any issues concerning it or its results were raised with me.

Wider Patient Access to Interferon Treatment

61.6. Discussion of the broader issue of access to Interferon treatment generally covered a wider range of topics, including:

1. Funding for treatment with Interferon prescribed as result of the lookback exercise;
2. As part of a broader discussion about the challenges posed to the NHS, in seeking to respond to Hepatitis C infections in the population at large; and
3. More narrowly and in response to correspondence, at the level of resisting demands for centralised or ring-fenced funding for Alpha Interferon treatment.

Funding for Interferon Prescribed as a Result of the LBE

61.7. In relation to the first issue, the IBI has referred to correspondence from Dr Bell to me. I have already explained that I would generally see letters

addressed to me, but was not necessarily involved in the process of drafting a reply, and that others might reply on my behalf.

61.8. A minute dated 2 June 1995 from Mr Levy to Dr Doyle and others asked for input to a reply for a letter from Dr Bell [DHSC0003595_018]. Dr Bell, from Ipswich Hospital, wrote to me as CMO on 6 April as a result of my CMO's letter of 3 April 1995 [see DHSC0002556_022]. He asked how interferon treatment identified as required as a result of the lookback exercise should be funded. Dr Bell suggested that it was unclear whether the GP or the hospital/DHA should pay. The writer within the DHSC noted that no separate allocation of funding for treatment identified through the LBE had been provided.

61.9. Dr Nicholas provided comments on 6 June 1995 [DHSC0003595_024]. He stated that it was not envisaged that patients with HCV, or their treatment, should be managed by GPs – as the CMO's letter advised, they should be referred to a specialist. On costs, he stated: *"It would seem to me therefore, that in this instance interferon would be prescribed by the hospital with the costs falling to the health authority or the GP fund-holder as appropriate presumably through the necessary contracts or ECR [extra-contractual referral]. Others with more experience on the division of prescribing costs between HAs and GPs may have different views."* Whilst GPs could prescribe interferon by GPs wishing to treat their own patients, the Department would not commend this.

61.10. Mr Levy provided a draft answer on 13 June 1995 [DHSC0003595_016]. He too noted that it would for hospitals to prescribe interferon, not GPs. *"In the case of your particular patient, it may therefore be appropriate for you to prescribe interferon, if that is what you decide on a clinical basis. Your patient's Health Authority or GP fund-holder would then need to consider their priorities and decide, as a purchaser whether or not to fund the treatment."*

61.11. Mrs Phillips (HCD-SCS) provided further comments on a draft provided, on 23 June [WITN3430026]. She commented that the reply dealing with the GP/primary and second care interface required further work. There was a

"standard line" for similar letters about the prescribing of beta interferon for MS sufferers that should be incorporated. *"If I were Dr Bell, I am not sure that I would be happy with the letter as it stands; after all, the treatment of hepatitis C is a new and additional cost which will have a considerable impact on liver services and I am not aware that this new priority will be reflected in local purchasing plans. How are Trusts to be funded for the provision of Alpha Interferon for these patients? We have been advised by one hepatologist that about 70% of patients presenting to his unit are there because they have hepatitis C".* It is apparent from these last comments that she was addressing the general pressures related to HCV treatment funding, rather than as a result of the LBE only; see further below.

61.12. I have been advised that the final version of the reply to Dr Bell has not been traced. But there was a similar exchange in response to an email from Professor Griffiths. [DHSC0003595_015] shows Dr Metters asking for comments on this; this was sent to Mr Pudlo for action, 19 May 1995. On 13 June, Mr Levy replied [WITN3430027]. His reply was in similar terms to the suggested reply for Dr Bell, stressing that the prescribing decisions were for hospitals. The final answer sent out was dated 19 June 1995 and is at [DHSC0002556_004].

61.13. I do not believe that this correspondence or these funding matters were ones that I had any personal involvement in, at the time. I cannot now remember any issues about the funding for interferon required as a result of LBE referrals being brought to my attention.

<u>General Financial Pressures – Interferon Treatment</u>

61.14. The Annex sets out examples of documents discussing the general issue of the pressures on the NHS budget as a result of HCV prevalence in the population more generally and patient treatment needs. The Annex notes that

papers on HCV and its implications for the NHS were being drafted in (for example) October 1995, and commented upon by Dr Metters amongst others.

61.15. It appears that the suggestion that the NHS Executive Board should consider this wider topic was picked up and ultimately led to a paper being submitted in 13/14 June 1996. Please see Question 62 below.

61.16. However, it is not apparent that I had any particular personal involvement in this issue in 1995, from the documents that I have been referred to.

61.17. I do note, however, that on 13 December 1995 [DHSC0004469_076] I sent a Ministerial submission to the Private Secretary of the Minister for Health (M(H)) on the subject of Clinical Trials for major new drugs. A copy was sent to Mrs Phillips, given its relevance to Alpha Interferon issues [WITN3430028]. I discussed the handling of the guidance that had been issued for the introduction of beta-interferon (for MS sufferers) and what lessons the NHS had to learn from the process. I noted that the guidelines had been developed by the Association of British Neurologists, but at the last moment the ABN "*was not prepared to have its name attached to the guidelines for fear of litigation and the Standing Medical Advisory Committee (SMAC) agreed to 'underwrite' the Association's guidelines."* In relation to the wider issues about the process for introducing new drugs (rather than beta-interferon specifically), I asked a number of questions including:

> *"Is it the role of central government to issue clinical guidelines on the use of new drugs? If it is, what is the appropriate machinery – COG? CSM? SMAC? Do we need a new body? What mechanisms are needed to keep guidelines up to date? …*
>
> *To what extent would such guidelines replicate or get in the way of the licensing process? We are aware that some professionals are strongly in favour of more drugs/therapeutic areas being covered in a similar way to beta-interferon …."*

61.18. Officials were being asked to consider these issues further. I draw attention to this Submission as it illustrates that at the time there was no established

mechanism or practice whereby the DH would issue guidance on the use that should to be made of licensed drugs, and that a number of issues would need to be resolved if this was to become a practice. There was also scope for different views on whether it would be appropriate for it to do so, and if so, how – see my submission. The Inquiry will see that, as a result of all these issues, the approach adopted with Alpha Interferon for HCV was that the DH supported clinicians to develop guidelines. This was in accordance with general practice, which was that the DH did not issue clinical guidelines – the professions did.

61.19. There is an account of the arrangements in the briefing papers for the informal meeting of the House of Commons Select Committee on Health, 15 February 1995, about which I was asked in Section 7. The role of the Clinical Outcomes Group (COG), the Standing Medical Advisory Committee (SMAC) are explained, as well as the fact that clinical guidelines were developed by the professions (although they might have government support to do so).

61.20. The Inquiry will also be aware that ultimately, the National Institute for Clinical Excellence (NICE) was established in spring 1999 to create consistent guidelines about the use of treatments and to end inconsistencies in their availability across the UK. NICE created processes to consider these issues, including an administrative structure to support decision-making. I have been reminded that in October 2000, NICE issued Guidance on the treatment of Hepatitis C with alpha interferon and ribavirin. But in 1995, the establishment of NICE was still some years away.

Q.62 Discussions on HCV treatment and its funding, 1996

62.1. At Question 62, the IBI has asked about the discussions that took place *"in 1996 concerning guidelines for treatment of HCV and its funding"*. This Annex picks up the discussions about guidelines that started in 1995 and continued into 1998; it was not restricted to 1996.

62.2. In summary, the position is that the Department supported the medical profession and specifically the Royal College of Physicians (the RCP) to produce clinical guidelines for the use of Alpha Interferon. However, although this process seems to have started by about June 1996, it took a long time. In mid-1996, it was expected to take about a year. But in November 1997, civil servants were reporting that they expected them to be available and to be commended by the NHS Executive "early next year". It seems that the process ultimately finished in 1999.

62.3. The Annex sets out references to further papers developing these issues, but the CMO's office appears to have had little direct involvement. I can see that there was "brief" discussion of Hepatitis C at the CMO's Medical Group on 14th May 1996 [see DHSC0004056_013]. There was apparently some difference of view between Dr Bourdillon and Dr Metters about the need for screening (testing) of the asymptomatic; I asked that they discuss the matter further.

62.4. The final paper on HCV was submitted for a meeting of the NHS Executive on 13/14 June 1996: was EB(96)42: Hepatitis C [DHSC0006348_083], with a covering Note from Dr Winyard. The covering Note stated:

> *"It is clear that there is no obvious preferred way forward. The key dilemma that we and Ministers face is the conflict between what **may** be desirable public health policy and the capacity of the NHS to deliver. In this situation guidance recommending action which cannot in practice be undertaken could result in more embarrassment for us and Ministers than the current situation where we are criticised for not making such recommendations."*

62.5. The main paper noted that there were essentially two groups of patients. Some, including haemophiliacs and recipients of blood transfusions (minimum of 7000 cases) had been infected as a result of NHS treatment. The other group were current and past drug misusers who had shared equipment; this group, unlike the first, was likely to grow. The current best estimate of those infected was 300,000.

62.6. The paper noted that, in respect of the first group that Ministers had given commitments to help if haemophiliacs had experienced difficulties accessing HCV treatment; *"So far the few cases identified have been readily resolved".* Equally, a Ministerial assurance had been given that patients identified as a result of the Lookback Exercise would be tested and, if appropriate, treated. It is apparent that the real pressures stemmed from the numbers in the second and wider group. But:

> *"Distinguishing between people infected through NHS treatment and through other routes such as drug misuse would be contentious. Ministers would be exposed to criticism if it appeared that the Department/NHS was operating a selective policy on testing and/or treatment depending in the mode of infection (shades of the "deserving" and "undeserving" poor). Pressure groups like the British Liver Trust would rapidly identify any evidence of a two tier approach if Ministers fail to follow the "Tackling Drugs Together" commitment. The only acceptable grounds for refusing treatment would be a medical contraindication. Similarly, appearing to withhold treatment on costs grounds would be politically unacceptable…"*

62.7. The DH's view was thus that to distinguish between different groups of patients on other than clinical grounds would not be ethical (as well as unacceptable to voluntary groups such as the British Liver Trust). I believe that I would have agreed with that, based as the concerns were on the principles of equality and non-discrimination.

62.8. The paper referred to a commitment to issue purchasing guidance on drug treatment services, but added that *"Clinical guidelines along the times of those issued by SMAC on Beta Interferon may also be useful…. Issuing any guidance, however, implies a new signal about the relative priority to be attached to treatment. Initial soundings of purchasers indicate that, particularly in the current climate of serious strain on the acute services, such guidance is unlikely to be welcome particularly if prescriptive."*

62.9. The Minutes and Action Notes of the NHS Executive Board meeting held on 13/14 June 1996 record [DHSC0044009_023], under the heading of Hepatitis C:

> *"Graham Winyard introduced this paper which sought the Board's views prior to producing a submission for Ministers. The Board agreed that measures needed to be taken on the public health perspective, recognising the limits of current knowledge, and that further policy development would be affected by the views of professionals (including possibly SMAC), research findings and other information.*
>
> *ACTION: DR WINYARD TO TAKE FORWARD."*

62.10. The attendees are listed in the Minutes; they did not include myself as CMO. I was not a member of the NHS Executive Board.

62.11. Mrs Phillips recorded the outcome of the meeting in an undated note of June 1996 [DHSC0004056_006]. She wrote to colleagues: *"As you know, the paper on hepatitis C was considered by the NHS Executive Board last week. There were no surprises and basically we should proceed as planned. None of these specific questions were answered although the preferred option was apparently two and a half! - in other words, somewhere between do nothing pending further advice/research and accepting the need to embark on measures to increase awareness."*

62.12. It is difficult to remember now exactly what I would have known or been told about these developments. I expect that I would have been briefed in general terms at least. I can see that in the further minute dated 17 July 1996 from Donna Sidonio to Mr Dobson [DHSC0004056_005], Ms Sidonio refers to the outcome of the Executive Board meeting. She noted that officials from the Department had "*already approached the profession (hepatologists) informally and asked them to develop clinical guidelines."* In the absence of a firm view on handling from the Board, a cautious approach seemed necessary. The fact that she said that "*last night, at a meeting with CMO and HCS SCS colleagues, Dr Winyard apparently put forward the same line"* suggests that I

was being updated by colleagues about developments, but was not more actively involved.

62.13. Ministers were also kept updated and asked for their views on the policy direction. A draft Ministerial submission was circulated to colleagues by Mrs Phillips on 7 November 1996 [see DHSC0004203_031]. A note from the CMO's Assistant Private Secretary dated 22 November records *"CMO has seen this and commented: 'A very useful review'".* [WITN3430029 at page 4].

62.14. A Ministerial Submission was then sent on 23 December 1996, from Mrs Phillips to the Private Office of the PS(H), Mr Horam [DHSC0004203_013]. It was copied widely including to my Private Office. The Annex refers to this Submission, but I am advised that there no record of any direct response or advice from the CMO's office about it has been identified.

1997

62.15. I have been shown the minute of the Secretary of State's response to the Submission, in the minutes of a meeting held on 12 February 1997 [DHSC0004203_005]. This records that the Secretary of State's intention was that the framework for policy "*should be to develop appropriate research and planned health promotion without causing unnecessary health scares or swamping NHS services."* There should be a properly coordinated R&D programme on HCV. *"On health promotion, Ministers would not want to see a separate identifiable HCV prevention campaign which would unnecessarily raise its profile and thus public concern. It should continue to be addressed through the safer sex and drug misuse programmes."*

62.16. The note of the meeting continued:

> *"On clinical guidance, Secretary of State noted the plans to promulgate guidance produced by the RCP [Royal College of Physicians], following the meeting scheduled for June. He suggested that GPs should have a greater role in identifying, diagnosing, treating and referring HCV as appropriate, and that GP involvement should be secured before the June meeting. The most effective way to do this should be through a*

letter from CMO to the RCGP [ie Royal College of General Practitioners].

It was agreed it would be very useful to have on record a statement of the Government's action on researching, preventing, diagnosing and treating HCV. If CMO was in agreement, a further CMO letter, this time to District Directors of Public Health, setting out all the elements of the policy should be sent out in the near future."

62.17. A memo from Dr Metters to Dr Shepherd (PS/CMO) [DHSC0004203_003] shows that I asked Dr Metters to suggest how action on the last two paragraphs quoted above could be taken forward.

62.18. Dr Metters set out proposals to ensure liaison between the RCGP and RCP, noting that "how" GPs might be further involved would not be clear until after the RCP conference in June. He was not supportive of the need for the CMO to write to the RCGP, suggesting that there was already contact between the two bodies and that discussions with their respective Presidents might be more effective. Dr Nicholas might put together a statement of government action on HCV so far. Dr Metters raised some concerns with regards that a profile that a letter to District Directors might have, advising that CMO might wish to suggest that a letter be deferred *"until at least we have advice from RCP".*

62.19. The direction of policy seems then to have been set and did not change throughout 1997, including after the General Election of May 1997 and subsequent change of government.

62.20. The documents suggest that the next Ministerial submission was sent in late 1997. It was dated 13 November 1997 and headed 'Hepatitis C - Issues for the NHS.' It was copied to my Private Secretary (Dr Shepherd) [DHSC0004457_107]. It was primarily addressed to the Private Offices of MS(PH) and MS(L) (Ms Jowell and Baroness Jay). It referred to general issues concerning Hepatitis C. It set out background information on the virus, its prevalence and effects. It discussed research efforts, the lack of availability of testing and the look-back exercise, noting criticism of slow

progress. *"The look back raised expectations that testing and treatment would be available for those infected through NHS treatment."*

62.21. On guidance for the use of alpha interferon, the submission stated that the medical profession was (still) being supported to produce clinical guidelines on prescribing practice:

> *"In response to the variety of opinion and clinical and commissioning practice in the use of alpha interferon, we are supporting the medical profession financially and administratively in the production of clinical guidelines.[2] The intention is to bring about a more consistent approach to prescribing (for both clinicians and commissioners) and to maximise cost-effectiveness in the use of the drug. A workshop has been convened in December for representatives of the professions and patient groups involved to present papers on different aspects of diagnosis and treatment with alpha interferon. The clinical guidelines will be independently appraised under the existing arrangements (overseen at present by the Clinical Outcomes Group and in future by the External Reference Group to the new Executive Board sub-committee on quality). If the appraisal is favourable, which will depend in part on whether the appropriate methodology has been followed, the NHS Executive would commend the guidelines to the NHS early next year."*

62.22. A series of recommendations were set out, including with regards to raising awareness of HCV. There was a suggestion that Ministers might find it helpful to have a seminar on hepatitis.

62.23. A paper in the BMJ's medical journal Gut[3] suggests that a workshop to develop guidelines was held at the Royal College of Physicians on 3 December 1997, co-ordinated by the NHS Executive, the Royal College of Physicians, the British Society of Gastroenterology, the British Liver Trust and

[2] From [DHSC0006282_107], it is apparent that there was funding provided to the Royal College of Physicians for this purpose.
[3] https://gut.bmj.com/content/gutjnl/49/suppl_1/I1.full.pdf

the British Association for the Study of the Liver (BASL). *"The guidelines were presented at the 1999 BASL meeting in London where consensus was achieved on some of the more controversial issues."* The process therefore concluded after I left office.

Reflections.

62.24. Looking at this process, it seems to me that it reflected issues that were common across the NHS when new drugs or treatments emerged. There was a lengthy process to introduce new treatments, involving consideration of, first, the science. On this, it took a long time for judgments to made and a consensus to emerge about the effectiveness of new treatments and appropriate treatment protocols. When they did, or also as evidence and information was emerging, there were decisions to be made about what information to be given to patients. Third, there was the issue of funding: it also took time to secure access to funding for new treatments in a world of tight and finite resources. I do not think that the picture that the IBI has been shown, with regards to Alpha Interferon, was any different to that which would be seen if the picture was examined in any other specialist area, e.g. oncology, although the numbers of those with HCV did make the issue of funding yet more acute.

62.25. I have already referred to the fact that at the time, there was no established administrative or governmental route to develop clinical guidelines. The primary group for this task were clinicians, including bodies such as the Royal Colleges. But this could be a slow process: it took time to gather specialists together, for example. The eventual establishment of NICE was a real gain in this area.

62.26. Generally, decision-making on health matters could be slow. This was a product of a number of factors. One was there were a very large number of stakeholders. Another was the desire to 'get it right' and to avoid errors. Ministers and officials could be very concerned to ensure that they had support for policies, etc, announced. At times this could mean that policy-making was cautious or conservative. See for example the comments of Dr

Metters at paragraph 62.18 above, on wanting to wait for the RCGPs before a CMO letter went out; there was often a desire to ensure that consultation had taken place and that there was a consensus on steps to be taken, all of which took time even when it also helped to eliminate mistakes.

62.27. Looking back on this, it seems that in broad terms, policy was set by (i) the NHS Executive Meeting of June 1996 and (ii) the subsequent Ministerial Submission sent in November 1996 and the Secretary of State's response in February 1997. The Department worked on the implementation of that policy thereafter.

Q.63 Dr Nicholas' note of 30 June 1997.

63.1. The IBI has referred to the drafting process which informed the answer to a written Parliamentary question answered by Mr Boateng MP, then the Parliamentary Under-Secretary at the Department of Health, on 19 June 1997 [see DHSC0004799_223]. The Secretary of State for Health had been asked whether he would require health authorities to provide counselling before and after blood tests for hepatitis C. Mr Boateng replied on his behalf:

> *"No. In general, patients should be given sufficient information to enable them to make an informed decision before any diagnostic test. For hepatitis C, this would include discussion of the treatment options, the consequences of a positive test and advice about lifestyle. However, when the Chief Medical Officer wrote to all doctors on 3 April 1995 about the "Look Back" exercise to identify those infected with hepatitis C through blood transfusion, the letter specified that counselling should be made available before and after testing for those found to be infected in this way."*

63.2. The civil service correspondence discussing the draft answer for Mr Boateng is referred to in the Annex. The IBI has specifically referred to the further comments in a minute from Dr Nicholas dated 30 June, evidently written after a period away from the office [DHSC0004426_132].

63.3. In this last document, Dr Nicholas set out detailed comments on the question and answer. He noted that there were semantic problems with the word "counsellor" *"and the unfortunate connotation that this process can only be adequately provided by dedicated "Counsellors"".* What was important was the provision of adequate information at each stage, by a trained person on a professional basis, to enable patients to deal with the various issues faced. With respect to those who had been diagnosed as infected with hepatitis, they would be likely to be referred to a specialist centre for further assessment:

> *"Such centres will be able to offer patients further advice about their condition and its ramifications, both with regard to the possible management of the individual and further advice on minimising the risks of transmission to others will stop one would expect such advice to be available from those healthcare workers normally involved in the management of a case, although it would be up to an individual centre to decide if it wished to call upon professional counsellors.*
>
> *Healthcare workers have always been responsible for discussing potentially serious test results and serious medical conditions with their patients. The way forward will be to educate health professionals (including GPs) so as to enable them to provide their patients with the necessary information about these illnesses, rather than established new groups of "Counsellors" for each serious disease that occurs."*

63.4. Dr Nicholas suggested that the reference to "counselling" in the CMO's letter of 3 April 1995 was intended in this way, and did not call for the use of dedicated "Counsellors" at any stage; and, he suggested, no special services were likely to have been set up for those identified by the LBE. *"Other than anything provided by the blood transfusion service or haematologists, those infected by modes of transmission other than blood or blood products should thus have the same opportunities for receiving advice, although this may come from a wider source of healthcare workers."* However, it had been necessary to spell out the advice about counselling in the LBE because *"unsuspecting patients were to be told out of the blue that they had received*

blood from an infected donor, and two years ago the average practitioner would have been less conversant with hepatitis C than might be expected now."

63.5. He continued, in paragraph 6:

> *"I think we need to reflect these semantic problems engendered by the word 'counselling' in the background note to Ministers so they are aware of the nature of the problem under discussion. It may be important to draw attention to the use of "Counsellors" in HIV issues as a comparison could draw further criticism, not that we would advocate following that line for hepatitis C. I think... we should play down the suggestion that special counselling has been given for those infected by contaminated blood, as I suspect in general some of these avenues of advice are open to those infected in other ways."*

63.6. The IBI has asked about the reasons why the phrase "*we should play down the suggestion that special counselling has been given for those infected by contaminated blood"* was used. I did not have any involvement in this interchange and have no personal knowledge about it. However, the reasons for Dr Nicholas's comments appear to be evident from the letter. The sentence continues (as set out above): "… *as I suspect in general some of these avenues of advice are open to those infected in other ways."* This in turn refers back to the point he had made earlier, at paragraph 6, about the fact that it had not been envisaged that specialist counsellors would be created for the LBE and that, in the main, existing sources of advice, information and support would be drawn upon. It also reflects the general principles of equality and non-discrimination, which I commented on above.

63.7. The IBI has further asked what counselling was provided to those infected via blood or blood products, over and above that available to those infected via other routes. I did not have any real personal involvement in this area, so am dependant on the documents available now. However, it would appear that:

(a) The CMO's letter of 3 April 1995 set out clear expectations with respects to the counselling that should be available to those contacted as a result of the LBE;

(b) Such counselling could, as Dr Nicholas suggested, be provided by a variety of healthcare workers, or – on occasion – by the BLT, whose grant was increased to reflect an increased workload as a result of the LBE.

(c) The decisions upon the most suitable person or persons to provide information, particularly at the specialist centres to which those contacted were to be referred, would have been a matter for local decision, and those centres themselves.

Q.64 Steps taken to address the stigma suffered by those who had been infected by blood or blood products

64.1. An overview of what done in the years in question can be seen in a "Hepatitis C: Question and Answer Briefing" (undated at [DHSC0006282_107]).[4] This sets out that:

64.2. The Department allocated £1 million for HCV research in 1996, with a further £500,000 to be allocated "this year" (i.e. 1998) to expand the research programme. In addition, the NHS Health Technology Assessment commissioned a research project to establish the effectiveness of early treatment of chronic hepatitis C with alpha interferon.

(a) The Department was providing the British Liver Trust with a three-year project grant of £38,250 years for a hepatitis awareness and assistance project, payable from 1997/98 to 1999/2000 inclusive, and two smaller project grants for the general publicity and a helpline (for all liver patients). Prior to this, the organisation had received several other grants, both core and project grants.

[4] This document was part of briefing process for the Ministerial to the Written Question of 11 February 1998 (see [WITN3430030] which sets out the answer given).

(b) Publications to increase awareness of the issues and appropriate treatment from or supported by the DH included: the CMO letter of April 1995; revisions to the Guidelines for Doctors on the Clinical Management of Drug Misusers (issued in 1991, reviewed and to be republished in 1998); the support for the Royal College of Physicians to produce clinical guidelines on the use of Alpha Interferon; funding to the British Liver Trust for leaflets and advice; the Health Education Authority's leaflet on Hepatitis C which was obtainable from GP surgeries, as well as the DH's Health Advice for Travellers booklet which contained advice on the avoidance of HCV abroad.

64.3. I do not think that, now, I can add anything to these records.

Section 9: Retention of samples and consent

Q.65 Retention of tissue samples and patient consent

65.1. The Inquiry has referred me to the Preamble of the 2nd edition of "The retention and storage of pathological records and archives" guidance from the Royal College of Pathologists (RCPath), dated October 1998 [JPAC0000149_015], which said:

> "*Sir Kenneth Calman, Chief Medical Officer (England) has advised in correspondence that the principles in the Department of Health's guidance on Preservation, Retention and Destruction of Records HC(89)20 (Scotland, MEL(1993)152) apply with equal force both to the preservation of paper records and to the preservation of non-paper records such as pathology material and other biological samples which provide a record of a patient, adding that information which seems likely to provide material for medical research should be scrutinised with a view to permanent preservation, and acknowledging the value to genetic services of retaining informative medical records and biological samples where resources are available for this.*"

65.2. I have exhibited a copy of the Department of Health's guidance on Preservation, Retention and Destruction of Records HC(89)20 [WITN3430031].

65.3. I am asked to explain why the consent of patients for the retention of and research using human tissue samples was not considered to be required.

65.4. It is difficult for me now - with the passage of time and without knowing in full what I said, when and its context - to comment on why there was no express reference to consent in the quotation from my correspondence.

65.5. My legal advisers made unsuccessful attempts to find the correspondence from me to the RCPath Working Party, including making enquiries with the

Royal Colleges of Pathologists and of Physicians.[5] I therefore do not know when I sent the correspondence – but it must have been 1998, or earlier.

65.6. I recognise the quotation attributed to me says nothing about patient consent. I do not know the context in which my words were written or the relationship between the issue of consent and the HC(89)20 guidelines referred to in my correspondence. I am also conscious my comments were directed to experts in their field, who would have been aware of the prevailing ethical framework.

65.7. It ought, however, also to be recognised that the situation on consent was very different in 1998 (or earlier – I do not know the date of my correspondence) to when the 3rd edition was published in 2005.

65.8. I would have thought the most useful material about the situation prevailing in 1998 regarding patient consent and retention of and research using human tissue samples is contained in the documents listed at pages 4-7 of the 2nd edition [JPAC0000149_015].

65.9. I note the 2nd edition says the Working Party considered the Nuffield Council on Bioethics' publication "Human Tissue: Ethical and legal issues" (April 1995) which concerned the issue of use of human tissue and patient consent (available online: https://www.nuffieldbioethics.org/publications/human-tissue).

65.10. This is a lengthy and detailed report, and I have not been able to review its detail for the Inquiry. But the Inquiry may wish to do so, and in particular the passages underlying the Summary of Recommendations (page vi): *"Where tissue is removed in the course of medical treatment: 1 Consent to treatment should be taken to include consent to disposal, storage and any other ethically acceptable use of removed tissue (paragraph 13.12)."*

65.11. I wish, however, to make a general point. Medical ethics is a subject of particular interest to me. I have authored books on the subject, for example "Healthy Respect: Ethics in health care" (second edition, 1994). I was President of the Institute of Medical Ethics and a member of the Nuffield

[5] The 2nd edition also refers separately to correspondence from me to the President of the Royal College of Physicians in 1993, although I am told this has not been found either.

Council on Bioethics from 2000 to 2008. Consent has been an important issue in my professional life as a clinician, a public health doctor and a civil servant. I would not have advocated an approach to consent that was in any way at odds with the contemporaneous expert guidance.

65.12. Over the years, practices in relation to patient consent have changed. I have seen this personally in my own experience in vascular and transplant surgery, cancer care and palliative care, and in broader public health. In the 1960s, consent was important but not at the top of the agenda. Today, it is a very formalised process. The 1990s was in the middle of that change regarding consent.

65.13. I am asked to comment upon the Preamble of the 3rd edition, which discusses the issue of patient consent [JPAC0000149_004]. The 3rd edition was published in 2005. The background to the 3rd edition is explained as follows:

> "*The few years since the 1998 revision of this document have seen rapid changes in attitudes towards the use of personal data and human tissue. In 1998, following the guidance of the 1995 report from the Nuffield Council on Bioethics, most pathologists believed that human tissue samples held in their laboratories could be used for any ethically acceptable purpose (as defined by the Nuffield Council) without further consent from the patient, as long as the tissue was surplus to diagnostic requirements. A similar view pertained to research and other work using confidential patient information. Confidentiality should be maintained, but consent was not regarded as necessary. The Chief Medical Officer of the time reinforced this view, and the preamble to the 1998 version of this document quoted his opinion as:*
>
> > *'information which seems likely to provide material for medical research should be scrutinised with a view to permanent preservation, and acknowledging the value to genetic services of retaining informative medical records and biological samples where resources are available for this.'*

This comment makes no mention of consent. The potential benefit to society of such work was regarded as sufficient. Of course, the patient's interests must not be harmed by such work, or the patient would have had recourse to redress under common law.

This situation has changed. The most public manifestation of this change has been the publicity surrounding concerns about the retention of tissue removed at post-mortem in hospitals in the UK. This has led to the introduction of the Human Tissue Act 2004. But even prior to this, a change in society's attitudes was evident in the wording and interpretation of the Data Protection Act 1998, which demands 'fair processing' of information. This Act puts particular emphasis on controlling the use of 'sensitive' information, a category that includes essentially all medical information about identifiable, living individuals."

65.14. I assume the reference to publicity surrounding concerns about retention of tissue removed at post-mortem in hospitals refers to the investigations into events that took place during the late 1980s and early 1990s at Bristol Royal Infirmary and at Alder Hey Children's Hospital.

65.15. I provided two written statements to the Bristol Inquiry. I can make these statements available to the Inquiry, if required. I also gave oral evidence for one day in October 1999, which I referred to earlier in Section 1. Due to the passage of time, I cannot now remember either giving a statement or oral evidence. The transcript shows my evidence did not touch on retention of tissue samples or patient consent, although I have been made aware the Inquiry did investigate the issue.

65.16. The Royal Liverpool Children's Inquiry into events at Alder Hey Children's Hospital, which, I understand, arose out of evidence given at the Bristol Inquiry, took place after I left my role as CMO England. I do not believe I had any involvement with the Alder Hey Inquiry, although I cannot now recall any details.

65.17. It is not necessary for me to say more about the detail of the two Inquiry's reports here (and I have not read them for the purpose of this statement),

although they plainly would have been important milestones in the shifting approach to the issue of consent and samples.

65.18. My legal advisers have drawn to my attention the following further documents, although I have not read them for the purpose of this statement. I mention these publications to assist the Inquiry and because they are likely to indicate how the position on consent continued to evolve after my time in office ended in 1998 and in the run up to the 3rd edition (2005) of the RCPath guidance:

(a) In March 2000, RCPath published "Guidelines for the retention of tissues and organs at post-mortem examination" [WITN3430032].

(b) The same month the Department published interim guidance on post-mortem examination, which considered consent for retention of body parts [DHSC0041464_022].

(c) In October 2000, the BMA published interim guidelines on retention of human tissue at post-mortem [DHSC0006943_094].

(d) My successor, Sir Liam Donaldson, carried out a survey of organ retention throughout the UK and produced guidance entitled "The Removal, Retention and Use of Human Organs and Tissue from Post Mortem Examination. Advice from the Chief Medical Officer" (2001) [NHBT0001136_010].

(e) In 2001 also, the MRC published operational and ethical guidance for researchers on human tissue and biological samples for use in research [WITN3430033].

Q.66 The HCV Register

66.1. The Inquiry has asked me to set out a chronological account of the establishment of the HCV Registry and to include my knowledge of why the HCV registry was established; the people involved in the decision-making processes; the content of discussions regarding the need for patient consent

for their details to be entered on the HCV registry; and why patient consent was not considered to be required.

66.2. I do not recall having direct involvement in this issue. I have sought to refresh my memory by reading the document provided by the Inquiry [NHBT0009891_001], which does not suggest that I had any significant direct involvement. However, Dr Metters did make a number of contributions and it is likely that he would have discussed these matters with me at the time.

66.3. The Inquiry may be more assisted by information from those who were directly involved. The Annex sets out a chronology of the matter following review of the documentary records and names some of the individuals who were more directly involved.

66.4. Although I do not recall the detail, I do recall there being much discussion about the topic of consent. I see from the Annex that Dr Metters referred to the need for "informed consent". I believe that he would have discussed this with me and that it reflected the Department's position at that time. Looking at matters overall, it is fair to say that consent was considered by different groups of those involved as the HCV Register was developed, but the expectations and standards in relation to patient consent and data retention were also developing at the same time, and can be seen to have led to an amended approach. Ethical approval was sought and obtained for the work.

66.5. The HCV Register was not originally established as a nationwide register of all HCV cases. Rather it started as a research proposal – which came to be funded by DH – to analyse HCV infections with a known date of acquisition. The HCV lookback exercise involved the identification of a group of patients for whom there was a known (or likely) date of infection. By registering and monitoring a cohort of patients whose date of HCV infection was known, it was considered that valuable information could be obtained about the nature and progression of the virus and its effects by studies that could be carried out using the anonymised data held on the register. It was one of many research

strands that were being undertaken in the interests, ultimately, of seeking to prevent, tackle and treat HCV.

66.6. In terms of the overall chronology, the research proposal was conceived in 1995 – 1996, funding was eventually secured in 1997 and the HCV National Register was launched in July 1998, which was a few months before the end of my tenure as CMO for England. Discussions about patient consent and the approach to patient consent continued and evolved during 1998 and beyond.

Section 10: HIV and AIDS issues in the 1990s

Q.67 Aids Workshop in Edinburgh, September 1992

67.1. The Inquiry has asked me to set out the contents of my address to the 2nd MRC Aids Epidemiology Workshop in Edinburgh in September 1992 and the priorities that I was highlighting in relation to HIV and public health policy at that time.

67.2. HIV and AIDS was one of the major issues that I dealt with during my time as CMO for Scotland and England. However, given the passage of time, I can recall neither the event nor the address.

67.3. I see from the documents that on 13 August 1992, a Department Medical Officer circulated a first draft of a speech for me to give to the MRC Workshop [DHSC0002439_019; DHSC0002439_020]. The subject of the speech was described as *"where we are in public health terms"* and *"future priorities"*.

67.4. I generally tried to avoid delivering speeches by simply reading out lengthy sections of text. I preferred to adopt a more discursive approach and to use slides. The covering minute said that, on this occasion, officials had been asked to provide a full text speech. This was not usual practice. It says this was done because I was out of the office a lot during this period.

67.5. Given I have no memory of the event, I think the best I can do is simply to allow the draft to speak for itself. It is entirely possible I would have amended sections of the draft. I also see spaces have been left for slides to be inserted, which, as I have said, I would have used.

67.6. Page 10 of the draft carries the header "Priorities" and was concerned with the strategy for HIV from 1993 and beyond. Page 12 said:

> "*I started off this talk with a reference to monitoring, surveillance and research being one arm of the Government's five part strategy to counter the threat of HIV. This strategy [SLIDE OF THE FIVE POINTS] has been the foundation of policy on AIDS across all government*

departments since it was formulated […]*. We are now building on this strategy and intend to develop certain features as a priority in the wake of the white paper* [Health of the Nation]."

67.7. The draft said the features to be developed as a priority in the wake of the White Paper were:

- Increasing availability of HIV antibody testing and post-test counselling;
- Better targeting of publicity;
- Making concerted efforts at tracing contacts of infected people. The draft noted that contact tracing for HIV infected people had *"tended to be neglected"*;
- Re-examination of the place of HIV in public health legislation, which was noted to be a *"thorny issue which will take much time and work"*; and
- Finally, "*better research on treatments for HIV infected people and improvement in their quality of life"*.

67.8. I have read the Summary of Workshop Proceedings document provided by the Inquiry [MRCO0000230_003], but it does not add anything further to what I have said above.

67.9. I am also asked how my priorities in relation to HIV and AIDS changed during the 1990s. While I of course had input into the formulation of policy, I did not set the Department's policy priorities. HIV and AIDS policy, as with other areas, was formulated with involvement from officials and ministers from across the Department.

67.10. The CMO reports are likely to be of most assistance to the Inquiry in charting developments in this area. Please see Section 2 of my statement, which notes the references I made to HIV and AIDS in the introductory sections of the CMO Reports for 1993 and 1996.

67.11. To further assist the Inquiry to chart how policy priorities changed in relation to HIV and AIDS during the 1990s, my legal representatives have produced an Annex. The Annex highlights relevant aspects of the CMO Reports and refers to a CMO Fact Sheet on HIV and AIDS (November 1993) (Annex at paragraphs 67.1 onwards).

67.12. The Inquiry has asked that I do not provide comments on the Annex, so I limit myself to recalling that HIV and AIDS was highlighted as one of the key areas in the Government's strategy for health in the 1992 White Paper, *"Health of the Nation"*. HIV and AIDS remained an important part of Government policy during my tenure as CMO for England, with the overarching aim being to reduce the incidence of HIV transmission.

Q.68 Knowledge of and involvement in Gamma Bulin recall, 1993.

68.1. The Inquiry has asked me to describe my knowledge of and my involvement in the recall of Gamma Bulin and human albumin solution 4.5% in 1993. Given the passage of time, I do not now recall this issue.

68.2. The summary of the contemporaneous documents contained in the Annex suggests that I did not have any significant direct involvement. The names of individuals who were involved are mentioned in the Annex.

68.3. The Inquiry has referred me to a DH press statement dated 5 November 1993, in which I was quoted [NHBT0005295]. I do not now recall giving this statement. I was quoted as saying:

> "*The Medicines Control Agency has been in contact with the German authorities about this issue. The MCA is today notifying hospitals and doctors in this country that the Austrian company Immuno is recalling 8 batches of 2 products from this country. These are Gamma Bulin, an intra-muscular product used to boost the body's*

immunity; and human albumin solution 4.5 per cent, which is used to treat patients who have suffered substantial blood loss.

"This measure is purely precautionary and is to ensure total patient safety. There is no evidence that HIV has been transmitted by these two products.

"We are self-sufficient in blood. We do import some blood products which are licensed by the Medicines Control Agency. Under the Medicines Act, every company is inspected and licensed and individual products are licensed for safety, quality and efficacy. The National Institute for Biological Standards and Control have batch tested all blood products released for use in this country, including those from Immuno. No HIV contamination has been found in any products authorised for release by NIBSC."

68.4. It appears this issue would have first come to my attention on the same day as I made the press statement. I see on 5 November 1993, the MCA sent a submission to the then Parliamentary Under Secretary of State for Health, Tom Sackville, which was copied to my Private Secretary, Dr McGovern, [DHSC0006466_031]. The content of the submission is set out in the Annex (paragraph 68.1).

68.5. Although, I do not now have any recollection of it, I expect that I would have read the submission prior to giving the press statement. The only other direct involvement that I appear to have had relates to some correspondence with Dr Peter Hamilton, a haematologist at the Royal Victoria Infirmary, Newcastle.

68.6. On 16 November 1993, Dr Hamilton sent me a letter about the recall of human albumin solution [DHSC0046990_034]. His hospital had treated patients with one of the implicated batches. His letter asked me to confirm that the product could not transmit hepatitis or HIV. Dr Hamilton was anxious to avoid causing unnecessary alarm to patients.

68.7. I signed a letter of reply to Dr Hamilton on 6 December 1993 [DHSC0046990_028]. My letter said that the product was subject to heat treatment during manufacture and also that NIBSC carried out control testing of samples from the plasma pool and the finished batches. My letter advised the recall was purely precautionary, the human albumin solution did not represent a safety hazard and advised it was not necessary to contact patients who received the product.

Q.69 Investigation into HIV infection through transfusion, 1997

69.1. The Inquiry has asked me to describe my knowledge of and my involvement in an investigation in 1997 into HIV infection transmitted through transfusion. Given the passage of time, I do not now recall this issue.

69.2. I see that I had some personal involvement, as summarised in a Minute dated 29 September 1997 [DHSC0006775_003]. The Minute says that I set up and led a team tasked to investigate the incident and its consequences and to manage the handling of the presentation. The scientific investigation was carried out by the Public Health Laboratory Service ("PHLS").

69.3. I understand from the documents that the Department seemed to have become aware of the incident on 21 March 1997 and that I was involved until about 18 April 1997. My role involved overseeing the way in which information about the incident was released to the press and the public. Information about the incident was ultimately published on 18 April 1997 and the national press first reported on the incident the following day.

69.4. The Annex names those individuals who were directly involved and sets out a chronology of how matters continued to unfold after 19 April 1997.

69.5. I see that officials from the Department, including Dr King and Dr Rejman, received regular updates during March and April 1997. I assume at least some of these updates would have been relayed to my office. I have

addressed the Inquiry's question by reference to those documents which were copied to my Private Secretary, Dr Shepherd, as well as those documents that refer to my direct contributions.

69.6. Ms Wellsteed sent a Minute to the Department's press office, copied to Dr Shepherd, on 21 March 1997, which said the Department had just become aware of a leukaemia patient, with no known risk factors for HIV, having become HIV positive between July and November 1996 [WITN3430034]. It stated that the Department was taking steps to establish the details and that investigations were underway to establish the possible sources of infection.

69.7. I have seen another Minute from Dr Rejman to the Department's Press office, copied to Dr Shepherd, dated 27 March 1997. Dr Rejman said that the line to take was that the matter was being investigated by the local hospital and the Liverpool Blood Transfusion Centre was also involved [WITN3430035]. The source of infection was unknown, and the line indicated one patient only was implicated.

69.8. I have been shown draft notes of the Fifth Incident Meeting of the Liverpool Health Authority, which took place on 14 April 1997 [WITN3430036]. An "Incident Group" had been set up by the Liverpool Health Authority. I see the Incident Group agreed that I should be kept informed of proceedings and be sent copies of their notes. I assume these notes were therefore sent to me at some stage, although I do not have any recollection of seeing them before.

69.9. The notes indicated that this incident concerned three patients who were infected with HIV following blood transfusions at hospitals in north west England. The meeting was attended by hospital and public health clinicians from the Liverpool area, plus Dr Vanessa Martlew of the Liverpool Blood Transfusion Service and Dr Bill Wagstaff of the National Blood Service. I refer to the contents of the minutes in respect of the matters discussed, which included issues of consent to testing of a deceased person, donor tracing and confidentiality, and how to reassure and communicate with the general public.

The attendees wished to issue a public statement, but at that stage the NBA were not inclined to do so.

69.10. I have also seen an exchange of emails amongst officials in the Department shortly before the fifth meeting took place about the difference in opinion between the NBA and Professor John Ashton, public health director in the North West, over the need for a public statement [WITN3430037]. I note that the view of Departmental officials was that, at that stage, a public statement was not justified on public health grounds, that there was a concern that patient confidentiality may be breached and that it would *"not really achieve anything, other than unnecessary worry, and possibly panic"*. These emails, also dated 14 April 1997**,** were copied to Dr Shepherd.

69.11. On 15 April 1997, Mr Guinness sent a Minute to Stephen Dorrell MP, the Secretary of State, copied to Dr Shepherd [WITN3430038]. The Minute said the indications were that this was a "*window period*" case (i.e. where the donor gave blood after becoming infected with HIV but before producing the antibodies which are detected by HIV testing). Further testing was required. The public were not at that time aware of the incident, but it was suggested it should be made public knowledge through the Communicable Diseases Report ("CDR") and also an NBA press notice. The Minute noted this was the first such known transmission in England since screening of blood for HIV was introduced in 1985 (and that there was one transmission in Scotland in 1986). Mr Guinness' Minute attached a line to take and Q&A briefing [WITN3430039].

69.12. I have been shown the final notes of the Sixth Incident Meeting of the Liverpool Health Authority, which took place on 16 April 1997 [NHBT0081212_010]. This is a document to which the Inquiry has referred me. The minutes note the day prior I had a meeting with Ministers, and that the fifth meeting minutes were not available to me at the time of the meeting. Following my meeting with Ministers it seemed the Department provided the

Incident Group with a press statement, should the incident reach the press before being announced.

69.13. The sixth meeting minutes refer to a conversation I had with Professor Ashworth the previous day. I do not now have any recollection of this conversation. The minutes say I set out what the Department would do in terms of publicising the incident to the medical community and more widely. I also said I would raise the Incident Group's concern about the need for representation from the NBA at their meetings.

69.14. Also, on 16 April 1997, Mr Guinness sent a further update Minute to Mr Dorrell, copied to Dr Shepherd [WITN3430040]. The Minute referenced the donor's sexuality and the NBA policy on self-exclusion. Further tests were required before it could be finally confirmed that this was a window period case. The Minute attached an updated line to take and Q&A briefing [WITN3430041].

69.15. The Inquiry has referred me to a letter of 17 April 1997 from PHLS to Dr Angela Robinson, Medical Director of the NBA, enclosing the final text for the following day's CDR weekly [NHBT0008791_005]. The letter refers to my office and Dr Walford, then Director of PHLS, having had the final say over the draft.

69.16. I have seen the draft notes of the Seventh Incident Meeting of the Liverpool Health Authority, which took place on 17 April 1997 [WITN3430042]. The notes seek to correct a matter that had appeared in a draft version of the sixth meeting minutes, which I have also been shown [NHBT0081212_012]. The draft of the sixth meeting minutes had said I expressed the view to Professor Ashton that testing a sample from the deceased patient without consent was in conflict with GMC advice. This was deleted from the final version.

69.17. I do not now recall having expressed any opinion on the ethical considerations around testing a deceased person for HIV. My legal representatives have

located relevant GMC guidelines from the time, which refer to the limited circumstances when testing may be carried out where a person has died from a serious communicable disease, and indicate that the agreement of a relative should usually be sought before testing ('Serious communicable diseases: replacing the booklet "HIV and AIDS"', General Medical Council, 1997) [WITN3430043]. I also note the Incident Group decided to implement a "look-back" exercise for health care workers.

69.18. On 18 April 1997, Christine Corrigan sent a further update Minute to Mr Dorrell, copied to Dr Shepherd [DHSC0014981_036]. The Minute attached a further updated line to take and Q&A briefing [WITN3430044]. The Minute expressed confidence that the only infectious blood donation was from the single donor donation made in August 1996. The intention was to publish the CDR report the same day and for the NBA to issue its press notice. I have seen a copy of the NBA's press release [DHSC0002376_006] and the final CDR weekly report, which is a document to which the Inquiry has specifically referred me [BPLL0010960].

69.19. Also, on 18 April 1997, Ms Corrigan faxed Dr Shepherd in relation to queries received by the NBA about why blood donations were not subjected to PCR testing as a matter of routine [WITN3430045]. Ms Corrigan put together a draft response explaining the technical difficulties and asked Dr Shepherd to raise this with those present at a meeting.

69.20. Again, on 18 April 1997, Dr Shepherd wrote to Dr Metters, Dr King, Mr Guinness, Ms Corrigan and others to express my thanks for their efforts preparing the briefing and press lines on the incident over the previous days [DHSC0014981_061].

Section 11: High Purity Products

Q.70 Use of High Purity products for HIV positive patients

70.1. The Inquiry has asked me to set out my involvement in the debate about the need for and/or use of high purity products for HIV positive patients; why the original decision was made to decline to fund high purity products; and, why that decision was subsequently reversed by my letter to clinicians on 13 December 1992.

70.2. Given the passage of time, I am no longer able to recall any direct involvement in this issue. The summary of the contemporaneous documents contained in the Annex suggests that I did not have any significant direct involvement in the debate around the use of high purity products prior to late 1992, although the Deputy CMO, the late Dr Jeremy Metters, did make several contributions. It is likely that Dr Metters would have discussed these matters with me at the time, although I do not now have any memory of such discussions.

70.3. The Inquiry may be more assisted by information from those who were directly involved. The names of individuals who were involved are mentioned in the Annex.

70.4. The documents sent to me by the Inquiry included a summary note on Factor VIII produced by Dr Rejman [DHSC0002464_031]. I see this document was sent to my office on 11 December 1992. I have used this document to refresh my memory of intermediate purity ("IP") and high purity ("HP") products and the distinction between the two. I see that IP referred to factor concentrate that had been subject to heat treatment or solvent detergent methods to destroy viruses and other impurities. I am reminded that in the two to three years leading up to December 1992 factor concentrate products were made even more pure by additional steps. I understand these products became known as HP (or sometimes "*very high purity*" or "*third generation*") factor concentrates. I understand from the document that the two main methods of

producing HP products, at the time, were by monoclonal technology and by chromatography (or ion-exchange chromatography).

70.5. The documents shown to me indicate that my first involvement in the debate seems to have come in May 1992. On 29 May 1992, Dr Graham Winyard, in his then capacity as Director of Public Health at Wessex RHA, wrote to Dr Diana Walford, who was then one of the Deputy CMOs, asking for a national policy directive on the funding of HP Factor VIII. Dr Winyard was concerned that without such a policy different RHAs would reach inconsistent decisions about funding for HP products [DHSC0002461_068]. While I note Dr Winyard's letter was copied to me, I do not have any personal recollection of the matter being raised with me.

70.6. I see from the available documents that Dr Metters replied to Dr Winyard on 22 June 1992 [DHSC0002463_061] and that I was sent a copy of the reply. Dr Metters said:

> "*We have seen the recommendations of the UK Regional Haemophilia Centre Directors, which included specific recommendations about the use of high purity factor VIII and IX products. These recommendations are not, of course, Department of Health guidance. Officials were surprised and somewhat disappointed in the document. There are comments within it which detract from its scientific basis and which may lead some readers to doubt its impartiality. Specific examples have been discussed informally with the Chairman of the Regional Haemophilia Centre Directors.* […] *As is made clear in the recommendations, they are primarily intended for clinical guidance, and purchasing authorities should be aware that the Regional Haemophilia Centre Directors have made them. It is a consensus document, not a unanimous one, as is made clear in the opening paragraph.*"

70.7. As to funding, Dr Metters said HP Factor VIII and IX should be treated like any new treatment and regions should finance its purchase through main funds,

with health service spending steadily increased to cover such advances. There was no intention to provide specific funding for HP factor concentrates and no such commitment had been given by the Department. Dr Metters said regions were best placed to decide how to allocate the resources available and the Department did not wish to get involved in detailed decisions on resources for individual treatments. Dr Metters also anticipated the price differential between IP and HP products would narrow in future.

70.8. I do not have any recollection of Dr Metters' response. It is possible he would have discussed the issue with me. I understand from the Annex that Dr Winyard sent a follow up letter (i.e. his second letter) to Dr Metters in July 1992 and that Dr Gwyneth Lewis of the AIDS Unit replied on behalf of Dr Metters in August 1992. I do not seem to have been copied into Dr Winyard's second letter and have no recollection of any personal involvement in coordinating the response.

70.9. On 5 October 1992, Dr Winyard sent a third letter, this time addressed to me directly, seeking clarification of the Department's policy on use of HP Factor VIII [WITN3430046]. From reading the Annex, it appears this is the first time correspondence was sent to me directly about HP products, although I have no recollection of this independent of the documents. Dr Winyard noted that while HP Factor VIII offered "*significant benefits above conventional products*", his RHA had decided the cost was disproportionate and refused funding. He referred to a letter from Mr Sackville, which Dr Winyard said had implied the sole criterion on whether to fund HP Factor VIII was clinical benefit without regard to proportionality of cost and implication for other services. The copy of Dr Winyard's third letter that I have seen carries a handwritten comment from Dr Walford, saying "*I would favour the use of ring-fenced 'AIDS' monies to allow the purchase of high purity FVIII…I understand, however, the AIDS unit may have vetoed this*".

70.10. I see from the documents shown to me that on 10 November 1992, I signed a letter of reply to Dr Winyard [DHSC0002463_069]. I would have received

advice from officials and they would have produced a draft letter. This was the way we normally worked. I believe the reference in the first paragraph to a letter in the Lancet was a reference to an article by Dr Charles Hay published on 27 June 1992 [HSOC0002607_001]. Dr Hay's article had set out evidence that ion-exchange purified Factor VIII, a type of HP product, conferred no advantage for HIV positive patients over IP products (unlike monoclonally purified Factor VIII). I further said:

> "*I take* [t]*his opportunity to reinforce the Department's view that in prescribing of any expensive new drug or treatment, clinical judgement will need to be exercised within locally agreed priorities and availability of resources. Therefore in making decisions about whether to prescribe a high purity factor VIII product clinicians will need to have regard not only to the Recommendations and to general considerations of costs and benefits, but also to policies agreed by doctors and managers locally on prescribing expensive new drugs or treatments*."

70.11. My letter also emphasised that if abrupt withdrawal of AIDS money funding of HP Factor VIII would have a detrimental effect on the treatment of an individual HIV positive haemophilia patient, then it may be necessary to allow time to make the transition to other funding sources. I had no recollection of this exchange of letters with Dr Winyard prior to being shown them while preparing this statement.

70.12. I have been shown by my legal advisers further items of correspondence sent from clinicians to me in late 1992 on the topic of High Purity products.

70.13. I see that on 22 October 1992, I was sent a letter from Dr Muir Gray of the Oxford RHA [DHSC0002462_017] enclosing a paper by Dr Jill Meara dated September 1992 setting out the views of public health doctors in Oxford about HP Factor VIII [DHSC0002464_102]. As an aside, I am reminded of the point made by Dr Meara that the difference between IP and HP products is more to do with the type of contaminant rather than the level of a particular known

contaminant. Dr Meara's paper summarised some of the literature in this area before stating:

> "*the published work does not provide a clear case for a shift from the current products to new products…current evidence would not support a definite benefit from changing to the new products for any patient sub-group* [who suffer Factor VIII deficiency] *…This summary does not agree with the recommendations in the recent document from the UK Regional Haemophilia Centre Directors…* [However] *There is good evidence for a shift to high purity factor IX for Christmas disease…*".

70.14. Dr Christine Lee of the Royal Free Hospital then wrote to me on 20 November 1992. Dr Lee referred to the fact that we had apparently discussed the issue of HP Factor VIII and earmarked AIDS funds at the Marsden lecture I gave the previous day [DHSC0002463_018]. From my personal notes I have refreshed my memory of the lecture, which was on a subject unrelated to blood products. I do not now have any recollection of any discussion with Dr Lee. Dr Lee's letter refers to '*increasing evidence*' that monoclonal HP Factor VIII delays immunosuppression in HIV positive haemophiliac patients and that providing such treatment to HIV positive haemophiliacs was a legitimate call on AIDS monies. The papers Dr Lee referred to are not attached to the letter I have seen, but I note these are considered further in the Annex.

70.15. On 2 December 1992, I received a further, handwritten, letter from Dr Lee attaching an abstract of a paper that appeared in the journal "Blood" [DHSC0002464_078]. The copy of the letter I have seen does not include the abstract as an attachment, but my legal advisers have identified the likely attachment, which is addressed further in the Annex (paragraphs 70.45-70.46).

70.16. On 4 December 1992, I replied to Dr Lee's letter. In my reply, I explained that I had asked medical and other colleagues to look at the new evidence and

review the relevant papers and that I would discuss the matter with the Secretary of State in light of the review [DHSC0002464_052].

70.17. My legal advisers have shown me a ministerial submission, dated 4 December 1992, sent to the Secretary of State and also to my office seeking the Secretary of State's agreement to shift policy to designate HP Factor VIII as a specific treatment for HIV, as well as haemophilia, and thus allowing earmarked AIDS funds to be used to meet the price differential between IP and HP Factor VIII [DHSC0032075_064]. The submission noted:

> "New Developments
>
> *Data have since been accumulating which are tipping the balance of probability that the high purity product is beneficial in respect of HIV in seropositive haemophiliacs. This view was given further support when Dr Christine Lee, Director of the Haemophilia Centre at the Royal Free presented an abstract just published in the USA Scientific Journal 'Blood'…which appears to lend further weight to the view that high purity Factor VIII benefits seropositive haemophiliacs by slowing down the rate of decline in CD4 count, a marker of immune suppression and disease progression. These data when added to previous information have led medical and administrative colleagues in the Department to the view that, on balance it appears more likely than previously thought that high purity Factor VIII is of benefit.*"

70.18. I do not now have any recollection of being involved in the discussions that would have gone on and the decision making process. I believe there would have been a number of people involved in the decision making process, which would have taken time.

70.19. On 14 December 1992, I see I wrote to clinicians concerned with the care of haemophilia and HIV patients giving notice that in light of accumulating data the Department had decided that if clinicians felt the use of HP Factor VIII would benefit HIV positive haemophiliacs in terms of HIV infection as well as

haemophilia per se then the price differential would be an appropriate use of earmarked AIDS funds [DHSC0002464_020]/ I emphasised the decision was for the treating clinician to make. I also wrote in similar terms on the same date to Dr Lee [HSOC0002574]. The decision was also the subject of a press release issued the following day [DHSC0004764_052].

Summary on High Purity products

70.20. This summary draws on the matters I have set out above in the body of my statement and is supplemented by what is apparent to me from reading the material contained in the Annex. To summarise, the issue of efficacy of HP factor concentrates was debated by the profession and officials within the Department prior to my involvement. At the time of publication of the Fourth Recommendations, in around spring of 1992, the Department was conscious that the recommendations, which were not a DH document but rather were guidance to clinicians, represented a consensus and were not a unanimous document, and that the science around the efficacy of HP products was contestable. The Department's line was that it was a matter for individual clinicians to make prescribing decisions in accordance with local agreed guidelines and that RHAs were best placed to make decisions on how fast any particular medical treatment, such as HP Factor VIII, should be introduced. The Department did not simply "decline" to fund HP products. Rather it took the view that, for a combination of reasons, it was not appropriate for earmarked AIDS monies to be used to purchase Factor VIII when such funds had been allocated - in broad terms - to address a new epidemic (AIDS). Instead, the initial view was that the main NHS funding allocation should be used. However, as the science developed and the case for HP Factor VIII having benefit for HIV positive haemophiliacs became stronger, the Department's policy shifted to recognise that HP factor concentrates could be regarded as an HIV treatment, as well as a haemophilia treatment. Accordingly, in December 1992, the Secretary of State agreed to change the policy to allow clinicians, if they considered it justified, to

use earmarked AIDS funds to pay the differential cost between an IP and HP product.

Section 12: Recombinant

Q.71 Introduction of recombinant products in the UK

71.1. The Inquiry has asked me to provide a chronological account of the introduction of recombinant products in the UK. I understand the Inquiry wishes to know about my involvement in and knowledge of the relevant events.

71.2. Given the passage of time, I am no longer able to recall any direct involvement in this issue. The summary of the contemporaneous documents contained in the Annex does not suggest that I had a significant degree of direct involvement in issues around introduction of recombinant products, although I note letters were sent to me directly from clinicians. The Deputy CMO, the late Dr Jeremy Metters, did make several significant contributions. It is likely that Dr Metters would have discussed these matters with me at the time.

71.3. The Inquiry may be more assisted by information from those who were directly involved. The names of individuals who were involved are mentioned in the Annex.

71.4. I see from reading the Annex that the progress of the introduction of recombinant products varied across the four nations. As CMO for England, I am not able to speak in any detail about developments in Scotland, Wales and Northern Ireland.

71.5. To refresh my memory about the nature of recombinant products I have been referred to Dr Rejman's minute on "Recombinant Factor VIII and VAT" of 2 November 1995 [DHSC0003540_096]. To summarise, in 1984, the gene for Factor VIII was identified and manufacturers started trying to produce a recombinant Factor VIII ("rFVIII"). Trials were performed in various countries including the UK and in late 1993 to early 1994 the first rFVIII products received a UK licence.

71.6. As I understand from Dr Rejman's minute, the Factor VIII gene was obtained from human cells and then transfected into hamster cells. These then synthesise the recombinant Factor VIII, which went through various other processes including the addition of a stabiliser, human albumin. I am aware later processes changed and rFVIII became available which did not use human albumin as a stabiliser, but this was after my time in office. I am aware rFVIII was used to treat haemophilia and was the first recombinant product in the UK, although later other recombinant products became available to treat other clotting disorders.

71.7. The documents shown to me indicate my first involvement apparently came in September 1992. On 3 September 1992, Dr Rejman sent a Minute to Dr Nicholas, my then Private Secretary, ahead of a meeting of European CMOs which I subsequently attended in London [WITN3430047]. The Minute records that replacing plasma derived Factor VIII ("pdFVIII") with a synthetic product was at "*too early a stage to be given unqualified support*". The Department's line to take was to generally support developments in biotechnology and watch progress with interest.

71.8. From reading the Annex the next significant development seems to have been in late 1994. On 18 November 1994, Dr Lee of the Royal Free Hospital wrote to me directly [BART0000634_003]. She referenced what she called my "*intervention*" in the debate around HP products. Her letter set out her concern:

> "*that we continue to use blood products that are derived from plasma when there now is a licensed synthetic, non plasma-derived equivalent. We cannot in all honesty, say that the present products we are using have exposed our patients to risk but, there are reports from time to time for example, of hepatitis A transmission and more latterly, of parvovirus or B19 transmission. There therefore lurks in the minds of both the haemophilia treaters and the patients, a concern that there may be some hidden virus with which they could become infected.*"

71.9. Dr Lee noted the cost of synthetic Factor VIII was unaffordable for her hospital. She asked me to persuade government that haemophiliacs should in future be treated with recombinant products to prevent any possibility of viral transmission.

71.10. I see from the Annex that officials within the Department coordinated a response and that it fell to Dr Metters to reply. I refer to the fuller details given in the Annex.

71.11. The Inquiry has referred me specifically to two documents from May 1995 concerning a meeting between the UK's Permanent Representation in Brussels, Mr Angus Lapsley, and the pharmaceutical company Rhone-Poulenc Rorer ("RPR"), who owned Armour Pharmaceutical. I have no recollection of these meetings taking place or any involvement in discussions about them. I do not believe I would have had any personal involvement.

71.12. I have seen a letter to me, dated 15 June 1995, from Sir Colin Dollery, the Dean of Hammersmith Hospital [DHSC0003540_126]. He explained that the new drugs panel at his hospital had declined to use rFVIII, largely on grounds of cost. He raised points about safety measures for plasma derived factor concentrates, risk of hepatitis A and human parvovirus transmission and the risk of unknown viruses. He concluded:

> "*The Panel felt that there were policy issues involved and it was right therefore to raise them with the Chief Medical Officer. They felt that it would be better if there was a national policy rather than a series of different policies in different Trusts because inevitably the patient groups concerned compare policies and draw attention to discrepancies. The other problem is the potential difficulty persuading fund-holding general practitioners to prescribe very expensive drugs and the Panel felt that drugs used to treat haemophilia ought to be dealt with on a supra-regional basis.*"

71.13. I replied to Sir Colin Dollery on 11 July 1995 [DHSC0032176_094] and referred him to Dr Metters' letter to Dr Lee of 25 May 1995 (my legal advisers have pointed out my reply erroneously referred to Dr Lee writing to me in August 1994, when it was in fact November 1994). Dr Rejman's Minute to Ms D Jeffrey in my Private Office indicates that he advised on my response [WITN4486055]. I can see this is an area in which my response would have been guided by the advice I received from officials.

Hepatitis A in children treated with pdFVIII

71.14. I have been shown a minute from Dr Ennis Lee of the MCA, dated 2 August 1996, which was copied to my office, Dr Metters and others, regarding an MCA investigation of three cases of hepatitis A in children in Manchester who had received a plasma derived product, called "Alpha VIII" [MHRA0018323_140]. I understand from the Annex that this incident served to heighten the calls for funding of recombinant products.

NBA recall of "Replenate" pdFVIII

71.15. I have seen that on 6 August 1996, Roy Alder of the MCA sent a Minute to Mr Dorrell, copied to Dr Susan Shepherd, my Private Secretary, Dr Metters and others [WITN3430048]. BPL had notified the MCA that one batch of "Replenate" pdFVIII (plus three batches of albumin) which had gone on to the UK market was produced from a plasma pool that tested positive for hepatitis C. MCA's advice, supported by independent experts, was that a recall on scientific grounds was not indicated. The Minute acknowledged there was nevertheless an issue of perception should the findings become public knowledge.

71.16. I see I was copied into a subsequent Minute on 16 August 1996 from the Private Secretary to Mr Horam confirming that Mr Dorrell had taken the view the products should be recalled in the interest of "*absolute safety*" [WITN3430049]. It was agreed the NBA would liaise with BPL to set in place a

voluntary recall of the affected products, which was announced publicly on 19 August 1996 [WITN3430050]. The Department's public line was that it was a matter for the NBA, but the Department supported the recall in the interest of maintaining public confidence [WITN3430051]. The incident triggered press interest and led to further calls for the government, including from the Haemophilia Society, to provide specific funding for recombinant products.

UKHCDO guidelines on recombinant products

71.17. I see that the Annex sets out background to the publication in 1997 of the UKHCDO Guidelines on recombinant products. In so far as my personal involvement was concerned, I have been shown a letter dated 19 June 1996 in which Dr Colvin, Chair of UKHCDO, wrote to me directly enclosing a copy of the draft guidelines and asking for comment [DHSC0003986_026]. I cannot now recall being sent the draft guidelines.

71.18. I also see that Dr Rejman attended the UKHCDO AGM on 3 October 1996. He sent a minute, copied to my Private Office, to inform recipients that publication of the guidelines had been delayed [WITN3430052]. His minute also raised concern for the Department about the wording of the draft guidelines. I do not recall this issue and do not believe it was something with which I would have got involved. I also see from the Annex that the matter was picked up by Dr Winyard, who wrote to the NHS to make clear the guidelines were not endorsed by the Department. I see my Private Office was copied into some of the minutes, but this is not something with which I can now recall any personal involvement.

Concern about transmission of vCJD by blood and blood products

71.19. On 6 October 1997, I made a public statement regarding the unknown risk of whether vCJD could be transmitted through blood and blood products [WITN3430053]. The possibility of transmission of vCJD through blood had raised significant public concern. I deal with these issues in more detail in

Section 13 on vCJD. I see from the Annex there was an interrelationship between concern about vCJD and calls for funding of recombinant products.

71.20. I also see from the Annex that on 28 November 1997, the Irish CMO, Dr Jim Kiely, wrote to inform me his government had decided to make rFVIII available to all haemophilia sufferers in the future [DHSC0046971_113]. His letter referred to the decision being based on "*a number of other factors relevant to Blood Product Safety*", although provided no further detail. I am also told by my legal advisers that in around early February 1998, a decision was taken in Wales to enable all haemophiliacs access to recombinant products, although I am not able to provide any further detail.

71.21. The Inquiry has sent me a document concerning a meeting on 22 January 1998 [WITN3430054]. The document refers to Dr Frank Hill and Dr Mike Williams expressing the view that it is "*untenable to continue to use BPL products given the currently available information about nvCJD*" and urging change to use of rFVIII or US plasma products. I have no personal knowledge of this meeting and am not able to assist further.

Impact on BPL of UKHCDO press release

71.22. The Annex refers to a paper on blood services produced by the Department for the NHS Executive Board in January 1998. Although I, along with Dr Winyard, am named on the paper as a "*sponsor*" I do not have any direct recollection of this paper. This paper is addressed in more detail in the Annex (paragraph 71.78).

Move towards national policy on use of rFVIII

71.23. The Annex refers to a ministerial submission dated 5 February 1998 authored by Dr Metters and Dr Winyard (paragraph 71.80 onwards). I can see Dr Shepherd, my private secretary, was copied into the submission. I do not now recall any involvement with formulating this submission but I believe it is likely that Dr Metters would have discussed the matter with me, especially given the

significance of the submission and the fact it was related to issues arising as a result of concern about vCJD.

71.24. On 16 February 1998, I see from the documents I have been shown that I sent a Minute to Dr Winyard following a meeting I had with Directors of Public Health in the north west [DHSC0032262_076]. I reported to Dr Winyard that they wished for national guidance on Factor VIII and remarked that this was interesting as it illustrated a shift from the wish to have locally determined priorities to national ones. Seen in the context of the various other documents summarised in the Annex, my comment to Dr Winyard indicates to me, and in accordance with my recollection, that I had relatively limited involvement in the prior debates about the need for national guidance on rFVIII.

Q.72 Haemophiliac patients' access to recombinant blood products

72.1. The question presupposes that recombinant blood products were not available to haemophiliacs at a time when they otherwise could have been available. rFVIII was available under the NHS since the product was first introduced in the UK, if it was clinically indicated and the funding decision supported by the local health authority. The two pillars of clinical effectiveness and affordability are important because resources spent in one area of the health service necessarily means less in other areas. Plasma derived products had a good safety record since 1985, on the evidence at the time were probably just as effective and were cheaper than recombinants. Because both products were of similar efficacy, it was left to health authorities to make decisions at a local level.

72.2. I do not think I now have sufficient information about the state of knowledge at the time to disagree with the line taken by the Department. In respect of the relative safety of pdFVIII compared with rFVIII, I do not think I am able to disagree with what was said in Dr Metters' letter of 25 May 1995 [WITN4486055]. I note that as for hepatitis A risk, vaccination was recommended, and some companies had introduced a second viral

inactivation step for their plasma products. As for parvovirus B19, the view was this is a common infection which is usually mild except in a small number of particular groups.

72.3. The decision in early 1998 to provide central funds to make recombinant products more widely available was driven not by a change in the science nor by a change in the Department's understanding of the respective merits of plasma derived and recombinant products, but because of the entirely understandable fear felt by haemophilia patients and their carers in the face of the unknown but theoretical risk of vCJD and against a background history of infection with blood borne viruses.

Section 13: vCJD

Q.73 The Emergence of vCJD

73.1. Question 73 relates generally to the development of Departmental understanding of the risks posed by Variant CJD (vCJD) (or New Variant CJD (nvCJD) as it was often called at the outset) in blood and blood products. Question 73 has been withdrawn by the Inquiry, I understand on the basis that the remaining questions posed relate more directly to my personal involvement in this issue.

73.2. However, for the sake of context I note that an account of the emerging understanding of vCJD within the DH could usefully start in March 1996, with:

a) The meeting of SEAC on 8 March 1996, introducing findings concerning nvCJD; Ministers were advised the same evening;

b) A further meeting of SEAC at the request of Ministers on 16 March;

c) A meeting of Ministers chaired by the PM on 19 March, which I attended, and which was followed by a further SEAC meeting on 19 March which I also attended [MHRA0020323];

d) Public statements to the House of Commons by Mr Dorrell (the Secretary of State for Health) and Mr Hogg (the Minister of Agriculture), followed by a press conference;

e) My Statement on the new development to the medical profession's Directors of Public Health and Consultants in Communicable Disease Control via EPINET, CEM/CMO/96/1 [DHSC0041192_144] as well as a press statement [WITN3430055];

f) Further statements to the House on 23 March, to address the specific issue of children which SEAC had been asked to consider further;

g) Further, on 21 March 1996 all neurologists in the UK were circulated with a description of the clinicopathological features of nvCJD and asked to refer any suspect cases to the CJD Surveillance unit in Edinburgh [DHSC0041442_093]; and

h) The publication in the Lancet on 6 April of the article "A New Variant of Creutzfeldt-Jakob Disease in the UK" by Dr Will and co-workers at the Edinburgh CJD Unit.

73.3. However, at this stage the focus of the discussion was upon the implications for the safety of meat and other foodstuffs, as (to summarise very generally) it was presumed that nvCJD was likely to have developed from eating beef before safety measures had been taken. Further EPINET messages were sent in March and April, giving reassurance about beef and milk and the safety of pharmaceutical products.

73.4. Announcements from this point onwards are picked up at Question 77, which addresses my CMO's letter of 1 July 1996. But to summarise key milestones relating to the domestic use of blood or blood products whilst I was CMO, for ease of reference:

a) 20 March 1996: Announcement of a new variant of CJD;

b) 1 July 1996: CMO's letter on CJD/nvCJD;

c) Summer 1996: initiation of planning for CJD 'Lookback' exercise, effective from early 1997;

d) SEAC recommendations on leucodepletion and risk assessment of blood products, 24 October 1997;

e) Recalls of blood products, from 30 October 1997 as a result of the inclusion of donations from those subsequently found to have CJD or if strongly suspected of having CJD (January 1998);

f) Decision not to use UK-sourced plasma in BPL blood products (February 1998);

g) Recombinant use mandated for new patients and the under 16s (February 1998); and

h) The introduction of leucodepletion (July 1998).

73.5. Much if not all of this was marked by a strong reliance on the 'precautionary principle'. I discussed this principle in my evidence to the BSE Inquiry (see reference at Question 8 of Section 1) [BSEI0000007; BSEI0000008; BSEI0000009; BSEI0000010; and BSEI0000011].

Q.74 Evidence to the Strategic Review of the PHLS

74.1. I have been referred to [CABO0000284_011] – said to be an extract from the minutes of the Strategic Review of PHLS in March 1994, recording my oral evidence to the Review. There are a large number of points about the role of PHLS set out, which I will not repeat. The very last point reads: *"Prion disease: the Department of Health does not think that the PHLS should be involved in this area of work."*

74.2. I have been asked why the Department held this view.

74.3. I have not been supplied with the Briefing Note or similar document that would have been given and discussed with me prior to giving evidence, so I have not been able to recreate the context for my evidence to the Review. However, there are details in the relevant sections in the Report of the Review body that I was giving evidence to [DHSC0046944_011, September 1994]. This was a largely independent Review carried out at the request of the PHLS Board itself (see p1 for an account of its remit and composition). The issue of "prion disease" or vCJD is covered at p78 as follows:

> ***"Strategic Issues***
>
> ***Should the PHLS be involved in any aspect of the surveillance of transmissible spongiform encephalopathies, such as Creutzfeldt-Jakob Disease (CJD)?***
>
> ***Present Position***
>
> *411. The transitional agents ("prions") which cause spongiform encephalopathies in animals and humans are unlike any known micro-organisms in that they have no detectable nucleic acid. Given this fact*

> *and the fact that the government has established a UK national Creutzfelt-Jakob Disease Surveillance Unit in Edinburgh, the DH has taken the view that there is no necessity for the PHLS to become involved in surveillance of transmissible spongiform encephalopathies at the present time. In evidence we received from the Chief Medical Officer, that remains the Department's view. However, we believe the Board should revisit the position with the DH from time to time in the light of the reports from the Edinburgh Unit and other sources.*
>
> *We recommend that the Board should periodically review with DH colleagues the need for PHLS involvement in surveillance and R&D in relation to transmissible spongiform encephalopathies."*

74.4. It seems that the DH position was based on a concern not to allow duplication of effort and expertise. It was accepted by the Review, subject to periodic review. A draft answer to a Newsnight question in April 1996 stated that this review took place [WITN3430056; see also WITN3430057 and WITN3430058, PHLS statements for a Panorama programme from 24 May 1996].

74.5. I have also noted that in 1996, Dr Walford stated that *"Ministers have not wished the PHLS to be involved in work on BSE, because of the lack of an apparent association with human illness",* which is a slightly wider perspective; see further below. Below, I have also noted that the topic of possible PHLS contribution to BSE/CJD/vCJD surveillance, including the reasons for the DH views on its involvement, was considered at length by the BSE Inquiry; its Report contains far more detail than is contained in the excerpt of my evidence to the Strategic Review, above.

Q.75, Q.76 Offers of Help from PHLS

75.1. The Inquiry has noted that following the Secretary of State's announcement of the transmissibility of vCJD, on 21 March 1996, Dr Diana Walford wrote to me stating that the PHLS's "*expertise in communicable disease epidemiology is*

at the disposal of the Spongiform Encephalopathy Advisory Committee" [MHRA0020475_008]. I have been asked to explain my response to this offer.

75.2. Before turning to this letter, as I have explained above the topic of possible PHLS contribution to BSE/CJD/vCJD surveillance was considered at length by the BSE Inquiry, at least up until 20 March 1996 (its Terms of Reference required it to consider *"the history of the emergence and identification of BSE and new variant CJD in the United Kingdom, and of the action taken in response to it up to 20 March 1996"* [MHRA0032000]). See:-

a) My evidence to the BSE Inquiry on this topic, summarised at [BSEI0000009], at pages 1 – 11;

b) Dr Walford's evidence to the BSE Inquiry [WITN4461007]: the attachments to this relate to the correspondence between PHLS and the DH and others on this issue, up to April 1996. Paragraph 23 of her statement acknowledged what was done thereafter, and is quoted at paragraph 76.7 below;

c) The BSE Inquiry Report, Volume 8 "Variant CJD", Chapter 3 [MHRA0032000] paragraphs 3.20 - 3.51, which outlined the history up to March 1996, and gave a brief mention of what followed; and Chapter 5, paragraph 5.170 – 5.173, where the Inquiry set out its conclusions on this topic under the heading *"Could PHLS have been usefully involved in surveillance?*";

d) On this topic, the BSE Inquiry concluded that PHLS involvement (up to March 1996, presumably, given the Terms of Reference) *"could have contributed to the CJDSU surveillance of CJD and their programme of epidemiological research."* But it continued: *"These comments in no way detract from the sterling work of the CJDSU team who so promptly detected the emergence of vCJD and so efficiently established the clinical and pathological characteristics of the disease. While assistance from the PHLS could have been valuable, it would not have enabled identification of vCJD at any earlier date. We do not criticise*

those who concluded that the task of monitoring CJD should be left to the Surveillance Unit." (paragraph 5.172).

75.3. It is apparent that the response to Dr Walford's letter of 21 March 1996 was handled by members of the DH civil servants' team. First, Dr Ailsa Wight asked for advice from Dr Metters [WITN3430059]. She noted that the MRC was setting up a group to look at epidemiological needs. A short (delayed) reply was sent by Dr Metters on 17 April, advising that the PHLS offer to help SEAC should be conveyed to Professor Pattison (the Chair of SEAC) [WITN3430060].

75.4. I wrote to Dr Walford to this effect on 23 April 1996 [CABO0000284_045].

75.5. I note that meanwhile on 2 April 1996, Dr Walford had sent a further and more detailed letter about PHLS input to Dr Eileen Rubery at the "Health Aspects of Environment and Food Division" of the DH [WITN3430061]. The Inquiry has withdrawn a question about the response to this as the letter was not addressed personally to me, but I have set out an account of what happened as it is linked to the original letter from Dr Walford.

75.6. The next day, a draft answer to a Newsnight question sent by Dr Walford to me restated the previous position about the role of PHLS [WITN3430056] but continued:

"However, with the evidence suggesting a possible association between BSE and a form of the human disease CJD, the Chief Medical Officer has announced that the surveillance of CJD and associated epidemiological research will be strengthened and the PHLS has been in discussions with him about ways in which its expertise could be used to the full." [version with handwritten amendments incorporated].

75.7. It is apparent that these issues were picked up by Dr Rubery: see her letter to Dr R.J. Will of the Edinburgh CJD Unit on 9 April 1996 [DHSC0004465_158],

highlighting the need to discuss the way forward; a meeting was to be arranged later in April. This visit to Edinburgh duly took place on 24 April 1996. A letter from Mr Peter Jones about the issues discussed [WITN3430062, 1 May] records that it was thought that PHLS might offer expertise in the field of data modelling and handling. Proposals for a meeting with Dr Walford were set out.

75.8. The progress of these discussions can be traced in:

a) A detailed "Action Note" of a meeting held between PHLS, Dr Will and Professor Peter Smith on 28 May 1996 [CABO0000284_050]; and

b) The letter from Dr Barlett (PHLS) to Dr Will dated 2 August 1996 and its attachment [WITN3430063].

Both of these documents set out details of the proposed epidemiological and surveillance work, which was extensive: see documents for details.

75.9. Returning to liaison between PHLS and SEAC: a minute from Dr Rubery to the Secretary of State dated 4 April 1996 [WITN3430064], copied to my Private Office, updated Mr Dorrell upon steps being taken about CJD/BSE. In relation to the PHLS, it recorded:

"5. HEF will be setting up a small management team chaired by Dr Rubery to ensure the [CJD] Unit has the resources it needs and carries forward work with appropriate priorities. PHLS will be represented on this co-ordinating team …

6. It is also proposed that SEAC considers setting up an epidemiology sub-group which will assess needs in this area. This will be in addition to the MRC co-ordinating committee on spongiform encephalopathy and its clinical sub-committee which identifies priorities and opportunities for research. These may also involve PHLS".

75.10. Research links with the MRC were also pursued: see [DHSC0004470_066], a fax to Dr Wight from Dr Tony Soteriou for the MRC. He enclosed a copy of the letter sent from the MRC to Dr Walford on 7 June 1996 [DHSC0004470_067]. It outlined the role that the MRC was taking, with the Department of Health, to respond to the research needs. There was to be a joint DH/MRC "TSE Research Advisory Group" and a Clinical Sub-Committee, the CJD Epidemiological Committee. Dr Walford, or an appropriate member of her staff, was invited to become a member of this new Epidemiological Committee (its other members are listed at [DHSC0004751_011]).

75.11. Overall, the steps that were taken to use PHLS expertise are summarised in the BSE Inquiry Report, Volume 8, Chapter 3 at paragraph 3.42 [MHRA0032000]:

> *"Since the announcement on 20 March 1996 of the possible link between vCJD and BSE, the PHLS has been involved in a number of aspects of work on CJD, including:*
>
> > *i. a project to detect, retrospectively, under-ascertainment of vCJD in Wales;*
> >
> > *ii. establishing active surveillance, through the British Paediatric Surveillance Unit, of progressive intellectual and neurological deterioration in children under 16 years of age in the UK, to determine whether cases of CJD were occurring in that population;*
> >
> > *iii. a project to set up a panel of clinical samples from patients with neurological disorders, for the evaluation of candidate tests for CJD;*
> >
> > *iv. a project to develop a diagnostic test for CJD;*
> >
> > *v. regular monitoring of the trend in incidence of vCJD, in collaboration with the CJD Surveillance Unit; and*
> >
> > *vi. various reviews of the methodology and work of the CJDSU.*

> *Furthermore, a PHLS statistician was appointed as a member of SEAC's Epidemiology Subcommittee and Dr Walford was herself appointed a member of the CMO's Committee on the Human Aspects of Spongiform Encephalopathies" (i.e., COHASE)."* [The Report's reference was to Dr Walford's BSE statement at paragraph 23].

Q.77 CMO letter of 1 July 1996

77.1. On 1 July 1996, I issued a CMO's letter regarding vCJD to all doctors. [BART0000554]. The purpose of this letter was to provide doctors with information about the new variant of CJD. Amongst other things the letter provided background information on CJD and transmissibility of CJD.

77.2. I provided a detailed explanation of the purpose of this letter in a minute I sent on 21 June 1996 to Claire Moriarty (the Principal Private Secretary to Stephen Dorrell, the Secretary of State for Health). It stated as follows [WITN3430065]. I noted the limits of the information that had been sent in March and April 1996 (see Question 73 above) and continued:-

> *"GPs, public health doctors and clinicians (neurologists, psychiatrists, paediatricians in particular) who have to deal with patients' concerns about a range of issues arising from the NVCJD announcement need an authoritative, comprehensive, but practical, document so that they can give appropriate advice and reassurances based on a clear statement of the facts.*
>
> *There are no other current or proposed documents that bring all the diverse strands of relevant information together."*

I sought the Secretary of State's approval for the letter (which was attached) to doctors to be issued, noting that it would complement a Scientific Briefing due to be given on 26 June 1996. (I can see that I was keen to get CJD figures into the public domain before the summer recess – see the records of

the 'stock-take' meeting at [WITN3430066] although these were not meetings I would have attended, so my views were being reported by others.

77.3. On 25 June 1996, Mr Shaun Gallagher, Private Secretary to the Secretary of State for Health wrote to my Private Secretary following my submission of 21 June 1996. He stated that the Secretary of State was content with the text and agreed to the letter being issued [MHRA0034594_013].

77.4. I have been asked by the Inquiry to set out:-

a. The information you had received, from whom and when, to enable you to say that there was "no epidemiological evidence that blood, blood products or whole organ transplants pose a risk of transmission"?

77.5. I cannot remember the information I had received to enable the inclusion of this comment. But I would not have drafted this letter myself. As was normal practice, it would have been drafted with input from all the relevant officials and experts. For example (although these are not letters that I would have seen):

a) There is a letter from Mr Sloggem of the MCA [MHRA0034594_045] dated 3 June 1996 which indicates that a draft version of this letter was discussed at the 'stock-taking' meeting on 30 May 1996; he flagged issues with the draft with Dr Wight's office.

b) On 11 June 1996, Mr Sloggem wrote to Dr Purves (Medicines Control Agency) concerning a further draft of my letter [MHRA0026214]. It appears from this that the section on pharmaceuticals had received input from the MCA. He commented specifically on the section on transmissibility, including by blood and blood products, and said that it was "*rather weak … and could beg the question about the safety of blood products being an open question.*"

c) On 14 June 1996, Dr Alisa Wight (DH) sent a minute to my Private Secretary, Dr Harvey, attaching an updated draft of the letter I later issued on 1 July 2021 ([MHRA0034594_020] and draft at

[MHRA0034594_021]). This minute was copied to various officials in DH to seek their input. Dr Wight asked whether I was content for it to go to MAFF, DTI and the CJD Unit to see it, to check its contents.

d) The version sent up to the Secretary of State on 21 June included some changes to the section on transmissibility, and further changes were made before the final version was made.

77.6. It is not clear from the documents that I have been shown when or by whom those further changes to the section on transmissibility were made; officials might hold further details. I would have seen and approved the final version. The statement highlighted by the IBI, that there was *"no epidemiological evidence that blood, blood products or whole organ transplants pose a risk of transmission"* was accurate at the time, so far as I am aware. (Later that year evidence of a theoretical possibility of transmission emerged, based on studies on mice: see Question 79 below). Generally, as I have explained in answer to Question 23, throughout the BSE/CJD crisis, I was concerned to ensure that the public were kept informed at all times about the disease, health risks and relevant research.

b. What were the precautionary exclusion criteria that were implemented?

77.7. The exclusionary criteria applicable to organ or tissue donation applicable in July 1996 are outlined in Health Service Guidelines, HSG(96)26, summarising MSBT recommendations as of March 1996 [DHSC0041369_018]. The following individuals were excluded from organ or tissue donation to prevent transmission of CJD:

a. *Recipients of pituitary derived hormones such as human growth hormones or gonadotrophins;*
b. *Suffers from CJD or with family history of CJD;*
c. *Suffers of degenerative neurological disease of unknown aetiology.*

These were only one set of precautions or exclusionary criteria for tissues and organs, aimed at preserving safety or minimising risk from a number of factors

or risks. There were similar measures relating to blood donations (see the summary in [WITN3430067] at paragraph 2 in particular). I believe that the ultimate source of precautions with respect to blood products were the Council of Europe and European CPMP[6], although the UK remained free to decide on donor exclusion criteria and other matters relating to the safety of blood (see Dr Metters' comments at paragraph 7.1 in [WITN3430067]).

c. Why were they introduced? Were they introduced because of "political pressures" as referenced in JPAC0000166_059? If so please explain what those pressures were.

77.8. [JPAC0000166_059] is a minute of a National Blood Service meeting held on 10 July 1996, at which Dr Hewitt referred to "political pressures", stating that for "*"political pressures as much as any clinical reasons it will become necessary to include in the questioning of all donors specific reference to CJD".* She would be better placed to explain what she meant by this than I am.

77.9. There may be some confusion about measures here. The reference to exclusionary criteria in the CMO letter of 1 July was a general one, coupled with the statement that these were kept under "regular review". I have set out the donor exclusion criteria applicable above. The reference to "political pressures" in the minute of 10 July 1996 appears to relate to the further step of explicitly questioning donors that was introduced with effect from 1 August 1996. There are further documents reviewed relating to this in the Annex.

d. When were the exclusion criteria implemented? What steps were taken to ensure that all relevant individuals and/or organisations were aware of the requirement of the precautionary measures?

77.10. The SACTTI minutes of 1 July 1996 indicate that the implementation date of the additional donor questioning was 1 August 1996 [JPAC0000109_025].

[6] [WITN3430068] (13.02.1995) refers to Council of Europe Decision

Details of implementation regarding donor exclusion would be a matter for the Blood Service to respond to in more detail.

Q.78 CJD Lookback Exercise

78.1. I have been asked to set out my knowledge of discussions about whether a lookback exercise should be conducted with respect to CJD infections.

78.2. The Inquiry has referred to documents showing that discussion and planning for a lookback exercise took place within the UK Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI), the MSBT and a group of National Blood Service's Consultants in Donor Health, amongst others. The lookback exercise was carried out by the CJD Unit in Edinburgh, in co-ordination with the Regional Transfusion Centres and relevant hospitals, following consideration of the ethical issues by the West Lothian Ethics Committee and also by Professor Ian Kennedy, as he then was.

78.3. The Inquiry has referred me to several documents to assist me in answering this question, including minutes and documents from several meetings of committees of which I was not a member (see above). The documents the Inquiry have referred me to do not suggest that I had direct involvement in the discussions the Inquiry is asking about. I have had regard to a summary of their contents, as set out in the Annex.

78.4. Looking back, I expect that I would have had some knowledge of discussions that took place and potentially some discussions myself with my DCMO or wider team regarding the ethics and mechanics of a lookback exercise, however I do not now remember any specific discussions that I was involved in, or had knowledge of, in relation to the specific questions asked by the Inquiry (see further below).

78.5. I have been asked to address specifically what discussions there were in relation to a number of issues. The quotations on which I have been asked to comment again come from the minutes of the meeting of the Consultants in

Donor Health held on 10 July 1996 [JPAC0000166_059]; see paragraphs 78.8-78.14 of the Annex for a further summary of the discussions. As I commented in response to the previous question, this was a National Blood Service meeting and I was not present.

78.6. Looking at the issues I have been asked to comment on:-

a. The "sensitivity and difficulties" of carrying out a lookback regarding blood products and the outcome of the discussions with fractionators referred to.

78.7. I do not think that I can now add anything to the references to these issues in the document.

b. The ethical problems of a lookback exercise "because diagnosis is currently by autopsy of brain material…and secondly that there is no effective prophylactic or preventive therapy". Please explain what, if any, different ethical considerations were considered to exist compared to Hepatitis C.

78.8. The references to ethical advice that had been sought and received are summarised in the Annex. On the topic of "differences" between lookback in HCV, and contacting the recipients of donations from those who had subsequently been diagnosed with or were suspected of having CJD, it will be remembered that the HCV Lookback exercise did not begin until there were licensed treatments for HCV available. Section 7 of my statement sets out how it appears that in 1991, one of the reasons for not undertaking such an exercise was that no treatment could be offered. The same ethical stance appears to have been taken in 1996.

c. Why it was considered appropriate to undertake a lookback exercise without notifying the recipient of the transfusion or their GP/clinician.

78.9. Again, the reasons are set out in the SACTTI document [JPAC0000109_021] and reproduced at paragraphs 78.12 – 78.14 of the Annex. I would comment that it is apparent that ethical advice was sought and received from Professor Sir Ian Kennedy and that approval was given by the Lothian Ethics Committee, which oversaw the Edinburgh CJD Unit.

Q.79 Media Briefing of 6 October 1997

79.1. The Inquiry has noted that on 6 October 1997, I was asked by the Secretary of State to give a media briefing regarding the risk of vCJD being transmitted through blood transfusions or blood products. I have been asked to explain:

a) Why I was asked to give a media briefing and what required the briefing to be given at that time;

b) Why this briefing was given before the SEAC reviewed the safety of blood at their meeting on 24 October 1997;

c) Who was involved in writing the media briefing; and

d) What the evidence was that I relied on to state (it is said) "that there was no evidence of any risk of vCJD from blood transfusions".

79.2. The background to the media briefing on 6 October 1997 can be picked up from, first, a chronology later prepared within the DH, I think for my successor since it is dated 19 November 1998 [WITN3430069]. It is useful in setting out that: (i) on 15 September 1997, I announced the establishment of a SEAC epidemiology sub-group to assess information about nvCJD; (ii) on 16 September, SEAC met and reviewed the pre-publication results of two studies which "*provide convincing evidence that the agent that causes BSE is the same as that which causes nvCJD",* but there was no further information on the route of infection and no additional measures to protect public health were recommended to Ministers (the minutes of the SEAC meeting at [WITN3430070] record the view that *"no further precautions were necessary as the Committee's current advice to Government and the measures to protect public and animal health were already based on the assumption that*

there could be a link"); (iv) on 2 October, the journal "Nature" published the results of the experiments which SEAC had reviewed on 16 September.

79.3. Second, at [DHSC0042286_126] there is a minute dated 30 September 1997 from Dr Metters to me, as well as to Mr Sutherwood from the Information Division, advising of possible French action to stop the importation of BPL products (albumin) as a result of the risk of nvCJD. Further enquiries were to be made. It is apparent, not least from the submission to the Secretary of State of the same date (below) that I called a meeting on 1 October to discuss this development. I have not been shown a note of the meeting but its outcome is recorded in the submission summarised below.

79.4. Following the meeting held by me, a submission was sent by Ms Corrigan to the Secretary of State's Private Office on the same day, i.e. 1 October 1997 [DHSC0004805_045]. It was copied to numerous copyees, including other Health Ministers and my own Private Office. Ms Corrigan updated the Secretary of State with regards to the issue that had arisen the previous day, as to French imports of BPL Albumin. She records that I had called a meeting that morning to ascertain, as far as possible, the facts of the situation and to determine what action was required. She noted that BPL had yesterday been advised by representatives of the French company PMC that they would be terminating, with immediate effect, BPL's contract to supply albumin. The action was said to be due, in part, to *"a new restriction which the French authorities are expected to impose shortly on the importation into France of any plasma product derived from UK donors, citing concern about the risk of transmission of nvCJD in the UK".* Ms Corrigan set out details of the possible French unilateral action (that is, this was not a EU measure, although the licensing and sale of blood products was a EU competence). She summarised the scientific evidence on the issue, referring to a science article in "Nature" that was to publish, on 2 October, the results of two studies effectively confirming that nvCJD was caused by the same agent that was responsible for BSE in cattle. She set out the limits of the known data. In relation to

political/public health implications, she stated *"The juxtaposition of the French action with the forthcoming Watchdog programme on CJD and blood (due to be shown on Thursday 9 October) is not helpful."* She set out a proposed low-key response, whilst noting that the Department was arranging for members of SEAC and MSBT to meet, hopefully early the following week, to discuss preparation of a joint statement.

79.5. In addition, there is a short note dated 1 October from Mr Peter Jones to Ms Corrigan [DHSC0041442_204]. Mr Jones wrote that Nick Wingfield *"has kindly explored the possibility of a "quick" experiment to detect the presence of nvCJD prion in blood in view of CMO's concerns expressed this morning. Professor Collinge has agreed to approach Dr Will at the Edinburgh CJD unit with a view to collaborating on an experiment taking blood from nvCJD patients, concentrating it down and applying his "Western Blotting" technique to see if anything can be detected. It is not clear how easy this will be, but if it turns out to be relatively straight forward it will be a pity to miss the opportunity. Of course a negative result would only mean that nothing can be detected by techniques at our disposal, which may not be sensitive enough."* So further scientific exploration had also been proposed and was to be pursued.

79.6. [DHSC0041442_186] is a note from the Secretary of State's Private Office in response to the submission received. There was to be a meeting the following day (3 October) in the Secretary of State's office to *"discuss the issues in the paper in Ms Corrigan's paper of yesterday's date [ie 1 October 1997, see summary above]. SofS has invited Professor Pattison to attend (and Joe McCrea will be there as well). SofS particularly wishes to address the problems around guaranteeing the safety of blood supply and the Watchdog programme."*

79.7. Thus, and to summarise: the immediate genesis of the media briefing was the Secretary of State's response to the submission from Ms Corrigan, on the potential French ban and the Watchdog programme.

79.8. Again, I have not been shown a record of the meeting with the Secretary of State. But it is apparent that following the meeting on 3 October and on the same day, Mr Dobson sent a letter to the Deputy PM, Mr Prescott MP [DHSC0041442_213]. It was copied to senior colleagues and officials including the PM and Sir Robin Butler. Mr Dobson explained the concerns about the Watchdog programme due to air on 9 October:

> *"All the indications are that the presentation will be sensationalistic, highlighting the issue as a "ticking time bomb" for public health. This is a difficult area where there are gaps in scientific knowledge which cannot be filled in the short term, and for this reason it is all the more important that the government is seen to be setting the agenda rather than reacting to the media."*

79.9. Mr Dobson had discussed the science underlying the issue with officials and with Professor John Pattison, the Chair of SEAC. The letter summarised the evidence on risk, including the view of Professor Pattison that it would take some time, years rather than months, before the science base existed to reach a definite view of the risk of transmission to humans by blood or blood derivatives. He continued:

> *"Against this background, it is important that we demonstrate that we are taking the issue very seriously and have action in hand to resolve so far as is possible the various scientific uncertainties. It is also crucial that we are open in setting out the full situation before the public to avoid accusations of coverup or complacency. I believe that public pronouncements on these complex scientific issues carry greater credibility when they are given by our scientific advisers, and I have*

> *therefore asked the Chief Medical Officer to head up a scientific briefing early next week to ensure that the media have the full picture and that "Watchdog" is not allowed to set the agenda. John Pattison has kindly agreed to help in any media follow up which proves necessary."*

79.10. He further noted reports of a possible ban by the French Government on plasma products derived from UK donors, *"because the possibility of nvCJD transmission cannot be ruled out".* This reinforced the need to act promptly, he stated.

79.11. Mr Dobson's office enclosed [DHSC0041442_214], a note of the key points about the present position, i.e., about what was known about CJD and blood, and the "main message", that blood and blood products were given only to those who had a clinical need for them, and that the risk of CJD transmission was far outweighed by the benefits. (This was also the view of the Blood Service: see its 'line to take' at [NHBT0004567]).

79.12. There is a further letter to the Prime Minister from Mr Dobson, sent on the same day, which covers similar ground and was copied to me: see [WITN3430071]. It may have been sent before the letter summarised above (see the reference to proposing to ask the CMO to hold a media briefing). The views that were to be expressed by me as the CMO are set out in the same terms as Mr Kenny used after the briefing in his letter of 6 October, referred to below, paragraph 79.15.

79.13. It is therefore apparent that the media briefing was set up at the request of the Secretary of State, for the reasons outlined in the letter to Mr Prescott.

79.14. [DHSC0004805_036] is a letter from Dr Metters to me dated 6 October 1997, outlining the information that would shortly be available for the briefing, following the morning meeting with the Secretary of State. It demonstrates

the preparations for this event, as well as naming those with lead responsibility for briefings. I have been asked who prepared the briefings used at the meeting; as to that, please see this document, together with [WITN3430072], a minute from Ms Corrigan dated 5 October to numerous copyees, asking for input on drafts of the three documents used at the briefing (see paragraph 79.15 below), which she had started, with help from Mike McGovern.

79.15. The media briefing which took place on 6 October 1997 involved not only me but Professor John Pattison, the Chair of SEAC, the Spongiform Encephalopathy Advisory Committee.

79.16. The contents of the briefing itself can be seen from the documents listed below but were summarised by a letter sent on behalf of the Secretary of State (Mr Dobson) by his Principal Private Secretary (Mr Kenny) on 6 October 1997 to Rob Read at No 10 Downing Street on the same day [CABO0000012_006]. Mr Kenny set out the background to the briefing and stated:

"The key messages which the CMO emphasised were:

a) blood transfusions offer an immediate prospect of saving lives which would otherwise be lost;

b) the risk of death from CJD is minute compared with the risk of not having a transfusion;

c) there is no evidence of any risk: risk would only arise if nv CJD behaves differently to standard CJD;

d) nvCJD remains very uncommon;

e) as new evidence emerges the Government will take whatever action is necessary to maintain the integrity of blood supplies."

79.17. He enclosed the documents prepared for the briefing:

a) A copy of the statement made by me: see [DHSC0041442_171];

b) A background briefing paper tabled [NHBT0085434_002, further copies of these two documents at NHBT0087461]; and

c) [CABO0000012_009]: this the Q&A document, which was not in the public domain but was there to aid with questions asked.

79.18. I have been asked by the Inquiry what evidence I relied on to state that there was "no evidence of any risk of vCJD from blood transfusions". The evidence on the topic is summarised in the background briefing paper, which was made available at the same time as the statement. However, the Inquiry's question does not accurately paraphrase or summarise the statement that was made, or the underlying evidence shared. I did not suggest that there was "no evidence" of "any risk". To quote from the statement (although it ought to be read in full):-

> *"One important question is whether nvCJD can be transmitted from person to person and this is of particular interest where blood and blood products are concerned. There is some evidence that under experimental conditions it may be possible to transmit TSEs in animals through blood, but only by intra-cerebral injection. There is no epidemiological evidence to suggest that classic CJD has been transmitted between humans through blood transfusions or the use of blood products. <u>However we do not know whether the same will apply to nvCJD.</u> Three confirmed and one suspected nvCJD patients have given blood and the Surveillance Unit are following this up.*
>
> *<u>It will be some considerable time before we have sufficient scientific data on nvCJD to be able to answer questions like this.</u> Meantime the most important point to bear in mind is this. Blood and blood products are only given to patients who have a serious clinical - and in many cases very urgent - need for them for their clinical care. <u>Any negligible risk of nvCJD transmission</u> is therefore heavily outweighed by the*

immediate benefit to the patient of the medical treatment…." (underlining added in this statement).

79.19. It should be apparent that I explained the uncertainties, given the state of scientific knowledge, and spoke of "negligible risk" of nvCJD transmission. It is possible that the question is derived from Mr Kenny's summary of the event (see paragraph 79.14 above) as well as in the earlier letter of 3 October, also from Mr Dobson's office. But even then, Mr Kenny qualified his reference to "*no risk*" with the statement that "*risk would only arise if nvCJD behaves differently to standard CJD*."

79.20. I have been asked why a media briefing was given on 6 October, rather than waiting for the SEAC meeting of 24 October 1997. The outcome of the SEAC meeting on 24 October can be seen from the Public Summary of the meeting [see WITN3430073]; this version also has a DH Q&A briefing following on]. SEAC determined that it was:

"… logical to seek to minimise any risk from blood or blood products by reducing the number of lymphocytes present.

SEAC recommends that the Government should consider a precautionary principle of extending the use of leucodepleted blood and blood products as far as it is practicable. It will be for the National Blood Authority to devise a strategy to implement such a policy. It will take time to achieve full implementation and SEAC recommends that planning begins soon while the risk assessments suggested below are carried out."

79.21. This recommendation was then considered by the MSBT (chaired by Dr Metters) on 27 October 1997. The Secretary of State was updated about these developments; [DHSC0041442_006] is a submission to the SoS dated 31 October 1997 and relates to the SEAC decision of 24 October.

79.22. Returning to the question about why a media briefing was given on 6 October, rather than waiting for the SEAC meeting of 24 October 1997:

a) The Secretary of State's letter to Mr Prescott of 3 October 1997 outlines the reasons why the Government's scientific advisors were asked to make a statement on that date, rather than allowing the "Watchdog" programme to "set the agenda".

b) SEAC had met as recently as 16 September and had not recommended further action then;

c) The Chair of SEAC was involved in the media briefing, and I have not been shown any records that suggest that he advised that it would be better to wait for a further SEAC meeting.

Q.80 Recall of vCJD-implicated blood products in October 1997

80.1. I have been asked to explain my involvement, if any, in the decision to recall vCJD implicated blood products in October 1997, and to explain the decision to "play [the recall] down as much as possible".

80.2. I have seen an account of the events relating to the recall of blood products in the Annex (Question 80). From the events there, it appears that these actions flowed primarily from the decision of the European Union's Committee on Proprietary Medicinal Products (the CPMP), although its recommendations were in turn prompted by a UK decision to seek advice along those lines (see the events of 8 – 13 October). I can see that I was copied into relevant documents, including the Ministerial submission of 29 October 1997 from Ms Corrigan to the Private Offices of the Secretary of State and Minister of State (Lords) [DHSC0004290_043]. This submission was copied to my Private Office. It informed Ministers of a *"product recall which will take place tomorrow as a result of the current tracing exercise to locate such products."* I was also copied into details of a further product recall which followed subsequently (see [WITN3430074]).

80.3. However, although I have no reason to doubt that I was kept informed of events, there does not seem to be any record of active participation or decision-making on my part. From a medical perspective, it appears that the lead was taken by Dr Metters, who was Chair of the MSBT.

80.4. As a result, I do not think that I am in a position to give any additional insight into the question of why in her submission Ms Corrigan noted that the response of the media was difficult to predict, but there might be quite a lot of interest as it was the first nvCJD-linked recall, and added: "*Our aim, however, will be to play it down as much as possible. This is, after all, likely to be the first of a series of such recalls*." The documents make it clear that the public or media were informed of the steps taken. I have noted that a further recall did follow, and that the recall was agreed to be a precautionary one.

80.5. It is also apparent from the NBA's Q & A [JPAC0000167_065], as well as the BPL letter to its "customers" (e.g. hospitals), see [GGCL0000109_011] that the ethical issue which arose, about informing patients, was a matter that was treated as being governed by the advice of the Lothian Ethical Committee which oversaw the epidemiological survey of nvCJD being carried out by the CJD Edinburgh Unit. See Question 78, which refers to this.

Q.81 SEAC Recommendations of 24 October 1997

81.1. Question 81 has been withdrawn by the Inquiry. For the sake of understanding how events progressed, however, I have noted above (paragraph 77.19) that on 24 October 1997, SEAC revisited the safety of blood and recommended that, as a precautionary measure, the Government should consider extending the use of leucodepleted blood and blood products, so far as practicable. The Committee recommended a two-pronged approach to the implementation of this recommendation: (a) carrying out an assessment of the risks of vCJD transmission through human blood; and (b) the drawing

up by the NBA of a strategy to move to increasing leucodepletion. The two should happen in parallel.

81.2. The recommendation was announced publicly due to a decision that had been made shortly before that the SEAC advice should be made public. There is a copy of its recommendations at [DHSC0041442_015].

Q.82 Changes to the Lookback Exercise, October 1997

82.1. Question 82 has been withdrawn by the Inquiry. There is some context provided in the Annex (paragraph 82.1).

Q.83 Further Recall of Blood Products, January 1998

83.1. I have been asked to explain my involvement in the decision to recall further nvCJD implicated blood products in January 1998, by reference to a document, [NHBT0005405_002].

83.2. [NHBT0005405_002] is a letter dated 29 January 1998, from Dr Metters to Dr Snape at the BPL. He in turn was responding to a letter from Dr Snape to Dr Rotblat, which had been copied to Dr Metters. A copy of the letter, dated 27 January 1998, is at [NHBT0004597]. Dr Snape noted that products that had not already been released were on hold. But, as Dr Metters noted in his letter, Dr Snape had proposed that no further action would be taken in respect of product already issued, pending confirmation of the nature of the patient's disease. If nvCJD was confirmed, there would be a recall.

83.3. Dr Metters recorded that he had discussed this issue with me, the CMO, in the light of the latest papers seen from the Working Group of the CPMP. He continued:

"This includes a recommendation that "it is not recommended to wait for confirmation but to initiate product recall as soon as a case of nvCJD is strongly suspected by a recognised reference centre."

No doubt MCA colleagues will advise on the formal status of this CPMP guidance. However, whether or not it is mandatory, the CMO and I believe there are substantial public health grounds for recalling product if, in this case, a contributing donor is suspected to have nvCJD. To delay recall for several months while waiting for the diagnosis to be confirmed could be much criticised if the diagnosis is confirmed.

You and BPL colleagues may wish to consider this further."

83.4. Further background on the recommendations being discussed can be seen at [WITN3430075], which is a minute from Mrs Skinner to Ms Corrigan and others, on the topic of Dr Metters' letter to BPL (i.e., to Dr Snape), written on the same day. Mrs Skinner was working on a Press briefing relating to the recall and attached a draft. This draft made it clear that:

"…. There is likely to be a further recall by BPL of Factor VIII and Albumin derived from plasma from a blood donation from a person now ***suspected*** *(but not confirmed) as suffering from nvCJD….*

This does not follow the pattern of other recalls, since the nvCJD diagnosis is suspected, but not confirmed.

The change of position arrives from notification by BPL to the MCA and the Department that they had traced the issue of the products derived from the plasma from a donation given in 1997 and received by BPL in September. They were holding products not yet issued, and planned no recall whilst the nvCJD case remained unconfirmed …. This was in line with the current publicly expressed CPMP view that as a precautionary measure it would be prudent to withdraw batches of plasma derived medicinal products from the market in the event that a

donor to a plasma pool subsequently has a confirmed diagnosis of nvCJD.

However, on 27 January CPMP recommended that the recall policy be extended to include implicated products from donors strongly suspected of having nvCJD by a recognised reference centre. This new guidance will not be announced until the next CPMP meeting at the end of February, but on behalf of CMO Dr Metters has written to BPL to advise that there are substantial public health grounds for recalling a product if, as in this case, a contributing donor is suspected to have nvCJD…"

83.5. There is some further background to this correspondence in the minute from Dr Jefferys of the MCA (Licensing) to Ms Corrigan dated 29 January 1998 (copied, amongst others, to Dr Metters and the CMO's Private Office) [WITN3430076]. Dr Jefferys attached a copy of the paper presented to the January CPMP meeting following the expert group meetings held on 15 and 16 January 1998. He noted that the recommendations, whilst still confidential, were likely to be accepted by the CPMP. The recommendations were in line with what was expected and with the emerging recommendations from the CSM and its Working Party. He discussed the need for a briefing on their release, perhaps jointly between the CMO and the Chair of CSM; he noted that Dr Metters might be discussing this separately with the CMO.

83.6. I have not been shown any further records of any discussions that I may have had with Dr Metters. But in summary:

Dr Snape had informed Dr Rotblat of the DH of potential steps to recall BPL blood products based on CPMP's recommendations in 1997; Dr Metters, having seen the letter, intervened to discuss it with me and to ensure that measures were taken to align it with the most recent recommendations from the CPMP, albeit that at that time, the Committee's recommendations had not been formally finalised.

Q.84 Precautionary Measures, February and April 1998

84.1. I have been asked to set out my understanding of the decision-making that took place regarding the introduction of further precautionary measures in February 1998 and further measures announced in April 1998.

84.2. The history of the developing policy on the availability of Recombinant blood products, and the various Ministerial submissions or other communications which preceded them, has been referred to in my statement and the Annex at Question 71, which at paragraph 71.73 and following sets out events from 5 February 1988 – 26 February 1988, culminating in the decision to ensure that Recombinant Factor VIIII should be made nationally available to children under 16 and new patients (paragraph 84.5 below repeats the announcement made).

February 1998

84.3. Focussing on the questions now asked about nvCJD, the nature of the further precautions that were announced in February 1998 can be seen from the press statement issued by the Secretary of State, Mr Dobson, on 26 February 1988: see [BART0002231]. Mr Dobson announced further precautionary measures *"to protect patients against the theoretical risk of contracting new variant CJD from blood products".* The release noted that the action followed the three recalls of blood products in November 1997 as donors contributing to the plasma used in them subsequently developed nvCJD. It continued:

> *"The further precautionary measures were announced after advice today from the UK Committee on Safety of Medicines (CSM), which considered all the current data including the conclusions of this week's Committee on Proprietary Medicinal Products (CPMP).*
>
> *The CSM advice signals a review of the use of UK-sourced plasma, a component of blood used in the manufacture of a variety of blood products. The CSM will accordingly be looking at all products*

individually to ensure a safe and sufficient supply of blood products to the NHS.

The CSM also advised an extension of blood product recalls to include donors subsequently identified as being strongly suspected of having nvCJD. Previous recalls were based on confirmed cases only."

84.4. Mr Dobson stated that the risk remained:

"… only hypothetical. But we must proceed on the principle that it is better to be safe than sorry.

I fully accept the advice of the CSM. I have decided that the NHS Bio-Products Laboratory (BPL), part of the National Blood Service, will only be allowed to import plasma to manufacture blood products. This will reduce the possibility of repeated recalls of blood products in the future and thereby help to maintain public confidence in these products."

84.5. He further announced measures related to Factor VIII:

"I have decided that all health authorities must make arrangements to ensure that the synthetic version of Factor VIII, known as recombinant, is made available to those children under the age of 16 who are not already receiving it, and to new patients".

84.6. Further details of the measures, together with the advice from CSM to Ministers, were attached.[7]

May 1998

84.7. On 13 May 1998, the Department of Health announced that the CSM's Review, announced in February, had been completed [BART0002128_004].

[7] [HCDO0000133_051] is the version sent to the NHS: CEM/CMO/98/5, focussing on the statements by Dr Metters and the CSM advice.

Their advice was that manufactured blood products should not be sourced from UK blood plasma for the present time. The Scottish Health Minister had accepted that advice. The press notice continued: *"The reasons for moving to non-UK sourced plasma for the time being are that, although there is currently no evidence that nvCJD can be transmitted by blood, there is nevertheless a theoretical risk."* There was no test that could be applied to donors to test for the prion associated with nvCJD. Although it was possible that the manufacturing processes used to produce blood products might destroy the infectious agent, equally there was no test available to confirm this. Plasma would therefore be imported, but only *"when quality inspectors are assured that the stringent safety standards applied to the new sources of plasma are equivalent to those available in the UK".*

Reasoning behind the further measures and their timing.

84.8. I have been asked, first, why further measures were introduced and the timing of them. I believe that this is reasonably well-explained by the press releases and their references to the CSM and CPMP decisions (as well as the further history of events relating to recombinants, Question 71).

Consideration given to the risk of blood borne viruses from paid donors in imported blood products

84.9. The 'alternative' risks posed by imported blood products (however sourced) were considered at the time. I personally wrote to Dr Winyard and Metters on 20 February 1998 [DHSC0041433_084]. I recorded that he had seen submissions on the issue of blood safety and blood products, together with the latest note on the Scots position. I stated:

> *"I would like to register with you that I have considered the issue of the quality and safety of imported plasma and blood products, and public confidence in these products, compared to our own UK products. I understand that the issue is not so much the donor pool, but the screening of blood thereafter and subsequent processing. However, I*

think that the UK will need to be absolutely certain about the quality of alternative sources."

84.10. I have been asked what I meant by what I meant in my memo of 20 February 1998 to Dr Metters that *"the UK will need to be absolutely certain about the quality of alternative sources"*.

84.11. There is a reply from Dr Metters sent on the same date which gives further context [DHSC0004390_143], in which he wrote to me:

"*I agree that the UK will need to be certain regarding the quality of alternative sources of plasma. This is the reason MCA will need to inspect any new donor sources, to satisfy themselves and CSM on the safety and quality of the sourced plasma and the screening procedures in place, before a new product licence was granted."*

84.12. I note that this issue of importing plasma did raise concern: see, for example, para 13 of the Submission of 17 June 1998 to Ministers, where Dr Metters and Dr Winyard wrote: *"Some clinicians remain unpersuaded about the need to take precautionary steps to protect the potential spread of nvCJD and have been particularly critical of the decision to import plasma. They dispute the clear advice of the Committee on Safety of Medicines that the known risks from using paid donor plasma are less than the theoretical risk from nvCJD…"* (see Question 86 below for this submission). However, whilst it appears that the issue of the technical safety precautions needed to be considered by the MCA and BPL, for example, I do not appear to have had personal involvement. Please see the Annex (paragraph 84.1) for reference to further documents relating to this issue.

<u>The change to the criteria for blood product recalls to extend to donors "strongly suspected" of having nvCJD</u>

84.13. This was a change in criteria recommended by the CPMP (see Question 83 above).

Availability of Recombinant Factor VIII

84.14. I have been asked about the rationale for the decision to ensure recombinant Factor VIII was available to children under 16 and new patients, but not for all patients. The history of the availability of recombinant Factor VIII, both as a matter of local policy-making and national strategy, has been considered at Section 12 of this Statement and Questions 71 and 72 in particular. The Annex at Question 71 contains extensive further detail, including reference to Mr Dobson's letter of 26 February 1998 to the Haemophilia Society [RHAL0000441_002] which set out the reasons for the policy adopted. See also paragraph 71.88 and following, which refers to later developments. These matters are included in the Annex as I do not appear to have any real personal involvement in the development of this policy.

Q.85 Det Norske Veritas draft report, April 1998

85.1. This question has been withdrawn by the Inquiry.

Q.86 SEAC Recommendations and Leucodepletion

86.1. On 15 June 1998, SEAC discussed the effect of leucodepletion and made recommendations on reducing the risk of nvCJD. I have been asked to set out my knowledge and understanding of the decisions that were made by SEAC and the steps taken in light of the SEAC recommendations.

86.2. SEAC's further consideration of the issue of leucodepletion and blood safety, on 15 June 1998, can be seen from the summary of its recommendations [DHSC0038638_067]. Information on the conclusions was rapidly passed back to the DH, including by the note from Ms Christine Corrigan to Dr Shepherd (of my Private Office). Ms Corrigan told her that she would be preparing a submission for Dr Winward and Dr Metters to send to the Secretary of State [DHSC0038638_072]. She further wrote:

"Basically the advice is to leucodeplete and do a review of the research underway to see if there is any more which can be done to elucidate all the unknowns about the possibility of blood / blood products and nvCJD transmission.

Apparently, Dr Metters told them about MSBT's view that deferring donors who had had transfusions would mean to replace a theoretical risk to patients with a real one (lack of adequate supplies) and they decided not to pursue that point further (thank goodness)."

86.3. On 17 June 1998, the submission was duly sent by Dr Metters and Dr Winyard to the Secretary of State and Baroness Jay of the decisions reached by SEAC on 15 June (copied to my Office, amongst others): see [DHSC0004467_055]. It outlined SEAC's recommendations (a copy was attached at Annex A, [DHSC0038638_067]) and sought agreement on the way forward for the implementation of leucodepletion. It noted the costs of the strategy proposed and the need for an approach to Treasury. A draft letter from the Secretary of State to No 10 was attached (see [DHSC0004467_057]).

86.4. It is apparent that this was followed by a letter dated 19 June to the PM. The initial response from the PM's office was contained in a letter dated 22 June 1998 [CABO0000018_015] from the PM's Office, responding to the SoS minute of 19 June. On the proposals for the introduction of leucodepletion, the PM was said to wish for further information on the scientific justification of this step before reaching a decision. The No. 10 letter was copied to my office (amongst others).

86.5. The initial Treasury response, refusing access to additional funding in 1998/99, is at [WITN3430077]; again it was copied to me. The Secretary of State for Scotland (Donald Dewar) also responded, querying the strength of the scientific case for SEAC's recommendations ([WITN3430078], letter of 23

June), although he also "reluctantly endorsed" the recommendation to accept the SEAC advice nonetheless.

86.6. Mr Dobson's Office responded, in detail, to No. 10 on 24 June 1998 [DHSC0004467_037]; again this was copied to my office. The justification for the proposed implementation of leucodepletion was elaborated. This, together with a conversation that took place between Mr Dobson and the Prime Minister, led the latter to agree to the proposals, albeit reluctantly: see the letter from No. 10 dated 29 June 1998 [DHSC0020862_021]; the PM still had *"considerable doubts about whether the scientific advice justifies this step."* He asked that full leucodepletion should be implemented in *"as measured and cost-effective way as is possible".* There is a note about its receipt at the DH [DHSC0020862_022; DHSC0020862_023] raising questions about how the policy was to be funded (given the Treasury's reaction); I stated that I was happy to lead a press conference, in conjunction with Dr Metters.

86.7. A public announcement about the acceptance of the recommendation was made on 17 July 1998; see below, Question 87.

86.8. I have not addressed the topic of financing for the NBA and BPL and further negotiations with the Treasury, since I had no real input into this. However, it is apparent from the Ministerial submission of 3 July 1988 [DHSC0038638_045], copied to my Office, on the subject of funding leucodepletion, that funding was one of the issues which affected the timing of the public announcement of the decision.

<u>Donors who had previously received blood transfusions</u>

86.9. I have been specifically asked to address the basis for the decision *"not to defer [i.e., exclude] donors."* This is a topic reflected in Ms Corrigan's minute to Dr Shepherd (from which the language of the IBI's question is derived). It is really a question that might ideally have been answered by attendees at the

SEAC meeting of 15 June, where the relevant decision was made. But, looking at the documents:

a) The minutes of the MSBT meeting of 4 June 1998 [DHSC0004026_033] record consideration of the Det Norske Veritas (DNV) risk assessment, through a report-back by Dr McGovern. The report had highlighted the risk of *"whole blood and labile products more than fractionated blood products. It was also suggested that donors who were past recipients of blood brought a higher risk of perpetuating any possible epidemic. Members raised concerns about this emerging conclusion and maintaining the blood supply."*

b) It is apparent that Dr Metters then attended the SEAC meeting on 15 June (see [WITN3430079]. There was a detailed consideration of the DNV report, as well as other sources relating to risks and their assessment. There were major uncertainties.

c) The question of the potential risk from donors who had previously received blood was discussed in detail. See the minutes at paragraphs 2.22 – 2.25, and the conclusion reached: *"Members concluded that on the basis of the information that was available any advantage that might be gained from such a measure was far-outweighed by the disadvantages."* It is apparent that the potential risk of collecting blood from those who had previously received blood was weighed against its possible effects, in reducing supplies. The memo from Ms Corrigan thus reflected SEAC's conclusions.

86.10. The issue of the adequacy or sufficiency of blood supplies was a real one at the time. I have addressed it further at Question 92 and I refer to the account there, which deals with matters such as the seminar that took place on 6 July 1998 at St Thomas' Hospital on the better use of blood in the NHS. These were all current concerns.

Q.87 Press Release of 17 July 1988 – Leucodepletion

87.1. In July 1998 a press release was prepared in relation to leucodepletion, following the SEAC meeting of 15 June 1998 and its advice upon leucodepletion, i.e. the removal of white cells (see the public summary of the meeting at [DHSC0020862_009] – and the Advice to Government at page 4 of [WITN3430080]) and Question 86 above. I have been asked to explain my involvement in the contents of the press release, including why I disagreed with the wording used of "safe" and "even safer".

87.2. I have noted from the documents provided to me that a press release was prepared for the announcement of the introduction of leucodepletion. A draft was sent to me before its release. On 6 July, my Private Secretary Dr Shepherd wrote setting out my concerns about the proposed line *"Blood in the UK remains very safe and leucodepletion will make it even safer."* [DHSC0038513_128]. She wrote:

> *"CMO has seen the draft press release and is not entirely content with the text of his comments and has suggested some changes.*
>
> *CMO does not like the use of the words 'very safe' and 'even safer' in the second line of the first paragraph of his comments. I suggest that the text is changed to read something along the lines of:*
>
> *'Blood in the UK remains of the highest standard and leucodepletion will improve this position even more' (or something like this). The use of the word 'safe' is inadvisable in the context of a press release of this nature".*

87.3. Dr Shepherd also went on to make further comments on the draft and asked for a further draft for my consideration.

87.4. I have been asked why I was concerned about the use of these terms. "Safe" does not mean "no risk" and it can send the wrong message. See the previous discussions in the minute above.

87.5. Dr Shepherd's report of my views was circulated internally (see the comments, at [WITN3430081], which somewhat discounted her observations but not mine). This was followed by the circulation of a revised version, which incorporated my suggested changes. See [DHSC0004467_002 and WITN3430080]; the first is a submission from Mr Glyn Austin dated 7 July to the Secretary of State and others, including both Dr Metters and my Office, sent seeking clearance of the revised press notice and noting that CMO's comments on the earlier draft had been taken on board; the second is a revised draft which included my suggested wording. (There is a handwritten note on the version at [WITN3430082] which reads *"CMO to note revised p.r*"). The author also asked for confirmation from the Press and Publicity Department (PPD) that the document would be issued as a Departmental press release rather than a notice from the CMO, i.e., myself, as SEAC provided advice to Ministers rather than the CMO.

87.6. On 7 July, Dr Shepherd wrote on my behalf to say that I was content with the revised press release on leucodepletion and had no further comments to make. She asked to be kept informed about when the notice would go out [WITN3430083]. Dr Metters also provided comments [WITN3430084].

87.7. However, the final version which was issued on 17 July [DHSC0004790_066] reverted back to the 'old' format. My Private Secretary wrote on the same day, on my behalf, to place on the record my strong disagreement with the retention of the words "safe" and "even safer" in the press release that had been used – see [DHSC0038638_027]; these words were now being attributed to Dr Metters.

87.8. I have now been shown a minute to the Permanent Secretary and a Note for the File prepared by Dr Metters, explaining his reasons for using the words "safe" and "even safer" – see [DHSC0020862_036; DHSC0020862_037[8]].

[8] Acknowledged by the Permanent Secretary without further commentary at [WITN3430085].

The first document is a note dated 21 July 1998 from Dr Metters to the Permanent Secretary (not circulated to anyone else) and the other is a Note for the File from Dr Metters. This gives a detailed account of events on 17 July and explains why Dr Metters considered that it was appropriate to use the language of blood being "safe", both in the statement and in a large number of press interviews that he gave.

87.9. The record of events is slightly puzzling, as it seems that the press release that was sent to Dr Metters on the morning of 17 July was the 'original' version, rather than the version that had been circulated after my comments and which I (or at least my Private Office) thought had been approved, see paragraphs 87.6 and 87.7 above.

87.10. However, it is also apparent from the documents that there was a great need for speedy activity on the 16th/17th, as a result of press articles linked to the claims of a Dr Dealler, giving a presentation in York at a conference taking place at the time [DHSC0038513_054]; there are further references to documents on this topic in the Annex. It is possible – although I am speculating, and I am highly reliant on the documents that have been recovered – that an earlier version was erroneously sent to Dr Metters as a result. It would normally have been expected that Dr Metters would have discussed any disagreement with me, given time. The topic of what reference to "safe or "safety" means is an important topic; see the discussion at the BSE Inquiry, for example. This issue could also be linked to the work that was being undertaken on the communication of risk (see Question 91).

Section 14: Other blood borne viruses

Q.88 Testing and/or screening for rare viral infections

88.1. I have been asked to describe my knowledge of, and involvement with regard to, the decisions, actions or policies of the DH regarding testing and/or screening donors for rare viral infections. I have been asked to specifically address: Parvovirus B19; Cytomegalovirus; Anti-HBc (antibody); and Hepatitis G.

88.2. Generally, my personal involvement in these areas was minimal. Dr Metters had a significant role leading on matters relating to testing and screening for blood borne viruses. Those few documents that were sent to my Private Office are discussed below. Further documents relevant to these issues, which indicated the involvement of others, are discussed in the Annex.

88.3. On 19 November 1993, my Private Secretary, Dr Mike McGovern, sent a minute to Dr Rejman that said I had recently discussed HTLV-1 testing with the Permanent Secretary, Sir Graham Hart [DHSC0042296_118]. The Minute said that I had requested "*a general paper setting out which tests are carried out and which are not and why*". The Minute further said any paper should include briefing on the organisms not tested for and *"the arrangements for managing (?compensating) blood recipients who subsequently are shown to have been damaged by organisms not tested for."* The internal development of events following my request is set out in the Annex.

88.4. On 26 January 1994, I sent a minute to Ms Melanie Harper (Private Secretary to Thomas Sackville, the Parliamentary Under Secretary of State for Health), regarding screening blood for rare viral infections [DHSC0042296_063]. I referred to an earlier submission of Dr Rejman and Mr Canavan dated 18 January 1994, which is discussed in the Annex (paragraph 88.7), and said:

> "*Dr Rejman and Mr Canavan's submission of 18 January sets out clearly the difficult issues involved in this area. The balance between sensitivity of the test, effects of the resulting disease and costs clearly must be considered.*
>
> *I agree with 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.*
>
> *Before proceeding further, if Ministers agree, more work on cost benefits is needed. PS(H) will wish to consider Dr Rejman and Mr Canavan's suggestion for a meeting to discuss these issues with a view to crystallising policy."*

88.5. I am not aware of how the position developed further after my minute.

a) Parvovirus B19

88.6. On 18 November 1994, Dr Lee of the Royal Free Hospital wrote to me regarding transmission of blood borne viruses such as parvovirus in blood products [BART0000634_003]. She referenced what she called my "*intervention*" in the debate around HP products. Her letter set out her concern:

> "*that we continue to use blood products that are derived from plasma when there now is a licensed synthetic, non plasma-derived equivalent. We cannot in all honesty, say that the present products we are using have exposed our patients to risk but, there are reports from time to time for example, of hepatitis A transmission and more latterly, of parvovirus or B19 transmission. There therefore lurks in the minds of*

both the haemophilia treaters and the patients, a concern that there may be some hidden virus with which they could become infected."

88.7. Dr Metters' reply to Dr Lee's letter is discussed in Section 12 above.

b) Cytomegalovirus

88.8. I have no recollection and no documents have been provided to me to show the extent of my involvement, if any, in relation to screening and testing for cytomegalovirus (CMV). If the Inquiry wishes to refer particular documents to me, I would be happy to consider them.

c) Anti-HBc

88.9. On 12 October 1993, Dr P Bourdillon (Department of Health) wrote a minute to Dr Metters and Dr Winyard (DCMOs) on 'Top Piece of News', which provided brief updates on various topics [DHSC0004020_041]. My Private Secretary Dr McGovern was sent a copy of this minute. One of the topics covered in this minute was routine testing of blood donations for anti-HBc antibody. It indicated that the MSBT had considered new information concerning routine testing of blood donations for anti-HBc antibody. The MSBT felt that the additional information did not justify the introduction of routine screening for anti-HBc.

88.10. On 14 October 1993, my Private Secretary, Dr McGovern, wrote a minute to Dr Bourdillon [DHSC0004020_030] in which he thanked Dr Bourdillon for his 'Top Piece of News'. Furthermore, in this minute it is stated that I had suggested "*Ministers might need to be informed about testing blood donations for HBc and I would be grateful if you would consider this.*" This is discussed further in the Annex.

88.11. My brief contribution is indicative of my limited involvement in this issue.

d) Hepatitis G

88.12. On 25 January 1996, Dr Nicholas wrote to my Private Secretary, Dr Harvey, regarding a report which was likely to appear in the American publication 'Science' and which detailed the recent discovery of hepatitis G [DHSC0004469_048]. Dr Nicholas stated that "*There are no routine tests currently available that could be used to detect donors infected with HGV; the report does not indicate when they are likely to become available. The full clinical significance of HGV infection and of its natural history are unknown and will require further study.*" Furthermore, Dr Nicholas indicated that the MSBT were appraised of information concerning HGV at their last meeting held on 8 January 1996, and a paper would be prepared for their next MSBT meeting on 2 May 1996. I refer to the further detail set out in the Annex (paragraph 88d.1 onwards).

Section 15: Financial assistance trusts and schemes

Q.89 Financial assistance for those infected with HIV through transfusion or donated organs

89.1. I have been asked to describe my knowledge of, and involvement with regard to, decisions, actions, or policies of the DH regarding the provision of financial assistance for those infected with HIV through blood transfusion or donated organs.

89.2. I cannot remember now what I knew or was told about this issue when I was in office. I expect that I would have had some knowledge at the time from ministerial submissions, from briefings copied to my Private Office and possibly also from discussions with my DCMOs or wider team.

89.3. As to the Inquiry's question about my involvement, I do not now remember having any personal involvement in this issue.

89.4. The Inquiry has referred me to a number of documents that pre-date my time as CMO of either Scotland or England.[9] Save for those noted in the

[9] The following documents referred by the Inquiry pre-date my time as CMO: [DHSC0003960_004];[DHSC0003960_019];[DHSC0003960_011]; [DHSC0003960_012];[DHSC0003960_015];[DHSC0003960_014]; [DHSC0003960_016];[DHSC0003960_010];[DHSC0003960_007]; [DHSC0003960_017];[DHSC0003960_009];[DHSC0003960_008]; [DHSC0003960_006];[DHSC0003960_005];[DHSC0003960_002];and [HSOC0007112].

paragraphs below, I have not commented on them in any detail because I would not have had contemporaneous knowledge of them. In so far as they are relevant, they seem to confirm that: (i) a financial scheme for those infected with HIV through blood products had been set up (the MacFarlane Trust) and there were discussions about extending it to provide financial assistance for those infected with HIV through blood transfusion or donated organs [DHSC0003960_011; DHSC0003960_012; and DHSC0003960_015] (and others); (ii) my predecessor, Sir Donald Acheson, appears to have had some involvement in those discussions [DHSC0003960_016; DHSC0003960_009]; and (iii) as I see from a document provided to me by my legal advisers [DHSC0002537_262; DHSC0002537_263], at around the time I took up the role of CMO, in September 1991, two proposed and costed options to extend the scheme to those infected with HIV through blood transfusion or donated organs were in the process of being submitted to Ministers for decision and approval.

89.5. The Inquiry has also referred me to various newspaper extracts from 1989 [DHSC0003960_002 and HSOC0007112] and 1992 [DHSC0002584_005]. These do not appear to have been sent to me at the time. However, given the apparent media coverage, it is entirely possible that I would have read one or more of them.

89.6. The documents the Inquiry has referred me to do not suggest that I had direct involvement in decisions about whether to provide financial assistance or in policy development in this particular area. My legal advisers have set out in the Annex to Question 89 a summary of certain documents to give some context to my response. Whilst I do not now remember having had any involvement, I can see from the documents that:

a) On 20 February 1992, Mr Scofield minuted the Private Secretary to the Secretary of State (who was then, Mr William Waldegrave). The minute

concerned proposals for a payment scheme for those infected with HIV through blood transfusion or organ/tissue transplants. In the minute, he suggested that medical officers within the Department were to advise on the appointment of medical assessors to the expert panel (see Question 89 in the Annex). It is possible that I was involved in advising on the appointments, although I have no recollection of this now.

b) The Inquiry has referred me to a minute from Dr Rejman to Dr J Reed of HC(M), dated 9 March 1992 [DHSC0002635_005]. This minute is the first of several documents that discussed a draft letter [OXUH0001251_004] for me as CMO to send to all NHS hospital consultants in England, to inform them of the scheme for those infected with HIV through blood transfusions or donated organs and invite them to refer patients they may have, who would be potential beneficiaries. I note the minute was copied to Dr Metters as DCMO but not to my Private Secretary, so I am unlikely to have seen it. The Inquiry has also referred me to a letter dated 13 March 1992 from Andrea Challis to Dr Rivett [DHSC0002658_002]. The letter discussed whether the letter to doctors should be sent to GPs as well as consultants. This also was not sent to my Private Office.

c) The Inquiry has referred me to a minute from Mr Scofield to Mr Heppell dated simply 'April 1992' [DHSC0002659_005]. A version of this minute dated 7 April 1992 and showing copy recipients (including my Private Office) has been located by my legal advisers [DHSC0003883_138]. Both copies/versions of this minute stated that they were accompanied by two annexes: annex A was a draft payment scheme and annex B the draft letter to doctors mentioned above. The two minutes provided to me do not contain either Annex. This minute of 7 April 1992 was then re-drafted as a draft ministerial submission to the Secretary of State, dated 13 April 1992 - [WITN3430086]. This submission appears to have formed the basis of the scheme of payments for those infected with HIV through

NHS blood or tissue transfer, signed by an Assistant Secretary on the Secretary of State's behalf, on 24 April 1992 [DHSC0006182_033].

d) On 16 April 1992, Ms Verity, my Assistant Private Secretary, minuted Mr Scofield [DHSC0002683_004]. The minute read:

> *"HIV INFECTED RECIPIENTS OF BLOOD AND TISSUE*
>
> *CMO has seen your minute of the 7 April to Mr Heppell about the payment scheme for HIV infected blood and tissue recipients.*
>
> *CMO has made a few comments to Annex B of the submission ie: the CMO letter. His comments are as follows:-*
>
> 1. *Paragraph 2 - CMO feels that the wording should be patients who <u>may be</u> entitled to payments.*
> 2. *Paragraph 4 – CMO feels the wording should be patients who may <u>fall within this category</u> for payment rather than who may be eligible for payment.*
> 3. *CMO wonders if there is a time limit for responding by.*
>
> *CMO also asked if this scheme will cove[r] any new HIV infections for those who slip through the 'window period'."*

e) On 22 April 1992, Mr Scofield replied to Ms Verity [DHSC0002683_001]. Mr Scofield wrote:

> *"…I agree with CMO's comments on the Annex B of the submission, the CMO letter. A revised draft is attached…"*

89.7. Whilst I have no recollection of it now, I infer from points b) to e) above, that I provided feedback on a 'dear doctor' letter sent out in my name to publicise the new scheme for those infected with HIV by blood transfusion or donated organs and to invite referrals from medical professionals of possible

beneficiaries. I think it is likely in doing so, that I would have read not only the covering minute of 7 April 1992, but also the annex setting out the proposed payment scheme, as it accompanied the draft letter (as set out at c), above).

Q.90 Financial assistance for those infected with HCV

90.1. I have been asked to describe my knowledge of, and involvement with regard to, decisions, actions or policies of the DH regarding the provision of financial assistance for those infected with HCV through blood products, blood transfusion or donated organs. I have been invited to address particularly *"any discussions that were held regarding the decision not to provide financial assistance for a number of years".*

90.2. On the latter point, I have assumed that the Inquiry intended to ask me about discussions on providing financial assistance that may have taken place over a number of years, rather than asking me whether there was a positive decision not to fund assistance for a particular number of years.

90.3. I cannot remember now what I knew or was told about this issue when I was in office. I expect that I would have had some knowledge at the time from ministerial submissions, from briefings copied to my Private Office and possibly also from discussions with my DCMOs or wider team.

90.4. As to the Inquiry's question about my involvement, I do not now remember having any personal involvement in this issue.

90.5. As mentioned in Section 2, Dr Metters (as DCMO) often took the lead on certain policy areas and did so in relation to blood policy issues. This appears to have been the case in respect of consideration of financial assistance for those infected with HCV through blood products, blood transfusion or donated organs, in so far as it was not solely a political decision.

90.6. The Inquiry has referred me to three documents to assist me with answering this question [DHSC0003527_008; DHSC0002548_159; and

DHSC0002501_103]. As noted in the Annex (paragraph 90.5), versions of these documents are all included within Mr Burrage's minute of 16 November 1994 [DHSC0041152_220; DHSC0041152_221; DHSC0002501_103; HSOC0021550]. Whilst I acknowledge that the minute and its attachments were copied to my Private Office, I do not now have any recollection of having read the documents at that time, in 1994. I cannot say whether the versions of the document provided by the Inquiry were the versions sent to my Private Office.

90.7. On 24 May 1995, although I do not now recall it, I note that Mr Leonard Levy wrote (on my behalf but from, and signed by, him) to Dr V Pizura, a GP in Reading [DHSC0002556_051]. The letter was in reply to a letter sent by Dr Pizura to me, on 5 May 1995, which sought the NHS's views on compensation for those infected with Hepatitis C from blood transfusions [DHSC0002556_253]. In the letter, after writing about the look back exercise, Mr Levy wrote [§§6-7]:

> *"… The Government does not accept, however, that there has been any negligence and they have no plans to make payments to such patients. On the more general issue of compensation, the Government has never accepted the case for a no fault scheme of compensation for medical accidents. It is unfair to others and still requires proof of causation which is often difficult to establish. Every individual case where a medical accident has occurred is a personal tragedy for both the individual concerned and their family. If the NHS is proved negligent in a Court, it accepts its liability to pay damages.*
>
> *It is the Government's view that the most effective use of resources is to seek to improve the understanding, management and treatment of the condition. Only in this way can the impact of the disease on individual patients and their families be effectively minimised…"*

Section 16: Other Issues

Q.91 The 1997 Guidance on communication of Risks

91.1. I have been asked to set out my knowledge of and involvement in the publication of the DH guidance, *"Communicating about Risks to Public Health: Pointers to Good Practice",* including:

a. the reason why this work was undertaken;
b. the particular issues it was seeking to address; and
c. who was involved in this work.

91.2. I regarded this as an important subject, as will be seen from the work summarised below.

91.3. The booklet in question can be found at [WITN3430087] and is dated November 1997 (later recirculated in early 1998; this is probably the version exhibited at: [WITN3430088]). Also relevant is a BMJ article that I wrote jointly earlier in 1997 with Mr Royston (Head of Operational Research, NHS Executive): "*Risk Language and Dialects*" BMJ 1997; 315: 939-42 (exhibited at: [WITN3430089]). The paper discussed the absence of a common language for discussing hazards in life, and made some suggestions as to how this might be addressed. The "community risk scale" contained in it (page 941) was reproduced in the December 1997 "pointers" document and I understand is still cited and used on occasion.

91.4. The best way of explaining the genesis of not only the DH guidance but this work more generally is probably to refer to the book that I subsequently co-edited with Mr Bennett after leaving the DH, *"Risk Communication and Public Health"* (OUP, 1999) [WITN3430090]. This explains in the preface that the book with Mr Bennett had its origins in a conference organised by DH in November 1997 (although the book itself was not a collection of the papers 'as presented' at that point, but a development of the discussions then). It is apparent from the introduction that we considered that the topic of risk

communication was a key challenge for public health practitioners involved in public policy processes. The book presented, first, an overview of risk communication as a topic of research before turning to a series of case studies, and then to conclusions that might be drawn from those, and identifying good practice.

91.5. The topics discussed in the specific chapters published in 1999 were: (i) The media and trust: E. coli and other cases; (ii) Reflections on the government's handling of the BSE/CJD crisis (reproduced in the excerpts exhibited to this Statement); (iii) Experiences in risk communication – drawing on the Welsh experience of various environmental issues and public anxiety over the same; and (iv) Benchmarking – research sponsored by the Health and Safety Executive during 1997 – 98, relating to risk and communication in a number of areas including drink-driving and infant feeding.

91.6. Chapter 16, "*Risk Communication as a decision process*" (Peter Bennett, David Coles and Anne McDonald, Department of Health) has been copied as an Exhibit to this statement. I will not reproduce its contents, but (in answer to the Inquiry's question) draw attention to the section at pp218 – 221. This outlines a "*programme of work within the Department of Health, in progress since the summer of 1996*", although the authors noted that it was only one of a number of relevant activities: "*Much else of relevance is happening within the Department and among the expert committees that advise government*." It explained that the programme in the DH had four linked elements:

a. "*General guidance on risk communication has been provided through a booklet summarising relevant research and offering suggestions on the communication process."* It noted that the contents of this booklet (i.e., that at [WITN3430087] or the revised version) had evolved in response to comments and had been circulated in late 1997 as a Departmental booklet and reprinted in early 1998. The 'checklist' contained in it had been refined in the exercises which were further described, below.

b. *Developmental workshops* (described in the book itself in Chapter 19). These enabled staff to work on fictional but realistic cases; *"The aim is both to promote personal learning and to indicate possible improvements to Departmental practice."*
c. *Case-study seminars*, based on discussion of past cases, aiming at 'lessons learned'.
d. *Decision-support* undertaken to underpin the handling of various live issues.

91.7. The authors noted that they could not expect *"these relatively small-scale efforts to have a revolutionary effect, but they may be contributing to an overall change in climate"* (p220).

91.8. I believe that this account sets the booklet referred to in its context. As the Inquiry will be aware from Section 13, CJD and then nvCJD were prominent topics in the sphere of public health at the time (1996/1997) and I am sure they will have been part of the reason for this work in the DH; but they were not the only reason, as can be seen from the breadth of topics discussed in the book. The DH's responses were influenced not only by public health challenges, but also changing public expectations as to participation and involvement (see the observations in the 1997 CMO's report quoted below).

91.9. I had written about this issue in the CMO's reports for 1995, 1995 and 1997. I have already referred to my observations on the topic of risk in the 1995 report (see paragraphs 12.29 – 12.31 in this statement) and the 1996 one (see paragraph 12.23, which referred to the programme outlined in the 1999 chapter I have summarised above). In the 1997 CMO's report, which was my last as CMO, I wrote, as part of a review of developments since the landmark Public Health Act 1848 was passed (HSG(97)13):

> "***Public and patient involvement***: *this is central to improving health and healthcare. Interestingly it was not a major feature of the 1848 Act. We need to explore better ways to ensure full public participation into*

the process of changing health. The public are allies to the professions, not the reverse. Over the past few years, public and patient involvement has grown, and this is to be welcomed. But there is a consequent need for those who have responsibility for health and healthcare to ensure that they communicate effectively with the public on a whole range of issues - in particular, the communication of risk. There is an equivalent need for the public to understand the complexities and uncertainties associated with decision-making in health and healthcare." (p11).

91.10. Under the heading of "Progress on action points identified in 1995" (p21) I wrote:

*"**Risk communication and the languages of risk**: as discussed in the last two reports, public reactions to risk can seem surprising, but are not totally unpredictable. Effective communication is necessarily a two-way process, requiring openness in the policy process; and good risk communication requires a coherent strategy, rather than ad-hoc reaction to events. While the challenges to effective communication of risk remain great, progress has been made to put these principles into practise. For example, the Advisory Committee system is being made more transparent, with publication of material on some dedicated websites. This process has been informed by wider exchanges of views involving Government, the NHS, academia, industry and non-Governmental organisations. Meanwhile, investigation into risk and its communication is to be stimulated by a substantial new DH research programme. The internal DH programme of staff development exercises, case studies and support for current episodes has continued, and a guidance booklet [i.e., Mr Bennett's booklet] was published in late 1997. The specific area of food safety has seen the establishment of the Joint Food Safety and Standards Group (JSSG) as the precursor to a Food Standards Agency … and a small Risk Communication Unit has already been set up. Cross-Departmental*

liaison continues via the Inter-Departmental Group on Public Health and the Inter-Departmental Liaison Group on Risk Assessment, which has established a risk communication sub-group chaired by DH."

91.11. This is a very general account of a substantial body of work, but I hope that it gives the Inquiry a general sense of what was being done to improve knowledge and practice in this area, as well the identities of those involved with me in this work.

Q.92 The "Better Use of Blood in the NHS" initiative

92.1. The Inquiry has asked me about a paper produced for the NHS Executive Board in January 1998 on blood services, discussions between the CMOs regarding a UK wide initiative about reducing the inappropriate use of blood and blood components in the NHS, and a seminar that took place on 6 July 1998 at St Thomas' Hospital on the better use of blood in the NHS. Again, I regarded this as an important initiative.

92.2. The reasons why this work was necessary is partly explained by the emergence of nvCJD and its consequences. Section 13 (nCJD) of my Statement explains in greater detail the decisions that were made from 20 March 1996 onwards as a result of the perceived risk of nvCJD being transmitted through blood or blood products. I refer the Inquiry to this to provide greater context. However, the introduction of leucodepletion as well as other measures in response to nvCJD risks presented significant operational and financial challenges to blood services in the UK at the time. (I note that there is some further material relating to these challenges in the Annex).

92.3. In addition, there were more long-standing issues relating to the appropriate use of blood (fresh frozen plasma). I have been reminded of a draft article for the CMO's Update in early 1996, on the Use of Clinical Fresh Frozen Plasma [WITN3430091]. This referred to the fact that although Guidelines for the use

of FFP had been available since 1985, "*there is continuing evidence that FFP is being inappropriately used*". The draft article referred to a retrospective audit conducted in London teaching hospitals in 1991 showing that only 21% of transfusion episodes of FFP complied with published guidelines. The draft was circulated for comments in January 1996 by Dr Rejman [WITN3430092], following discussion of the issue at the MSBT meeting on 8 January 1996 [DHSC0020692_118]; Dr Rejman noted that the Committee had recommended that clinicians should be reminded not to use FFP inappropriately.

92.4. I believe that the issues set out in the article also lay behind the initiative on 'better blood'.

Events from November 1997 onwards

92.5. On 11 November 1997, an update was sent to my Private Office on developments since the submission dated 3 November 1997 (referred to at paragraph 80.23 of the Annex). The minute from Dr Wight noted that the National Blood Authority (the NBA) was preparing for leucodepletion and also that the potential use of autologous blood transfusions, the collection and retransfusion of a patient's own blood, was being explored by the NBA in certain circumstances in order to reduce any potential human to human transmission of nvCJD [DHSC0041270_136].

92.6. On 12 November 1997, I replied to Dr Wight on the topic of nvCJD and blood noting that:

> *'I have followed the correspondence on this and I know that the Secretary of State has approved a programme for leucodepletion of all blood supplies by the MBA* [sic]*. However, this is not the end of the story. There are at least two other issues which need to be taken forward.*
>
> *The first of these is the use of blood within the Health Service. This is an important clinical issue and needs to be tackled anyway. I am not*

sure whether the Secretary of State or the NHS Executive are aware of this, and that we should be taking it forward.

The second issue relates to the use of autologous transfusion. This is, again, an important issue which is only partly related to the possibility of CJD in blood. Once again, action needs to be taken on this matter and I would like to be able to do this with the profession in the near future. However, before doing so I would need to have the views of the Secretary of State and of the NHS Executive.' [DHSC0041270_130].

92.7. Dr Metters responded to my minute on 14 November [DHSC0041261_092]. Dr Metters agreed with my view that '[…] *there are important clinical issues about the use of blood that need to be addressed now.'* Dr Metters outlined his views on the misuse of blood, autologous transfusion and leucodepletion and suggested that the Health Departments convene a meeting with the Presidents of the Royal Colleges, with a view to developing guidance on the appropriate use of blood:

'6. The most promising approach to safeguarding the blood supply would appear to be an initiative led by the relevant Royal Colleges to persuade clinicians not to use blood in inappropriate clinical circumstances. Perhaps the way into this would be for the Health Departments to convene a meeting with relevant Presidents or their nominees, to obtain their support for development of guidelines which hopefully the profession will regard as a priority and take forward themselves.'

92.8. On 18 November 1997, a minute from David Hewlett was sent to my Private Office noting that the relevant policy section (HSD1) agreed with Dr Metters' note. A suggestion that a meeting should be set up to discuss these issues further, with Dr Robinson of the NBA to be involved, was approved [DHSC0042286_039]. It was an educational initiative.

92.9. In December 1997, a paper prepared by the Health Services Directorate for the NHS Executive Board on CJD was sent to me. The paper outlined recent trends in CJD, the implications for human health, work in hand and emerging issues for health and social care, including in respect of blood and blood products [WITN3430093]. Amongst other things, the paper noted the need to safeguard supplies of blood: *"The NBA are also examining the scope for increased use of autologous transfusion. CMO will discuss with the JCC the possible scope for reducing "unnecessary" blood transfusion – in particular, the use of single unit – as well as the potential for the recovery of blood during surgery and autologous transfusion."* The Annex (paragraphs 92.5 – 92.7) sets out further details of this paper.

The draft Cash Report

92.10. In addition to the challenges posed by nvCJD to blood services, Professor Cash, the former Medical Director of the Scottish National Blood Transfusion Service, submitted his draft report, the "*Independent Review of Proposals for the Transfer of Bulk Blood Processing from Liverpool to Manchester*" in December 1997; I received a copy [WITN3430094, draft report as of 2 December 1997 at WITN3430095]. The Cash Report (at this stage in draft) addressed the situation in the Liverpool Blood Centre, which had led to concerns about the safety and reliability of supply of blood components in Merseyside and North Wales. But it also recommended wide-ranging structural overhauls of the NBA, further details of which are outlined in the Annex (92.12 onwards).

92.11. As illustrated by the exchanges and events outlined above, by late 1997 blood services were under considerable pressure. Alternative strategies to reduce any risk of transmission of nvCJD through blood and blood products (including leucodepletion, autologous donation and intraoperative salvage of blood) were both expensive and operationally challenging. In addition, the misuse of blood in clinical settings and the preliminary recommendations of the draft Cash Report were issues that required attention. The work that took place in 1998 was designed to address these particular issues. The complexity of

these issues, and their potential implications, required collaboration across DH, the NHS and blood services, to safeguard the blood supply and improve outcomes for patients.

January 1998 paper for the NHS Executive Board on blood services

92.12. In January 1998, a paper was produced by the Health Services Directorate for the NHS Executive Board on blood services [DHSC0041280_038; DHSC0041433_132]. The covering note to the paper [DHSC0041443_076] outlined the reasons for the paper, against the background on contemporaneous trends in blood services outlined above, as follows:

> *'A number of significant issues affecting the National Blood Service have arisen over the past year. Some of these (eg HTLV1) have been considered by the Board on an individual basis. However, the new Government's concerns about the blood service (leading to the "Cash Report" on Liverpool) and recent anxiety about the possibility of nvCJD transmission through blood and blood products, have now raised further serious and urgent issues and introduced a new dimension to those already in train. It is becoming increasingly clear that the cumulative effect of these individual issues will not only be substantial in the short term, but will have a major impact on the future of the National Blood Service and on the wider NHS.'*

92.13. The particular issues the paper was seeking to address included nvCJD, autologous donation and new screening tests as well as the wider cumulative impact on the NBS and the NHS, details of which are given in the paper and the Annex (paragraph 92.15).

92.14. The paper was accompanied by a further paper prepared by the Health Services Directorate for the NHS Executive Board on the clinical use of blood transfusion [NHBT0015864_002; NHBT0015863_003]. The summary note to the paper [DHSC0041443_028] outlined the key reasons for this additional paper as follows:

> *'CMO and Ministers consider that there is a need to reassure the public and the Service about the safety and integrity of the blood supply. This recognises publicity about potential shortages of the supply of blood and blood components, and the potential risk of infection particularly from blood borne viruses and nvCJD. The Department would wish the professions to consider how they might work with the Blood Services to address these concerns.'*

92.15. The paper noted that *'In the UK about 2.5 million donations are processed and over 800,000 transfusions are carried out in clinical practice every year.'* In light of the pressures facing blood services outlined above, it was crucial that DH, the NHS and blood services work together to preserve the blood supply.

92.16. The particular issues this paper was seeking to address included how to guarantee (as far as clinically possible) the safety of blood, how to make better use of blood, a re-appraisal of the clinical approach to blood and alternative strategies (including autologous blood transfusion, acute normovolameic haemodilution and inoperative blood salvage). Further details on the particular issues this paper was seeking to address are outlined in the paper and the Annex (paragraph 92.16).

92.17. The key outcomes following discussion of the paper by the Board were summarised in a minute that was sent by Mike McGovern at DH to me on 11 March 1998 (copying in, amongst others, Dr Winyard, Medical Director of the NHS Executive [DHSC0006986_019]). He wrote:

> *'2. Discussion of the paper indicated the need for a review* [of] *current blood transfusion practice with a view to:*
> *encouraging best practice*
> *engaging the professions in work with the Blood Services to address variations in the clinical use of blood components*

ensuring that trusts and commissioners of health services are fully involved in the proper management of blood supplies through local transfusion committees and

exploring new approaches to transfusion in particular autologous transfusion and intraoperative blood salvage.'

CMO's UK wide initiative about reducing the inappropriate use of blood and blood components in the NHS

92.18. Mike McGovern's minute to me dated 11 March 1998 noted that:

'5. CMO presented a paper on the above at several meetings this year including the JCC, the NHS Executive Board and MSBT. There was general support for a review or working group to lead UK wide work on clinical transfusion practice. CMO has discussed this with Sir David Carter who might consider taking the work on for the Government in collaboration with the Colleges, professional bodies, and the Blood Services.'

92.19. A draft letter to Sir David Carter (Scottish CMO) was attached to this minute [DHSC0006986_020], inviting Sir David to formally take on the UK wide initiative about reducing the inappropriate use of blood and blood components. This was sent by me to Sir David on 2 April 1998 [DHSC0038638_083] and enclosed the January 1998 paper prepared for the NHS Executive Board. My letter noted key issues in blood services at the time. I noted the key recommendations arising from discussion of the January 1998 paper for the NHS Executive Board, and invited Sir David to assist me in leading the implementation of these recommendations on a UK wide basis, suggesting that we discuss further when we met on 20 April 1998.

92.20. I do not now recall meeting with Sir David Carter on 20 April 1998, but the meeting is summarised in a submission from my Private Office to the Secretary of State as follows:

> *'2. The Chief Medical Officers met on 20th April, together with officials, to consider how best to take forward the blood initiative. Following discussion it was agreed that, rather than hold a series of meetings, which might serve only to delay decisions and hold up the production of good practice guidelines, the topic might best be dealt with at a one day seminar, involving key professional groups and Departmental officials from the four Health Departments in a collaborative exercise.*
> […]
> *3. Additionally it was suggested by the Chief Medical Officers that an independent Chairman should be sought for the seminar, thus reinforcing the Department's aim to draw in outside professional expertise. Sir Miles Irving (Professor of Surgery at Manchester University) has been suggested as a potential Chairman. Furthermore it was suggested that Dr Henrietta Campbell, CMO Northern Ireland, rather than Sir David Carter, could assist CMO in this work'.* [DHSC0042287_078].

92.21. Handwritten notes on this submission indicate that SoS approved this initiative and the steps outlined below were taken to organise the seminar that took place on 6 July 1998 at St Thomas' Hospital on the better use of blood in the NHS. Given that the issues in blood services applied on a UK wide basis, it was important that there was collaboration between the UK CMOs in order to achieve the best outcomes across all of the devolved administrations.

Seminar on the better use of blood in the NHS

92.22. In May and June 1998, I sent a series of invitations to individuals working in blood services to attend a seminar to be held on 6 July 1998 at St Thomas' Hospital '[…] *to explore with the professions how better blood transfusion practice in the UK might be encouraged, and supported'* [NHBT0015864_001; WITN3430096].

92.23. The invitations indicated that the seminar would be introduced by Baroness Jay, chaired by Sir Miles Irving and supported by the CMOs. It was expected

that around fifty people would attend including '[…] *the range of clinicians from cardiac surgeons to nurses as well as Trust and Health Authority Chief Executives."* The day was to start "[…] *with a plenary session of talks and discussions on various blood transfusion topics to inform group working in the afternoon. The afternoon group work will focus on specific areas of practice with the aim of the health departments develop* [sic] *policy in this area informed by advice and views from the seminar. This would result in a short communication to health services which the Blood Services, clinicians and Trust Chief Executives could then use as a reference. We would plan* [to] *review the policy at regular intervals over the coming 18 to 24 months if the process proves successful'* [DHSC0004467_007].

92.24. The topics listed on the agenda for the plenary session at the seminar included the safety of blood, autologous blood transfusion and intraoperative salvage. The subject matter for the working groups in the afternoon session included hospital transfusion committees, getting guidelines/protocols into practice, the safety of blood transfusion, transfusion of patients' own blood and systematic reviews of transfusion/research [DHSC0004467_008].

92.25. The seminar therefore sought to obtain advice and views from those working in blood services attending the seminar, in order to promote the better use of blood in the NHS and inform DH policy in this area (in light of the issues facing blood services detailed above and the recommendations following the discussion around the January 1998 paper to the NHS Executive Board). I do not have any further recollection of this.

<u>Further recommendations and decisions on blood services issues</u>

92.26. Following the seminar, on 14 August 1998 I received a minute from Mike McGovern at DH, which attached '[…] *a draft of the Health Services Circular based on recommendations from the Chief Medical Officers' seminar on blood transfusion held on 6 July'* [WITN3430097]]. The draft Health Services Circular ("HSC") was based on the recommendations from the seminar that were of the highest priority to the NHS at the time, including:

> '[…] *that trusts where blood is transfused should:*
> *put in place hospital transfusion committees to oversee all aspects of blood use*
> *implement agreed national evidence based guidelines for blood transfusion*
> *take an active part in the enquiry into the Severe Hazards of Transfusion – SHOT*
> *ensure that patients are aware of the option of autologous blood transfusion and*
> *consider the introduction of Perioperative Cell Salvage systems.'*

92.27. The draft HSC recognised that these were very much first steps in the process of developing better blood transfusion practices in the NHS. Some of the more complex recommendations were to be developed over the course of the following 18 months, when I was no longer in post as CMO.

92.28. The draft Health Services Circular referred specifically to the seminar noting that this was a *'first step'* and *'The aim of the seminar was to consider how to bring more rigour and accountability to blood transfusion practice in the NHS. Those invited to the seminar discussed specifically ways of encouraging the better use of blood within the NHS, defining more clearly the need for blood in clinical practice, and meeting future demand for blood components in the UK. This Circular draws heavily on the work of the Chief Medical Officers' seminar and makes a number of clear recommendations on blood transfusion practice within the NHS. Clinicians, trusts and health commissioners will be expected to take these forward in collaboration to ensure a first class blood transfusion service for patients. The position will be reviewed over the next 18 months.'*

92.29. I did not have any comments on the document at the time [WITN3430098]. The comments provided by others on the draft Health Services Circular are detailed in the Annex (paragraphs 92.21-92.22).

92.30. I held the role of CMO for England until 18 September 1998. I understand that the Health Services Circular was subsequently finalised and published on 11 December 1998 [NHBT0083701_002]. The Health Services Circular outlined the actions and decisions to be made by clinicians, NHS Trusts and health commissioners in respect of blood services following the recommendations of the seminar.

Q.93 Other Issues

93.1. I have been asked to explain any other matters that I believe may be of relevance to the Infected Blood Inquiry.

93.2. I do not have any further matters to discuss, over and above those already considered in this Statement.

Statement of Truth

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

Signed. GRO-C .....

Dated.....12th OCTOBER 2022.....

APPENDIX 1

CURRICULUM VITAE

Name:	KENNETH CHARLES CALMAN
Education:	Allan Glen's School, Glasgow Scottish Leaving Certificate, 1959 University of Glasgow, 1967
Most recent appointments:	Chancellor (January 2006 - 2020) University of Glasgow Chair (2016 - 2020) National Library of Scotland
Honours:	Knight Commander of the Order of the Bath (KCB) 1996

Previous Senior Appointments

Oct 1974 - Oct 1984	Professor of Oncology University of Glasgow
Oct 1984 - Dec 1988	Dean of Postgraduate Medicine and Professor of Postgraduate Medical

	Education; Consultant Physician,
	Victoria Infirmary, Glasgow
Jan 1989 - Sep 1991	Chief Medical Officer
	Scottish Home and Health Department, Edinburgh
1990 - 1998	Visiting Professor of Medical Education
	University of Glasgow
Sep 1991 - Sep 1998	Chief Medical Officer
	Department of Health, London
1998 - 2007	Vice Chancellor and Warden
	University of Durham

Past appointments

- Deputy Chair of the British Library and Chair of the Audit Committee (2007 - 2015)
- Chair of the National Trust for Scotland (2010 - 2015)
- Chair of Glasgow, City of Science (2010 - 2014)
- President of the Institute of Medical Ethics (2007 - 2012)

- Chair of the Glasgow Science Centre (2007 - 2010)
- Chair of the National Cancer Research Institute (2008 - 2010)
- Chair of the BMA Board of Science (2009 - 2010)
- Chair of the Commission on Scottish Devolution (2008 - 2009)
- President of the British Medical Association (2008 - 2009)
- Member of the Statistics Commission (1999 - 2007)
- Deputy Lieutenant, City of Glasgow
- President of the Charles Rennie MacIntosh Society

Qualifications, Fellowships and Awards

University degrees: BSc, MB ChB, PhD, MD, MLitt

1979 Elected Fellow of the Royal Society of Edinburgh

13 Honorary Degrees awarded: Durham, Glasgow, Strathclyde, Stirling, Aberdeen, Westminster, Brighton, Glasgow Caledonian, Nottingham, Open University, Birmingham, Newcastle, Paisley (West of Scotland)

Outside interests

- Member of the Nuffield Council on Bioethics (2000 - 2008)
- Member of the Nuffield Council on Bioethics' working group on Public Health: ethical issues (2006 - 2007)
- Chair of the Health Protection Agency's Risk and Society Group (2006)
- Member of the Board of the Moredun Institute (2006)
- Member of Universities UK Board (until 2006)
- Chair of the NHS Genetics Education Board (2005)
- Chair of the Radiation Risk and Society Group, National Radiation Protection Board, (2001 - 2005)
- Member of the Scottish Science Advisory Committee (2004)
- Chair of Review of Genetics in Scotland (2004)
- Chair of the Institute of Teaching and Learning (until 2004)
- Member of the Chemistry Leadership Council (2003)
- Member of the Ethics Committee Unilever (2003)
- Chair of Medical Aspects of Alcohol (2003)

- Chair of the Review of Medical Education in Scotland (2002)
- President of the Association for the Study of Medical Education (2002)
- Chair of Universities for the North East of England, (2000 – 2002)
- Chair of the Nuffield Council on Bioethics' working group on Ethics of Research in Developing Countries (2000 - 2002)
- Member of the Executive Board of the WHO and its Chair (1998 – 1999)
- Chair of the medical research committee of the Healing Foundation charity
- Member of the Board of Macmillan Cancer Relief
- Chair of the Policy and Ethics Advisory Group, Newcastle
- Chair of the Scottish Partnership Agency for Palliative Care
- Member of the Statistics Commission
- Chair of the Health Forum, House of Commons Associate Parliamentary Group
- Vice Chair of UUK Health Committee
- President of the Institute of Medical Ethics

- Founder member of the Academy of Medical Educators

- Trustee, Cancer Research UK and associated with other health-related charities

Books published

Surgical Aspects of Haemodialysis.

Churchill Livingstone. 1974, with P R F Bell

An Introduction to Cancer Medicine.

Macmillans. 1978, with J Paul

Basic Principles of Cancer Chemotherapy.

Macmillans. 1980, with M H N Tattersall and J F Smyth

Invasion. Experimental and Clinical Implications.

Oxford University Press. 1984, with M Mareel

Basic Skills in Clinical Medicine.

Churchill Livingstone. 1984, Second Edition, with C Hanning

Nutritional Support for the Cancer Patient. Saunders. 1986, with K Fearon

Manual of Clinical Oncology. 1987, with C D Sherman and others.

Living with Cancer. 1987, Third Edition. An introduction for patients, families and staff. With M Duthie

Royal Medico-Chirurgical Society of Glasgow, A History, 1989. With D A Dow

Healthy Respect. Ethics in Health Care. Faber and Faber.

Second Edition with R S Downie, 1994

The Potential for Health. Oxford University Press. 1998

Risk Communication and Public Health 1999, Edited with P. Bennett, OUP

Storytelling, humour and learning in medicine. 2001, The Eighth Queen Mother Fellowship, The Stationery Office, London. (Reprint) Chinese Edition 2004

Oxford Textbook of Palliative Medicine. 3rd Edition. Joint Editor, 2005

Handing on Learning. Medical Education: Past present and future.2007 Elsevier

A Doctor's Line. Poetry and prescriptions in Health and Healing 2014 Sandstone Press

Afterthoughts (Kennedy and Boyd) 2017

It started in a Cupboard Luath Press 2019 (Autobiography)