Witness Name: Dr Diana Walford CBE
Statement No.: WITN4461001
Exhibits: WITN4461002 – WITN4461157]
Dated: [05/07/2021]

INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF DIANA WALFORD – SUBMITTED TO THE IBI ON 05 July 2021

I, Diana Walford, will say as follows: -

My full name is Diana Marion Walford. My date of birth and home address are known to the Inquiry.

I am providing this statement in response to a Rule 9 request from the Inquiry dated 16 November 2020.

Contents

Preliminary Comments

A. Structure of this Statement

A.1. For the Inquiry's convenience I have tried to use question numbers to structure my witness statement. For example, paragraph 3.2 is the second paragraph in response to the third question.

B. Opening Comments

B.1. I should like to preface this necessarily lengthy statement with a few words. I have immersed myself in the many hundreds of papers that I have needed to study in order to provide the Inquiry with as full a picture as I can recreate of events as they unfolded at the time, of which I now have very little, or only partial, memory.

B.2. Although I had long forgotten the detail of that period, what has stayed with me as an enduring thought has been the fact that, irrespective of any errors or omissions that may have occurred, terrible infections happened to people who received blood or blood products provided by the State.

B.3. It has been my long-held view that the support the State has offered to those individuals and their families, at least in England and Wales, was both inadequate and rigidly administered. Accordingly, when I learned, in 2012, that the Government was establishing the Caxton Foundation, to award discretionary grants to people infected with Hepatitis C virus from contaminated blood products, I applied for the Chairmanship of the new body, in the hope that I might be able to influence matters for the good. Although I was short-listed for the post, I was not appointed. It was therefore with real pleasure that I learned that the Government had agreed, following recommendations from the Chair of this Inquiry, to provide parity of support to those in need, to match the support given elsewhere in the UK.

B.4. I sincerely hope that there may be other lessons learned from the Inquiry which may bring yet more tangible support to those infected and affected, and that the Inquiry may provide long-sought answers to the many questions that have contributed to their distress. That is why I have tried to answer - in so much detail - the questions that the Inquiry has put to me.

C. Papers and My Recollection of Events

C.1. The events which I am trying to describe in this statement and - where I can - to explain, took place some 40 years ago. At the outset, there was little I could remember, in any detail, about these events and much that I could not remember at all, until prompted by the hundreds of documents provided to me by the Inquiry and by the Government Legal Department.

C.2. From these papers, I have done my best to piece together the unfolding narrative of events within the Department of Health (DHSS), and my own involvement in them. At the same time, I have tried, where I can, to provide detailed answers to the specific questions that have been put to me.

C.3. I have needed to review some hundreds of documents by myself, many of which are lengthy and complex. I have needed to reacquaint myself with my own involvement and to try to understand what material would most assist the Inquiry and have had to make many judgments about what I should summarise and include and what appears to be more peripheral. In doing so, I have included material about issues in which I was only minimally involved, or not involved at all, in order to provide the fullest picture I can of events at the time. I have done my best to include key points, and have also exhibited the underlying documents so that readers may see for themselves.

C.4. I have been very dependent on the documents supplied to me. If there are gaps in the documentary records, I know that I will not be able to fill them now. If I am shown more papers, I would need to consider whether any changes need to be made to the account that I have pieced together in this Statement, or to the answers that I have given to questions. This is an important caveat which applies to the whole of my Statement.

C.5. I am very conscious that few of my former colleagues are alive today or are well enough to assist the Inquiry. I sincerely wish that this Inquiry had been held many years ago so that our many, varying, perspectives on events would have been available to assist the Inquiry and to provide more rounded answers than I am able to do, for those whose lives have been impacted by this tragedy.

D. The Department of Health and Social Security and its Operations

D.1. By way of context, I should like to make some comments about how the DHSS was organised at the time, and how medical professionals, such as myself, operated within it. The system operated through two, parallel, hierarchies: an administrative hierarchy populated by career civil servants, reporting to the Permanent Secretary of the DHSS; and a medical and scientific hierarchy, reporting to the Chief Medical Officer (CMO), who was also a Second Permanent Secretary in the DHSS and Chief Medical Adviser to the Government. As a general rule, Administrative Divisions took the lead on policy development and financial matters and in supporting Ministers. They sought input from the relevant Medical Division(s) as, and when, they felt it was needed, although the CMO had access to Ministers whenever he wished.

D.2. Departmental doctors were not necessarily expected to be experts in a particular specialty, although some were. Their broader role was to act as interlocutors between the external experts in the field and policy-makers in the DHSS. In effect, they were medically-trained go-betweens, not expected to have the full administrative skills of the career civil servant but able to gather intelligence and interpret medical developments in their area of responsibility, in such a way as to be of use in formulating policy for consideration by Ministers. Equally important was their role in feeding back to professional bodies such as, for example, the UK Haemophilia Centre Directors Organisation (UKHCDO) or meetings of the Regional Transfusion Directors, what the Department's position, or emerging view was, in relation to matters of mutual interest.

D.3 The DHSS was fairly 'hands-off' in relation to the day to day operations of the NHS. The most important lever for influencing behaviour, was through the funding of Regional Health Authorities. More importantly, in the context of this Inquiry and also my role as a medical officer, the Department's medical staff – including the CMO - did not attempt to interfere with the practice of clinicians, who jealously guarded the concept of clinical freedom. This concept of clinical autonomy extended to the generally accepted tenet that one consultant could not have authority over another in their practice of medicine. This was the reality

facing, for example, the leaders of the UKHCDO when they sought to influence their colleagues to avoid the use of Factor VIII (FVIII) concentrates in children and mild haemophiliacs, in connection with the risks of transmission of non-A, non-B hepatitis and AIDS. That is why, however weak it may seem now, their advice was couched as recommendations, not instructions. Similarly, attempts to persuade clinicians to accept packed (plasma-reduced) red cells for transfusion or, for example, to avoid using 'top-up' blood transfusions of one or two units (a practice that was rarely clinically indicated), often met with little success.

D.4. The way in which the Department attempted to influence good clinical practice, or to safeguard the public health, was through the appointment of non-statutory expert advisory committees, such as the Advisory Group on Hepatitis, and by the establishment, under statute, of bodies such as the Standing Medical Advisory Committee or the Medicines Commission's Committee on Safety of Medicines. Recommendations from these bodies, subject to the agreement of Ministers, could be promulgated to the NHS and to clinicians, without the Department being seen to trespass on the clinical autonomy of doctors. In general, such recommendations to the wider profession and the NHS tended to concern matters of general public health, rather than specific clinical practice. See, for example, the CMO/CNO (Chief Nursing Officer) letter on the Hepatitis B vaccine described in Section 5.

D.5. Funding, at the time, was exceptionally constrained. Both NHS and Departmental spending were badly affected by the poor state of the nation's finances. I understand that the Inquiry has established a number of expert groups including an Expert Group on Public Health and Administration which should be able to furnish the Inquiry with an accurate picture of the economic context in which the DHSS operated in the late 1970s/early 1980s, and the spending constraints that resulted. But I have not yet seen information from that Group, and it would seem wrong to ignore this issue in my Statement, as it forms the background to many significant issues. According to the Nuffield Trust, the Government spent approximately 4.52% of Gross Domestic Product (GDP) on the NHS in 1975/76. This fell to 3.96% of GDP by 1979/80 and was then followed by a deep recession in 1980. As should be apparent from the

events described below, 'the elephant in the room' for all discussions, including the redevelopment of BPL and the production of additional plasma for national self-sufficiency, was that funding from the Department's budget for centrally-funded services, such as BPL, was inadequate and capital funding was especially hard to obtain.

D.6. Finally, it is hard, now, to imagine, with our immediate access to the internet and to instant electronic communications, how different the reality was then. When a small number of cases of a previously unknown disease began to be reported from the United States, getting reliable and timely information about what was going on was exceptionally difficult. Peer-reviewed publications in the medical literature were inevitably months behind real-time events. Often, our most timely information came from the lay press and much reliance was placed on personal contacts such as those, for example, between the Communicable Disease Surveillance Centre (CDSC) and the US Centers for Disease Control (CDC), in Atlanta. It was often the case that we, in the Medical Divisions, looked to the experts on the advisory groups (such as Dr Craske, Chair of the UKHCDO's Hepatitis Advisory Group) to tell us what information they were gleaning from their own international contacts, rather than being, ourselves, in a position to supply them with the better intelligence we all needed.

D.7 These contextual features are, in my view, critical to understanding the decisions and actions taken at the time.

Section 1: Introduction

1. Q1: Personal Details.

1.1. I have set out my name above. My address is known to the inquiry.

1.2. I qualified (MB ChB) in Medicine from the University of Liverpool in 1968, after taking an intercalated[1] BSc (Hons) degree in physiology in 1965. In addition:

i) In 1972, I became a Member of the Royal College of Physicians UK;

ii) In 1974, I became a Member of the Royal College of Pathologists, the professional qualification to become a pathologist (haematologist);

iii) In 1976, I was awarded an MD by the University of Liverpool;

iv) In 1987, I gained an MSc in epidemiology (University of London) from the London School of Hygiene and Tropical Medicine;

v) In 1989, I became a Member of the Faculty of Public Health Medicine;

vi) In 1990, I became a Fellow of the Royal College of Physicians;

vii) In 1994, I became a Fellow of the Faculty of Public Health Medicine;

viii) In 1996, I became a Fellow of the Royal College of Pathologists.

1.3. I have given further details of my professional career below.

2. Q2: Employment Positions Held.

2.1. I have been asked to set out the positions I have held, with dates and the organisation in which I held them.

2.2. I set out overleaf a summary of my employment history with dates and a brief summary of the role and responsibilities of the post:

[1] This means that I did an extra year's study, inserted between the second and third years of the medical course with the aim of studying a subject – in my case physiology - at greater depth.

Table 1: Employment History

Date	Organisation	Role
Sep 1968 – Oct 1976	Liverpool Royal Infirmary; St Mary's Hospital, Praed St, London, W2; Northwick Park Hospital and Clinical Research Centre; The North London Blood Transfusion Centre	Clinical roles as detailed further below.
Nov 1975 – Oct 1976	MRC's Clinical Research Centre, Harrow	MRC Research (Training) Fellow / Honorary Senior Registrar
Nov 1976 – Aug 1979	Department of Health and Social Security (DHSS)	Senior Medical Officer, Medicines Division (assessment of new drugs, vaccines and biological products applications, for the Committee on Safety of Medicines).
Apr 1977 – Sep 1986	Central Middlesex Hospital, Park Royal	Honorary Consultant Haematologist (part-time)
Sep 1979 – Dec 1983	DHSS	Principal Medical Officer, Scientific Services, Equipment and Building Division (including pathology services and blood and blood products)
5 Apr 1982 – 4 Oct 1982	Maternity Leave	

Dec 1983 – Sep 1986	DHSS	Senior Principal Medical Officer / Under Secretary Medical Manpower and Education Division
Oct 1986 – Sep 1987	London School of Hygiene and Tropical Medicine (LSHTM)	Sabbatical, MSc Epidemiology
Oct 1987 – Sep 1989	Department of Health (DoH)	Senior Principal Medical Officer / Under Secretary, International Health, Microbiology of Food and the Environment and Communicable Diseases Division (including AIDS unit)
Oct 1989 – Dec 1992	DoH	Deputy Chief Medical Officer for England / Director of Healthcare, NHS Management Executive
1993 – 2002	Public Health Laboratory Service (PHLS)	Director
2002 – 2011	Mansfield College, University of Oxford	Principal

2.3. I can confirm that the above posts include all those listed in paragraph 2 of the Rule 9 request. They are discussed more fully below.

Clinical Career Prior to Entering the Civil Service

2.4. After graduating, I did my House Officer posts at the Liverpool Royal Infirmary. I held roles in Liverpool as follows:-

Table 2: Roles whilst in Liverpool

Date	Role
Sep 1968 – Feb 1969	House Physician to Professor Sir C Clarke
Mar 1969 – Aug 1969	House Surgeon to Professor F Stock

October 1969 – Aug 1970: Senior House Officer (pathology) St Mary's Hospital, London, W2

2.5. After a month spent as a General Practitioner locum in Rugby, I moved to London to a Senior House Officer post in the Pathology Department at St Mary's Hospital. As a junior doctor (trainee) I rotated through the four departments of pathology (microbiology, haematology, chemical pathology and morbid anatomy). A feature of this post was that junior doctors were on call at night to do the emergency pathology testing, including, for example, cross-matching of blood, and measurement of blood gases.

2.6. Of particular relevance to the Inquiry, St Mary's Hospital was a Haemophilia Centre and, when on call at night, I frequently had to prepare cryoprecipitate infusions for patients (often children) who came to the hospital as an emergency. They were often in severe pain, had already been waiting at home for the ambulance, the time taken to get to the hospital, to be seen and then had to wait again, at least 15 minutes, often longer, until the cryoprecipitate was thawed in a water-bath in the lab and prepared for injection. A proportion of the patients had antibodies to Factor VIII and were no longer responsive to the cryoprecipitate. For these patients, we had to resort to giving either porcine or bovine- derived product. Allergic and other reactions to these preparations were common and added to the patient's misery. I carried those memories with me when some years later, I found myself having responsibility for blood and blood products at the DHSS.

Sep 1970 –Dec 1971: Senior House Officer (Pathology) Northwick Park Hospital, Harrow.

2.7. After a year at St Mary's, I was asked by one of the consultant haematologists, Dr I. Chanarin, to move with him to the haematology department that he was setting up at the newly-opened Northwick Park Hospital and Clinical Research Centre.

2.8. I was recruited on the basis that I would occupy a Senior House Officer post but would expect to gain promotion to Senior Registrar, which happened after one year. Northwick Park Hospital did not routinely treat patients with haemophilia; Dr Chanarin's special interest was in megaloblastic anaemias but we also treated general haematology patients, patients with anaemia, lymphoma, leukaemia etc.

Jan 1972 – Oct 1975: Senior Registrar (Haematology)

2.9. I had decided to make haematology my career and entered the North West Thames haematology rotational Training Programme, which was a requirement to be able to take the Membership examination of the Royal College of Pathologists (MRCPath), the professional qualification to become a pathologist (haematologist). During the programme I rotated through St. Mary's Hospital, the North London Blood Transfusion Centre, Northwick Park Hospital and back to St Mary's. In 1972, whilst at Northwick Park Hospital I passed the Membership of the Royal College of Physicians (MRCP) examination, just prior to going on maternity leave from May 1972 — October 1972.

2.10. I then spent 6 months training in blood transfusion medicine at the North London Blood Transfusion Centre under its Director, Dr Tom Cleghorn. Amongst other things I learned how cryoprecipitate was prepared and how plasma was pooled into 5 litre bags for dispatch to BPL as fresh frozen plasma (FFP). Whilst based at the Centre, in a project given to me to review the full blood counts of donors measured using the new Coulter Counter model S, I noted that a number of donors had abnormally large red cells. After some persuasion, Dr Cleghorn agreed with me that they should be referred back to their GPs for further investigation and several of them were diagnosed with folate deficiency arising from previously undiagnosed coeliac disease.

2.11. Whilst on the Northwick Park Hospital arm of the rotation, I noted exactly the reverse situation, namely, that the full blood counts of patients measured on the Coulter Counter Model S were revealing numbers of patients from the local population (which had a large ethnic minority population, predominantly of Gujarati origin) who had abnormally small red blood cells. These patients had no evidence of iron deficiency, which is the commonest reason for small red blood cells. The possibility was that these patients might have abnormal synthesis of their haemoglobin. With the encouragement of my consultant, Dr Chanarin, I obtained a Medical Research Council (MRC) Research Training Fellowship to study the synthesis of haemoglobin in these patients.

Nov 1975 – Oct 1976: MRC Research (Training) Fellow / Honorary Senior Registrar, Clinical Research Centre, Harrow

2.12. During my MRC Research Training Fellowship, using globin chain biosynthetic techniques (a form of chromatographic separation of proteins), in collaboration with my biomedical scientist colleague, Ms Rosemary Deacon, we were able to show that these patients had a novel form of alpha- thalassaemia which had never before been described. We published our findings in the British Journal of Haematology and the research also formed the basis of my MD thesis, awarded during that year.

Apr 1977 – Sep 1986: Honorary Consultant Haematologist, Central Middlesex Hospital

2.13. I joined the DHSS whilst I was awaiting what I hoped would be an opportunity for a senior lectureship in haematology, of which there were very few posts available at the time. I was reluctant to leave clinical medicine for an administrative job but was attracted by the fact that I would still be able to spend a day a week undertaking clinical work. This was a recruitment strategy by the DHSS to encourage doctors to work in the Department who might subsequently want to move back into clinical medicine (which I hoped to do). It was also thought that it would help Departmental doctors to retain credibility with clinicians, when acting as a bridge between the Department and the medical profession. I was lucky enough to be offered an honorary consultant haematologist post at the Central Middlesex Hospital, where the consultant in

charge of haematology was Dr Misha Brozovic, with whom I had worked at Northwick Park Hospital. My clinical work at the Central Middlesex was to hold weekly outpatient sessions for their large local population of patients with sickle cell disease. I was a co-author with Dr Brozovic and Dr (now Dame) Elizabeth Anionwu of a 1981 British Medical Journal (BMJ) publication "Sickle Cell Disease in a British Urban Community".

Nov 1976 – Aug 1979: Senior Medical Officer (Grade 5), Medicines Division

2.14. My first three years in the DHSS were spent in the Medicines Division. This division – a forerunner of the Medicines Control Agency and, subsequently the Medicines and Healthcare Products Regulatory Authority (MHRA) - acted on behalf of the UK Licensing Authority, established under the Medicines Act 1968. Licences were granted on the advice of an expert body, the Committee on Safety of Medicines (CSM). This in turn was established under the statutory Medicines Commission, which had been set up after the thalidomide tragedy. The Licensing Authority (consisting of the Secretaries of State for Health and Agriculture and the Secretary of State for Scotland) was responsible for licensing applications for new medicines, both pharmaceuticals and biologicals. In practice (during the time that I was there) the functions with respect to medicines were delegated to the Medicines Division.

2.15. My role was to act as one of the assessors to the CSM, which meant reviewing and writing reports and making recommendations to the Committee, based on an analysis of the vast volume of data which pharmaceutical firms were required to submit for licensing purposes. The pharmacological and toxicological assessments of the drugs were done by expert pharmacologists, whilst the Senior Medical Officers (SMOs) in the division assessed the clinical trial and other medical data submitted by the companies.

2.16. Initially, I was involved with the assessment of new drugs, but in 1977 I was transferred to the assessment of biological products, including vaccines and blood products. As described in Q4 of the Inquiry's request for information, this appointment was announced at a meeting of the Committee on the Safety of Medicines Sub-Committee on Biologicals [MHRA0014566], in November 1977.

The minutes record that I would be taking over Dr Fletcher's "work on blood products". This also involved assessing the information provided by pharmaceutical companies in relation to their application for product licences and making recommendations to the CSM, through its Sub-Committee on Biological Products for the grant, refusal, or variation of the licences.

2.17. Each batch of a licensed biological product was subject to a Batch Release process. That is, every batch of biological product for use in the UK was subject to checking by the National Institute for Biological Standards and Control (NIBSC), who checked the composition of each batch against the manufacturer's specification, or any licensing conditions, including product labelling requirements, before allowing it on to the market. A product that did not meet specification could be prevented from being released by the decision not to issue a formal Batch Release Certificate.

2.18. Whilst working on biologicals, I accompanied colleagues from the Medicines Inspectorate to North America to inspect the manufacturing premises of a pharmaceutical company manufacturing FVIII concentrates. Now, over 40 years ago, I cannot recall which company it was, and to date I have not been provided with documents that would assist.

2.19. In April 1979 and again in August 1979, the Medicines Inspectors inspected the Blood Products Laboratory (now Bio Products Laboratory, BPL) and found it wanting in many respects. Whilst I have no recollection of being involved in these inspections, my role was to liaise with the Director of BPL, Dr Richard Lane (see further below at Section 2). In other, quite unrelated, duties, I also acted as assessor to two Advisory Panels on suspected serious adverse reactions to pertussis vaccines.

2.20. Towards the end of my time in Medicines Division I was invited by the publishers, Excerpta Medica, to write a chapter on 'Blood and Blood Products" for the reference work 'Meyler's Side Effects of Drugs, Ninth Edition' [WITN4461002] and a chapter on 'Blood and Blood Products' in the 'Side Effects of Drugs Annual 4' (1980) [WITN4461003] (both provided to the Inquiry as exhibits to this statement).

2.21. The content of these publications, which were largely concerned with recent publications about the transmission of hepatitis viruses in blood and blood products, can be taken as illustrating the state of my knowledge regarding hepatitis B and non-A, non-B hepatitis at the time (1979) and their role in blood transfusion or coagulation factor infusion-associated hepatitis. I have discussed them in further detail below, at Section 5.

Sep 1979 – Dec 1983: Principal Medical Officer (Grade 4) Scientific Services, Equipment and Building Division (Med SEB)

2.22. After three years in Medicines Division, I was promoted out of Medicines Division to become Principal Medical Officer (PMO) in the Scientific Services, Equipment and Building Division (Med SEB). This was an unusual career progression, as there tended to be few transfers from the specialist staff of Medicines Division to broader policy areas.

2.23. I went on maternity leave from April 1982 – October 1982. During this time, I very occasionally provided advice to the relatively new Principal within the HS2 division, either over the telephone or by post, but otherwise Dr Petronella Clarke represented Med SEB, in my absence.

2.24. Med SEB was part of the Chief Medical Officer's chain of command and was staffed by doctors and bio-scientists. Its role was an advisory one, in that the lead division for the policy areas covered by Med SEB, was an administrative division, Health Services (HS), which was part of the Permanent Secretary's chain of command. The policy areas covered by branches HS2 (Mr John Harley) and HS1 (Mr John Parker) for which I and my Med SEB colleagues provided the medical advice included: pathology services, laboratory safety, radiation protection, blood transfusion and blood products. I also had a personal role in acting as the Secretary to the Bone Marrow Transplantation Working Group of the Joint Consultants Committee of the British Medical Association (BMA) and the Royal Medical Colleges and was, in effect, the primary author of the report on the development of bone marrow transplantation services in England and Wales.

2.25. The policy division, HS, took the lead in formulating policy in these areas and in briefing Ministers, answering Parliamentary Questions etc., and they sought

medical/scientific input when they felt it necessary. This separation into parallel divisions of 'professionals' and 'administrators', was the same arrangement that Lord Fulton, in his 1968 report on reforming the Civil Service, had recommended should be abolished. It was the system that had been described as "the expert on tap, but not on top".

2.26. Whilst I had good relations with colleagues in HS Division, it is important to draw attention to this division of responsibilities, because it was up to the policy division whether or not – and on what – to seek medical/scientific advice at any time. Whilst due regard was had to such advice, it was by no means certain that it would be accepted or accepted without amendment when being passed to Ministers.

2.27. My rank, as PMO, would be considered a Grade 4 in more recent parlance. My 'opposite number' in HS2A division was John Harley, an Assistant Secretary, (Grade 5). He was very much involved in policy issues relating to self-sufficiency and the redevelopment of BPL. Mr John Parker in HS1 was the Assistant Secretary who was in the administrative lead, *inter alia*, on AIDS. Both reported to Mr Peter Wormald, Under Secretary (Grade 3), HS Division. In addition, I might be consulted by one of the Principals (Grade 7) in the Division, successively Messrs. Tom Dutton, Paul Winstanley and Stan Godfrey.

2.28. In my own Division, I reported to the Senior Principal Medical Officer, Dr Ronald Oliver, who, in turn, reported to the Deputy Chief Medical Officer (DCMO), Dr E.L. (Ed) Harris. The then Chief Medical Officer (CMO), Sir Henry Yellowlees, was succeeded by Donald Acheson (later Sir Donald) on 1 October 1983. The CMOs were each advised by an external expert, who was designated the Consultant Adviser in Blood Transfusion. Such Consultant Adviser appointments existed for only a few other specialties.

2.29. Initially, when I joined Med SEB, Dr Geoffrey Tovey, Chairman of the Regional Transfusion Directors Meetings, was the Consultant Adviser. He would meet with the CMO in private and declined to let me know what was discussed, as a result of which I was in the dark about what advice he was giving.

2.30. This was highly unsatisfactory but, happily, in 1981 Dr Harold Gunson was appointed to replace Dr Tovey. Dr Gunson and I had an excellent working

relationship. Although the meetings between the Consultant Adviser in blood transfusion and the CMO continued to be held in private, Dr Gunson kept me informed. The good working relationship with Dr Gunson proved particularly useful on occasion; see for example the work which we did on an AIDS leaflet for blood donors in spring 1983 (see Section 6).

2.31. Med SEB was not the lead medical division in relation to transfusion-transmitted infections. The lead division was Med IMCD (International Health, Microbiology of Food and the Environment and Communicable Disease). The parallel administrative policy unit was, I think, HS1. The Senior Principal Medical Officer in Med IMCD was Dr Terry Geffen, followed by Dr Ian Field. An SMO in the Division was Dr Mary Sibellas. The Deputy Chief Medical Officer (DCMO) was, I believe, Dr John Evans. I cannot now be certain that my memory of the posts held by my colleagues is accurate.

2.32. Med IMCD was responsible for the surveillance of infectious and communicable diseases, including those transmitted by blood transfusion and blood products, with data supplied by the Communicable Disease Surveillance Centre (CDSC), which was a part of the Public Health Laboratory Service. This meant that when reports of a new type of disease, which was causing infections suggestive of immune deficiency, began to appear in reports from the USA, the information was relayed to Med IMCD, not Med SEB. In addition, Med IMCD received the paper copies of the MMWR (Morbidity and Mortality Weekly Report) from the Centers for Disease Control (CDC) in the USA. Sharing of information between Med IMCD and Med SEB was good but not always as prompt as it might have been and there could be a time- lag before Med SEB received those reports.

2.33. Whilst I routinely read the BMJ (for which I had my personal copy) and, frequently, the Lancet and occasionally the New England Journal of Medicine (on circulation in the Department), their articles were inevitably written some time prior to publication so could not supply real-time information. I often found myself having to rely on reports in the lay Press for up-to-date information. Obviously, there were no electronic means of communication and no internet at that time, so the speed and completeness of the information we received in Med SEB were orders of magnitude less than would be possible these days. The rapid dissemination of information between countries that has

characterised the Covid -19 pandemic was not then possible, at what turned out to be the start of the AIDS pandemic.

Dec 1983 – 1986: Senior Principal Medical Officer and Under Secretary, DHSS; Medical Manpower and Postgraduate Medical Education (Med MME)

2.34. This post concerned medical manpower planning and postgraduate medical education. It had no relevance to blood or blood products or any of the issues of interest to the IBI.

1986 - 1987 Sabbatical year to study epidemiology at the London School of Hygiene and Tropical Medicine.

2.35. During this time, I had minimal contact with the Department.

1987 – 1989: Senior Principal Medical Officer DHSS, Med IMCD.

2.36. In 1988, the DHSS was split into the Department of Health ('DoH') and the Department for Social Security. My role was within the DoH. This Division carried a particularly heavy workload in relation to high-profile public health issues including foodborne disease outbreaks (e.g salmonella and eggs, listeriosis from chicken and soft cheese, botulism from yogurt and illnesses arising from environmental contamination e.g Legionnaires' disease, from cooling towers, cryptosporidiosis from drinking water etc.). In addition, my division had responsibility for the AIDS Unit, in which Sir Donald Acheson, CMO, took a very active interest. The Unit was very ably run by Dr Hilary Pickles, who reported directly to Sir Donald.

1989 – 1992: Deputy Chief Medical Officer, Medical Director of the NHS Management Executive

Deputy Chief Medical Officer

2.37. As one of the three Deputy CMOs I was responsible for deputising for the Chief Medical Officer and acting on his behalf in discussions with the national medical representative and statutory bodies and the Medical Royal Colleges. I participated in the overall management of the Department of Health through membership of the Departmental Management Board.

2.38. I also had specific responsibility for:

i) policy for undergraduate medical education, including medical student numbers and medical schools / teaching hospitals interface;

ii) national medical manpower planning;

iii) policy for postgraduate and continuing medical education, including the organisation and funding of medical audit in the NHS.

Director of Healthcare, NHS Management Executive

2.39. I was corporately responsible for the work of the NHS Management Executive in managing the NHS and personally accountable to the Chief Executive for the following areas:

i) developing the national agenda on the assessment of health care needs and indicators of outcome;

ii) developing operational policies including greater integration of primary and secondary care and policies to promote more effective prescribing;

iii) developing and negotiating the general practitioners' contract and developing the fund-holding scheme in general practice;

iv) developing and negotiating policy for hospital medical staffing, including reduction in junior doctors' hours ('*The New Deal*').

1993 – 2002, Director of the Public Health Laboratory Service (the PHLS).

2.40. In 1992, I was appointed, through an open competition, to be the Director of the PHLS. The PHLS was an Executive Non-Departmental Public Body, accountable to the Secretary of State for Health and the Welsh Assembly. Its remit was to protect the population from infection. It comprised a network of 48 public health laboratories distributed throughout England and Wales and two national centres: the Communicable Disease Surveillance Centre and the Central Public Health Laboratory. It had a budget of around £140 million and 3,200 staff. I discuss the work of the PHLS in greater detail in Section 7.

2.41. My responsibilities as Director were:

i) providing medical and scientific leadership and direction to the Service;

ii) ensuring the provision of timely and appropriate advice on communicable diseases to Government;

iii) managing the Service efficiently and effectively within the resources available;

iv) as Accounting Officer, accountable to Parliament, through the DoH Permanent Secretary, for the proper expenditure of public monies.

2.42. I left the PHLS in 2002 to take up the Principalship of Mansfield College, University of Oxford.

3. Q3: Membership of Committees relevant to the Inquiry's Terms of Reference.

3.1. I have been asked to set out my membership, past or present, of, or regular attendance at any committees, groups, associations, working parties or societies relevant to the Inquiry's Terms of Reference.

3.2. To the best of my knowledge, and based on the paperwork that has been supplied to me to date, the various committees or groups that I had been involved with were as follows:

Table 3: List of Committees

Date	Committee and Terms of Reference (TORs)	Role
1979	Working Group to plan the implementation of the inspection report on the BPL laboratory at Elstree. TOR: To consider and advise on ways to address the immediate improvements necessary at the BPL, Elstree in light of the recommendations made by the Medicine Division.	Member
1979 - 1982	Reconstituted MRC Blood Transfusion - Research Committee TOR: 'To advise the Council of research within the field of blood transfusion.'	Member
1980 - 1983	MRC Working Party on Post-Transfusion Hepatitis TOR: 'To promote research and assess the nature and size of the problem of post-transfusion hepatitis.'	Member
1979 - 1982	Joint Management Committee for the Central Blood Laboratories (JMC), superseded by Central Blood Laboratories Authority (CBLA) in late 1982. TOR: In summary: 1) to oversee the management of the Central Blood Laboratories and appoint senior staff 2) Receive annual reports from directors 3) To make recommendations for the financial provisions for the laboratories and approve certain expenditure 4) To consider long term management arrangements for the Laboratories [Full TORs are at WITN4461004]	Member (of the JMC only, not the CBLA)
1979 - 1981	Scientific and Technical Committee of the JMC for the Central Blood Laboratories.	Joint secretary

	TOR: "To advise the Secretary of State through the JMC on the scientific, technical, research and associated financial aspects of the running and development of the Central Laboratories of the National Blood Transfusion Services having regard to the origins of the material handled and the relationship of the Central Blood Laboratories with the Regional Transfusion Centres and indirectly with the blood donor. Advice should cover the scope of the work undertaken, improvement in methods, the introduction of new processes and the viability of the laboratories."	
1979	Reconvened Advisory Group on testing for the presence of Hepatitis B surface antigen and its antibody. TOR: In summary, to revise the second report of the Advisory Group and advise the Department on measures that should be introduced to offer greater safety to the recipients of blood and blood products and to protect the interests of blood donors. Full TORs at [BPLL0004826, page 2]	Member
1981	Protein Fractionation Technology Working Party (Ad-hoc Working Party of the CBLA) TOR: In summary, to consider and make recommendations to the Scientific and Technical Committee of the JMC on the technology to be used in the redeveloped BPL Full TORs at [BPLL0004826, page 9]	Member
1980 – 1983	Advisory Group on Hepatitis TOR: 'To provide medical advice to the chief medical officers of the Health Departments of the UK on all aspects of communicable hepatitis'	Attendee

1980 - 1983	Advisory Committee on the National Blood Transfusion Service (NBTS) TOR: To advise the DHSS and Welsh Office on the co-ordination of 1. The development and work of the Regional Transfusion Centres and Central Blood Laboratories in England and Wales 2. As necessary, the English and Welsh Blood Transfusion Service and that of Scotland.'	Joint Secretary
1981	Working Party [of the Advisory Committee of the NBTS] to advise on Plasma supplies for Self-sufficiency in Blood Products TOR: "To advise on the supplies of plasma for self-sufficiency in blood products in England and Wales"	Attendee
1981 - 1982	Policy Steering Group for the redevelopment of the Blood Products Laboratory TOR: "To be accountable to the JMC and within the Committee's terms of reference, to act on its behalf in planning the redevelopment of the Blood Products Laboratory"	Joint-Secretary

Attendance at other Committees, etc.

3.3. In addition to the list supplied by the Inquiry (reproduced above), I also attended or otherwise participated in the following groups:-

Table 4: Additional Committees

1979-1983	Haemophilia Centre Directors Organisation meetings	Observer
1979-1983	Regional Blood Transfusion Directors Meetings	Observer

13 July 1983	Special meeting of Biologicals Subcommittee of CSM to consider AIDS	Observer (a.m. only)
1978 - 1983	National Institute for Biological Standards and Control	Attendee
1983	MRC Working Party on AIDS TOR: 1. To review Scientific Knowledge and research on AIDS in the UK and abroad. 2. To encourage contact and cooperation between research workers in the field. 3. To advise the Council on the current state of knowledge in the field and on topics for research.	Observer
1979	Advisory Committee on Dangerous Pathogens	Attendee
Occasional	Haemophilia Reference Centre Directors	Observer, by invitation only
1988	AIDS: HIV-infected Health Care Workers: Report of the Recommendations of the Expert Advisory Group on AIDS (HMSO)	Medical Secretary
c. 1990	Expert Advisory Group on Aids: Working Group on HIV and infant feeding	Secretary
1993-2002	Joint Committee on Vaccination and Immunisation	Member, ex-officio, when Director of the PHLS

1998 - 2002	Expert Advisory Group on AIDS See Question 5 below for its remit.	Attendee, DHSS; Member, ex-officio, when Director of the PHLS

4. Q4: Committee on the Safety of Medicines Sub-Committee on Biologicals

4.1. I have been asked to describe my involvement with the Committee on Safety of Medicines Sub-Committee on Biological Products (CSM(B)) and my role and responsibilities with regard to work on blood products.

4.2. The document at [MHRA0014566] records that I would be taking over Dr Fletcher's "work on blood products". The work involved is described at paragraphs 2.16 – 2.18 above. It ceased when I moved to Med SEB in September 1979.

5. Q5: My Involvement with the Expert Advisory Group on AIDS (EAGA)

5.1. The EAGA had been set up by the CMO (Sir Donald Acheson) in late 1984 (the first meeting was held on 29 January 1985) as a source of expert advice on AIDS to the Government. Its terms of reference were: 'To provide advice on such matters relating to HIV/AIDS as may be referred to it by the Chief Medical Officers of the Health Departments of the United Kingdom.' Its membership can be seen in the press release at ([WITN4461005] 20 February 1985) and contained experts on all aspects of the disease.

5.2. It was usually chaired by the CMO or a Deputy CMO. I first attended its meetings on my return from the London School of Hygiene and Tropical Medicine in the Autumn of 1987, as one of the DHSS observers. Subsequently, I became a member of EAGA when I was Director of the PHLS. The minutes of the meetings record the discussions of the Group, which addressed a broad range of issues arising as a result of HIV infection / AIDS.

6. Q6: Senior Colleagues

6.1. I have been asked to identify by name senior colleagues with whom I worked in the DHSS in relation to decisions and policies relating to blood and blood products and the risks from such products, including advice to Ministers.

6.2. I have identified – in as far as I can remember - key officials at paragraphs 2.27 – 2.28 above. Other relevant key officials included Dr Wintersgill, SPMO (Med OS3); Mr Graham Hart (Under Secretary, Supply Division), Dr John Holgate and Dr Keith Fowler, Medicines Division, and Mrs Brechin and Mrs Fosh (Finance) and Mr Sloggem (Supply).

6.3. When I moved to Med IMCD, key colleagues were Dr Eileen Rubery (PMO) and Dr Hilary Pickles (PMO). Dr Pickles subsequently moved to Med SEB, at the CMO's instruction, taking with her Med IMCD's work on BSE, because Med IMCD was overloaded, dealing with a number of high-profile outbreaks of communicable disease.

7. Q7: Draft speech on "AIDS in the UK", March 1988

7.1. I have been asked to comment on a draft speech on "AIDS in the UK" delivered by Mr Norman Hale (Under Secretary, CMP Division) at an international symposium, with particular reference to what Mr Hale described as the "special network" within Government to enable decisions relating to AIDS to be taken "on the basis of the best scientific and medical advice available."

7.2. I have no recollection of ever hearing the term 'special network'. However, having reviewed the paper [DHSC0105063] it would seem to me to be a sort of rhetorical device – of a kind suitable for an International Symposium - to give a degree of coherence to various committees at Ministerial and official level which were considering AIDS-related issues.

7.3. The only one of these committees which had independent scientific members, as far as I can see, was the Expert Advisory Group on AIDS (EAGA). I do not know the dates of establishment of these groups, other than EAGA, which was established in late 1984. I have described my role in relationship to EAGA in Q5 above. From the papers provided I am not recorded as making any interventions in these meetings of EAGA, whilst I was in the DoH.

8. Q8: Involvement in other inquiries and litigation

8.1. I have been asked whether I have been involved in any other inquiries or litigation in relation to AIDS/HIV or hepatitis or vCJD.

8.2. As to the specific questions:

i) I have previously provided evidence to the BSE (Bovine Spongiform Encephalopathy) Inquiry, which dealt with vCJD and the Penrose Inquiry (see Sections 7 and 6 respectively). I have not provided evidence to or been involved in any other inquiries, investigations or litigation relating to HIV, HCV or HVB.

ii) I have been supplied with a copy of the minutes of the 6th Meeting of UK Regional Haemophilia Centre Directors Committee (19/09/1991). I did not attend the meeting. I note that under the heading "HIV Litigation", there is discussion of the settlement of the medical negligence claims in the litigation. Dr Hill was concerned that awards were being made without consultation with the Haemophilia Centre Directors involved, and that in some cases he believed similar patients were being assessed differently. He is recorded as stating that Dr Walford had "promised the Haemophilia Centre Directors would be consulted and that promise had not been honoured". I was not involved in the HIV litigation and have no recollection of such a discussion or promise. Further, as far as I can see from the minutes, Dr Hill was discussing the settlement of cases by the Health Authorities and not the Department of Health. The process adopted for assessing cases would presumably be a matter for the Health Authorities concerned and they would be able to consult with the treating doctors as and when was deemed appropriate.

iii) I had no involvement in the West Midlands case on AIDS and Factor VIII and no recollection of the case itself. But in my handwritten reply to Dr Gunson [NHBT0001758], in 1992, thanking him for his nice letter about my appointment to the PHLS, I mentioned that the case – of which I was obviously then aware - had prompted me to look over various pieces of correspondence between us concerning AIDS and Factor VIII; this had

reminded me how lucky the Department had been to have had the benefit of his advice.

8.3. I gather that I may be criticised by some for failing (it is said) to participate in the Penrose Inquiry. I did respond in writing to the Penrose Inquiry. When first contacted, I initially decided not to provide a statement because I understood that the Inquiry related to Scottish blood policy and events, and I had no role in those matters. However, when later contacted by the Inquiry for further information, I responded to the issues Lord Penrose raised with me. My letters are referred to in Section 6 below.

9. Q9: The BSE Inquiry

9.1. I have been asked whether my written evidence to the BSE inquiry in 1998 was true and accurate, to the best of my knowledge and belief.

9.2. I have been supplied with a copy of my evidence to the BSE inquiry, consisting of:

i) My first statement to the BSE Inquiry, dealing with my time at DH [WITN4461006].

ii) My second statement to the BSE Inquiry which dealt with my time as Director of PHLS. [WITN4461007], I have included a full copy as an exhibit.

iii) Transcript of evidence given by me and Sir Joseph Smith: Day 67, 16/10/98 [BSEI0000006].

iv) My proposed amendments to the transcript for Day 67, 16/10/98 [BSEI0000003].

9.3. I confirm my BSE statements are true and accurate to the best of my knowledge and belief. Given the passage of time, they are more likely to be accurate than any further attempts to remember details of the same issues now.

I have provided further information about my evidence to the BSE Inquiry in Section 7.

Section 2: Self-sufficiency in blood and blood products and the re-development of BPL

10. Q10: Chronological account of efforts to achieve self-sufficiency

10.1. I have been asked to provide a chronological account, in as much detail as I can, of my involvement in, and knowledge of, the DHSS'/the Government's efforts to achieve self-sufficiency in blood and blood products.

10.2. I have answered this question almost exclusively from the papers provided, as I have very little direct memory of much of the detail of the events which I describe in this Section. I have outlined the work to plan both temporary improvements to the Blood Products Laboratory (BPL) at Elstree and the wider work to estimate demand for blood products below.

10.3. However, several of the papers provided and some of the questions asked predate my own involvement in this matter. The Inquiry's questions start in January 1978. At that time, I was still in Medicines Division. My role in the DHSS was as an assessor of licence applications for vaccines and biological products, for the Committee on Safety of Medicines; I had no first-hand involvement in policy for blood and blood products. I have also been sent a number of papers, from before I arrived in Med SEB, about BPL's development and its finances or funding.

10.4. In relation to my role in Med SEB, it is important to recognise that as a medical professional within the Civil Service, I was not the person either responsible for, or with detailed involvement in, financial matters. My administrative colleagues would be better placed to deal with such issues.

10.5. In September 1979, I took up my role in Med SEB and started to be more directly involved in the policy aspects of blood and blood products. Although I have been able to provide some commentary in relation to events in 1978, the main focus of this statement is on events from mid-1979 onwards.

Events in 1978

11. Q11: Minutes of the meeting on 23 January 1978

11.1. I have been asked about the minutes of the meeting on 23 January 1978 of the Central Committee for the National Blood Transfusion Service (NBTS), which I attended on behalf of Medicines Division [MRCO0005118_002]. At para 6.1.2 there is reference to the "scheme devised in 1974/75 to ensure supplies of plasma for production of freeze-dried Factor VIII concentrate"; this was said to have been successful and the overall target had been reached.

11.2. I cannot now add to the minutes or comment on that scheme, which must have been formulated well before I joined the DHSS. At the time of the meeting in question, I was still in Medicines Division. Specific questions relating to matters dealt with in these minutes will have been for the policy divisions, HS and Med SEB and I am not recorded as contributing to the discussion.

12. Q12: 1977/78 Report of the Working Group on Trends in the Demand for Blood Products

12.1. I have been referred to a report (the 'Trends' Working Group Report 1977) discussed in the Central Committee for the NBTS meeting of 23 January 1978, on trends in demand for blood products. This forecast an increase in demand [DHSC0002189_014]. I have explained my lack of involvement in this area at the time. I do not think that I can properly comment on the development of policy in this area or on the DHSS response to this report.

12.2. I note, however, that the report, which was forecasting demand for albumin and Factor VIII over the next 5-10 years, suggested that the amount of albumin to be planned for was 200 g per 1000 population and of Factor VIII, approximately 1,300 i.u per 1000 population, equating to approximately 74 m i.u, which was said to be "an amount sufficient for all likely needs". Whilst the projection for albumin use was in line with later estimates, the projection for Factor VIII usage proved to be an underestimate (see [CBLA0001377] and my response to Q 15 below). The 1977 'Trends' Working Group report also stated that the long-term

aim should be the complete transfer of cryoprecipitate to a fractionated freeze-dried concentrate.

12.3. In relation to events in 1978 and the position reached by this date, my attention has been drawn to the answer to a Parliamentary Question by Mr Roland Moyle (then the Minister of State), given on 26 June 1978. He was asked whether Great Britain was self-sufficient in Factor VIII as, in 1976, Ministerial statements had said that Great Britain would be so by mid-1977. The Minister's answer reads: *"The production target of Factor VIII set for June 1977 was attained; however, new opportunities in the treatment of haemophilia and associated disabilities have been developed which have made further clinical demands for Factor VIII."* [DHSC0002187_049_001]. I would not have been involved in providing material for this update, for the reasons I have explained.

13. Q13: Dr Waiter's paper of August 1979.

13.1. On 23 August 1979, my predecessor Dr Sheila Waiter had written a minute to Dr Oliver in anticipation of her departure from MED SM4, regarding the future supplies of blood products and the options for achieving self-sufficiency. I have considered this below at paragraph 15.13.

14. Q14: Proposed scheme for the future production of blood products in the UK.

14.1. I have been asked about a minute that I wrote on 19 September 1979, setting out my preliminary ideas for a scheme for the future production of blood products in the UK [DHSC0002195_034 and WITN4461008]. Amongst the suggestions that I made was the proposal that the production of cryoprecipitate at RTCs should cease and the fresh frozen plasma should be sent to BPL. This suggestion was made in the context of a holistic scheme for the future production of blood products within the UK which I devised less than three weeks into my new job in Med SEB. My minute of 19 September was accompanied by a schematic diagram. My suggestion with regard to cessation of cryoprecipitate production at RTCs needs to be considered in conjunction

with the entirety of the proposed scheme and I have done so below at paragraph 15.17.

15. Q15: Chronological account of knowledge of and involvement in the redevelopment of BPL.

15.1. I have been asked to provide, in as much detail as I am able, a chronological account of my knowledge of, and involvement in, the redevelopment of BPL, setting out the decisions taken and actions implemented with regard to the redevelopment.

15.2. I have set out below an account of the steps that were taken to re-develop BPL, both in the short and longer term, and to make associated changes in the supply of plasma by the RTCs, from early 1979. In drawing up this summary and bearing in mind the complexity of the issues, I have been essentially dependent on the documents that have been provided to me. To assist the IBI to gain a full picture, I have tried to summarise the events described in these documents even where I am shown as simply attending a meeting or copied-in to documents for information, rather than being directly engaged in the substance of the decision-making.

15.3. My role in relation to the redevelopment of BPL was to supply medical and - where I could - technical input to the lead policy division, HS2. I had a similar role in relation to the preparation of briefing for Supply Division, to support their discussions with industry. I also liaised with Dr Richard Lane, the new Director of the BPL and tried to ensure that the Department understood his position in relation to the BPL redevelopment, the 'Stop-gap plan' (described briefly at paragraph 15.11 below) and the required remedial measures recommended by the Medicines Inspectorate; and that, likewise, he was apprised of the Department's views. In relation to the latter, my colleague in HS2, Mr Harley, was also significantly involved, particularly in respect of financial matters.

Decision-Making Structures in relation to the redevelopment of BPL

15.4. Before describing the course of events in more detail, it may be useful to summarise the decision-making structures at the time. These are set out in

papers such as the submission of 27 May 1981 to Ministers [DHSC0002309_002_000]. But to summarise:-

i) The Central Blood Laboratories in England comprised the Blood Products Laboratory (BPL) at Elstree, its sister Plasma Fractionation Laboratory (PFL) at Oxford and the Blood Group Reference Laboratory (BGRL).

ii) Until October 1978 they were managed for the Department by the Lister Institute.

iii) From October 1978, they were managed jointly by the Department of Health and the North West Thames RHA, as a temporary arrangement pending decisions in the longer term. There were the following Committees:

(a) The Joint Management Committee (JMC), composed mainly of officers of the RHA and the DHSS and chaired by Dr E.L. Harris (DCMO). The DHSS provided joint administrative and medical secretaries;

(b) The Scientific and Technical Committee (STC), composed mostly of outside experts. Again, DHSS provided joint administrative and medical secretaries;

iv) From 1 December 1980, these committees were joined by an Advisory Committee on the NBTS, which advised the DHSS and the Welsh Office on the co-ordination of the blood service and the central blood laboratories, and with Scotland. The same mix of administrative and medical support applied.

v) Ad-hoc Working Parties were added to these central committees, as needed. For example, I have described below how:-

(i) In January 1980, I was asked to chair a group involving Works Group (HS23) assessing BPL's interim operational requirements for 1981/82 and beyond, prior to provision of a new factory. I was also asked to chair another short-life working group to provide a

technical and policy briefing for Supply Division to consider commercial involvement;

(ii) An ad-hoc Protein Fractionation Technology Working Party was established in May 1980, chaired by Dr Peter Dunnill (an independent expert on the Scientific and Technical Committee of the JMC); this was established to evaluate the technology that could best be employed in a redeveloped BPL (paragraph 18.9 below);

(iii) A Policy Steering Group for the Redevelopment of BPL was set up by the Joint Management Committee, in August 1981 (paragraph 20.32); this Committee was chaired by Mr David Smart, a senior executive of Glaxo Holdings Ltd.

vi) In December 1982, the JMC decision-making structure that I have just described was replaced by the Central Blood Laboratories Authority, the CBLA. I have described this development in more detail below.

15.5. Generally, I attended these committee meetings – or some of them – as one of the joint secretaries, working jointly with administrative colleagues. One of the questions I have been asked, asserts that I was the "Chair of the Committee for BPL's redevelopment." This was not the case. My chairmanships of working groups are described above. Mr David Smart chaired the Policy Steering Group for the Redevelopment of BPL.

The Redevelopment of BPL: Events in 1979

15.6. Events in 1979 were dominated by the inspection of BPL by the Medicines Inspectorate in spring 1979, and its aftermath. It is apparent that the inspection and its findings interrupted both the progress of the 'Stop-gap' works that had been previously agreed for BPL and wider consideration of the need for redevelopment of the Laboratory. It is also relevant to note the General Election in May 1979, which brought a new Government with its own political priorities, as well as the spending constraints that I have mentioned in my opening comments, Section 1.

Events before my appointment to Med SEB

15.7. Picking up the thread of the regulatory issues that emerged during this period, I note that in a meeting of the JMC for the Central Blood Laboratories held on 21 February 1979 at BPL, there was a discussion of the licensing regime for BPL, and Ministers' requirements that, although the same licensing requirements did not apply to the NHS as to industry, the NHS should still be required to meet commercial standards. I attended that meeting as a representative of Medicine's Division. I explained that BPL manufacturing procedures would have to be approved by the Sub-Committee on Biological Products of the CSM. A formal visit was to be made to BPL in April 1979 and to PFL somewhat later [WITN4461009].

15.8. I have been supplied with a copy of Minutes of the meeting of the Scientific and Technical Committee for the Central Laboratories which took place on 26 March 1979 [BPLL0008430_001]. The meeting was attended by my predecessor Dr Waiter as one of the joint secretaries. It is apparent that the case for the redevelopment of the BPL was being put forward. Mr Smart, an independent expert member, offered to produce a "comprehensive report" which might offer a firm basis from which the Committee could make a recommendation to the Department. The paper was subsequently produced in May 1979. [CBLA0001004_004]. It set out the costs likely to be incurred and savings resulting if BPL were to be brought up to commercial standards. The paper modelled the capital costs against future savings depending on estimated demand for blood fractions. It suggested that the NHS could recoup capital expenditures in 15 months and achieve net gains in Year 4, compared with the costs of buying commercial products.

15.9. Inspections of BPL by the Medicines Inspectorate took place in April 1979 (the Conclusions and Recommendations of the Medicines Division Report is at [DHSC0001812_001]. The provisional findings were discussed by the Scientific and Technical Committee on 7 June 1979 [CBLA0000952] and the Joint Management Committee for the Central Blood Laboratories on 13 June 1979 [BPLL0008488], meetings attended by my predecessor Dr Waiter. The need for BPL redevelopment, the "new administration" (i.e. new Government) and its priorities were discussed, and the funding constraints. The "possibility" that

there might be no money available to make any radical changes at BPL for 3 – 4 years had to be faced.

15.10. On 13 July 1979, Mr Harley wrote to Dr Lane (BPL) to confirm that "at the very least" Medicines Inspectors will require some up-grading of BPL facilities. No money had been allocated for this purpose. Mr Harley stated that "we could find ourselves in a situation where we should have to choose between going ahead with the 'Stop-gap' programme or upgrading." He stated that it would be advisable not to incur further 'Stop-gap' expenditure, or expenditure on planning for the phased redevelopment, until the position had been clarified. [CBLA0000955_001].

15.11. The reference in the paper to 'Stop-gap' relates to the proposals prepared, in 1977, by Dr William Maycock, the then Director of the BPL, aimed at increasing production of protein fractions at BPL. The aim of the Stop-gap work had been to provide an increase of Factor VIII, rising over four years, to an additional 12.5 m i.u per annum. The plan also envisaged, *inter alia,* moving from 5-litre packs of plasma to single donor packs. It also proposed an element of upgrading of the facilities and included some detailed costings; but these were likely to be underestimates since it was subsequently shown that the cost of one item alone, the Sharples centrifuge, was £90K. For completeness, I note that there is a very detailed review of the Stop-gap proposals contained in the paper from Dr Lane (May 1979) [BPLL0001508] which sets out the position immediately prior to the visit of the Medicines Inspectorate.

Events after my appointment to Med SEB

15.12. In September 1979, I took up my role in Med SEB.

15.13. On 23 August 1979, Dr Sheila Waiter had written a memorandum to Dr Oliver in anticipation of her departure from MED SM4, regarding the future supplies of blood products and the options for achieving self-sufficiency [DHSC0002195_020]. The minute was copied to me [DHSC0003618_020]. I cannot comment (Q13) on the extent to which the matters considered by Dr Waiter had been considered or debated in the DHSS prior to this point in time. My thoughts on the subject at the time can best be seen from the Minute which I wrote on 19 September 1979, see paragraph 15.17 below.

15.14. On 7 September 1979, I was copied into a note from Mr Dutton to Mr Harley regarding improving manufacturing conditions at BPL, following a meeting with Dr Lane [CBLA0000987_001]. This set out an account of the short-term changes that would be needed to meet upgrading requirements - about £0.75m in buildings and equipment in the near future. On 10 September, Mr Harley asked for more information [WITN4461010]. He commented that the information in Mr Dutton's note of 7 September on improving manufacturing conditions at BPL was "too vague for our purpose" and stressed the need for a detailed itemised list showing all short-term improvements in priority order, with the cost of each.

15.15. On 12 September 1979, the fourth meeting of the JMC for the Central Blood Laboratories chaired by Dr E. L. Harris took place; I attended [WITN4461004]. There was a discussion about the report of the Medicines Inspectors. The Chairman noted that it was the responsibility of the JMC to inform Ministers of the options open to them for manufacturing blood products and this was the immediate task before the Committee.

15.16. Also dated 19 September 1979 is a paper from Dr Lane [CBLA0000998] entitled: "Future Preparation of Plasma Protein Fractions by NBTS. A Reassessment of Requirements." He drew attention to the complex interdependence of the manufacture of plasma protein fractions with the supply of plasma by the RTCs. He pointed out that the commercial value of BPL products was in excess of £10m p.a.; if the NHS were to become self- sufficient, this would equate to £30-40m by 1985. But the NBTS would have to increase supplies of plasma substantially and this would be severely hampered by lack of coordination in the NBTS and the significant discrepancies in the supply of plasma between regions. Dr Lane's paper proposed that a Special Health Authority (SHA) should be set up with control through a suitably constituted Board. BPL would deal with RTCs on a pro-rata basis with return of attributable products with defined yields. In discussing the proposed new arrangements he also posited service charges to health authorities but taking account of the freely donated blood.

Scheme for the Future Production of Blood Products in the UK, 19 September 1979

15.17. My preliminary response to these issues, in the context of my new role, was contained in a minute written by me on 19 September 1979, in which I set out my "preliminary thoughts on a complex matter" and attached a suggested scheme for the future production of blood products in the UK [DHSC0002195_034 and WITN4461008]. This drew on background material in Dr Waiter's 'options' paper of 23 August 1978. The minute was sent to Mr Wormald, Mr Harley and Mr Dutton, noting that "Dr Harris suggested you might care to have a copy". It proposed that 'Stop gap' [CBLA0000801] or an appropriate modification of it "should be implemented forthwith" at BPL. In addition, immediate exploration of the options for commercial fractionation should be instigated to see if this was, in truth, viable. I noted that Mr Harley was drafting a paper for Ministers.

15.18. The essential elements of the scheme I proposed were:

i) **BPL:** The 'Stop-gap' scheme or an appropriate modification of it should be implemented immediately, both to satisfy the Medicines' Inspectorate and to increase production.

ii) **Commercial involvement:** With agreement from Ministers, we should enter into immediate negotiations with likely commercial contenders for UK fractionation, bearing in mind the need to ensure that the cost of any product should reflect the free donations.

iii) **Liberton:** An essential fall-back capacity in the scheme would be provided by a suitably modified operation at Liberton.

iv) **Increasing Plasma Supply:** With the aim of achieving self-sufficiency in blood products manufacture, both the output and quality of plasma from RTCs should be substantially improved and a system of plasmapheresis introduced.

v) **Cryoprecipitate:** The production of cryoprecipitate at RTCs should cease and the donations which would otherwise have been used for cryoprecipitate should be sent in single packs, to the "upgraded" BPL

for processing, thus improving both the quantity and quality of plasma going to BPL, with a corresponding increase in Factor VIII per unit of plasma.

15.19. In relation to the suggested exploration of commercial involvement, my thinking was that BPL needed to be a pharmaceutical factory and not a research laboratory producing a small volume of product. A new facility would need to be managed and operated to full Good Manufacturing Practice (GMP) standards.

15.20. I have been asked a number of detailed questions about this Minute (Q14). First, I have been asked why I proposed that the production of cryoprecipitate at RTCs should cease, and the donations be sent instead to BPL. As to this, the demand from clinicians at the time was for NHS Factor VIII concentrates for treatment – on grounds of greater purity, improved quality, product standardisation, convenience for patients' self-administration and, to a degree, for prophylaxis - rather than cryoprecipitate. The use of cryoprecipitate was decreasing, and the earlier 'Trends' Working Party (1977) had anticipated its use being phased out. It followed that BPL processing should have priority for fresh frozen plasma over cryoprecipitate production by RTCs. Whilst my paper does not spell this out, it would be reasonable to assume that cryoprecipitate could still be available in the quantities clinically required, (either as frozen or freeze-dried cryoprecipitate); but, if all fresh frozen plasma were to be sent to BPL, any cryoprecipitate needed would be made at BPL (where generation of cryoprecipitate was the first production stage prior to a further purification step to produce intermediate purity Factor VIII), rather than by individual RTCs. My suggested scheme also stressed the need for Liberton to provide an essential fall-back capacity for the NHS.

15.21. I have been asked what attention I gave to the disadvantages of RTCs ceasing cryoprecipitate production. I do not recall considering that there were any particular disadvantages to ceasing this production at RTCs, but there were several advantages. The preparation of cryoprecipitate from single donor packs in RTCs often took precedence over the preparation of 5 litre pools of fresh frozen plasma to be sent to BPL. Preparation of the 5 litre packs required action from RTCs which took place following other priority tasks, such as the separation of blood for platelets, cryoprecipitate and Fresh Frozen Plasma

(FFP) for the regions. As clotting factors such as Factor VIII are labile, the delay in preparing this material could, according to Dr Lane's paper on "'Stop-gap' provision for plasma fractionation at BPL" (July 1978) [CBLA0000801], mean that both the quality and volume of the FFP sent to BPL could be compromised. The yield of Factor VIII from this 'older' plasma was less good than it would be from single donor packs of FFP sent promptly to BPL. As I remarked in the note of 19 September 1979, "both the quality and the quantity of the plasma going to BPL would be improved with a corresponding significant improvement in yield of Factor VIII per unit of plasma." Put very simply, there was a trade-off. If the RTCs retained plasma to make cryoprecipitate, less plasma could be sent to BPL and less high-quality NHS Factor VIII concentrate could be manufactured.

15.22. Although I doubt I was aware of it at the time, I see from the papers that there was an important additional reason why Dr Lane had recommended that all FFP should be sent directly, in single packs, to BPL (see the letter from Dr Lane to Professor Mollison (28 July 1978) [CBLA0000801]. That was to allow the most sensitive RIA test for hepatitis B to be used to screen the plasma once at BPL rather than that RTCs should, as they mostly did, use a less sensitive screening test for hepatitis B. This meant that BPL would then need to test again to the highest level of sensitivity.

15.23. I have been asked if the suggestion concerning cryoprecipitate was accepted or implemented by the DHSS. It was for the experts in the BTS and BPL, rather than DHSS, to decide on the optimum methods for production of blood products. However, my suggestions were intended to inform DHSS colleagues of the sort of potential improvements that I was aware of, in considering the needs for the redevelopment of BPL. Although I can see that the scheme I had proposed in my minute of 19 September 1979 was included in the papers for a meeting with Mr Wormald and Dr Oliver on 10 October 1979, it seems that it was not discussed at that meeting (see paragraph 15.33 below) and it appears it was not considered further within the Department.

15.24. The specific proposal that the RTCs should cease making cryoprecipitate was not implemented either. As far as I am aware, its production remained under the control of the Regional Transfusion Centres throughout the time I was

involved. In fact, I understand that there may have been some increase in cryoprecipitate production in 1983 or thereabouts in response to the concerns about AIDS.

15.25. In relation to the proposal that FFP should be sent to BPL in single donor packs, this had already been raised with Regional Transfusion Directors by Dr Lane in July 1978 [WITN4461011]. There was general willingness to consider this change and a Working Party on Single Donor Packs had been set up.

15.26. The implementation of single donor packs took some time to resolve. There was a fundamental issue here: BPL was not set up to receive so many donations in single packs; special single packs had to be designed and procured and a special machine to open thousands of these bespoke packs had to be procured for BPL. There was also a need to create space at BPL for undertaking this significant logistics exercise. In other words, this was not as straight forward as it may seem. Dr Maycock had earlier envisaged it taking 5 years to introduce fully. When tracked through the minutes of RTD meetings, at which Dr Lane generally reported on the progress of the Working Party on Single Donor Packs, it seems that these packs were only brought into use in late 1981.

Further Events – Autumn 1979

15.27. Meanwhile, on 20 September 1979, Mr Bayliss (FB3 i.e. Finance Branch) asked for financial and other information that would need to be part of the consideration of the various BPL options (copied to me) [WITN4461012]. On 25 September 1979, Mr Bayliss (FB3) provided costings (with caveats on the assumptions made) for the options in Mr Harley's paper prepared in July 1979 [WITN4461013].

15.28. On 26 September 1979, the Ad-Hoc group of RTC Directors met to consider the implications for RTCs of meeting the Medicines Inspectorate's requirements [WITN4461014]. I was present at the meeting, which considered a paper from Dr Lane "Future preparation of plasma protein fraction by the NBTS – a reassessment of requirements" [CBLA0000998].

15.29. On the same day, 26 September 1979, there was also a meeting of the NBTS Scientific and Technical Committee for the Central Blood Laboratories

[CBLA0001005]. I attended as one of the joint DHSS secretaries; Mr Harley was also in attendance. The Committee noted Mr Smart's Paper of May 1979 (STC 79(4)). It considered the report of the Medicines Inspectors. The Committee noted that as a result of the inspection, expenditure on 'Stop-gap' had been temporarily halted. In his paper, Mr Harley outlined the need to identify the features of the laboratory that needed attention, to price them and to put them in order of priority. For the time being, funding would be limited to the budget that had been made available for 'Stop-gap' work. Dr Lane regarded this as inadequate. Members doubted whether all the options put forward in Mr Harley's paper were available in practice and felt that the right course was to recommend that no time should be lost in planning a completely new plant, even if it was felt that other possibilities had to be examined concurrently. Dr Tovey noted that RTDs were "unsure about future requirements for plasma".

15.30. Mr Harley provided a later note to Mr Dutton with his recollection of what had been discussed at the meeting ([WITN4461015], copied to me), commenting on the non-departmental members' wish to start planning for a new laboratory, which he felt was premature. There is a note dated 17 October from the Chairman, Professor Mollison, to Mr Dutton about the minutes [WITN4461016] (not copied to me) and changes suggested to Mr Dutton's memorandum ([WITN4461017] – it is not clear that I would have seen these). The suggested changes were to emphasise, inter alia, the alarming nature of the Medicines Division report, the need to find immediate money to upgrade BPL and the need for a completely new plant to be built, noting that the Committee had been emphasising the need for new plant for some time.

15.31. A minute dated October 1979 from the Chairman of the Scientific and Technical Committee for the Central Blood Laboratories, entitled "Implications for the National Blood Transfusion Service of an adverse report on the Blood Products Laboratory at Elstree" summarised the situation from the Committee's perspective [DHSC0002195_069]. It reported on the implications of the findings of the inspection by Medicines Division, which had concluded that if the facility were a commercial one, it would have to close until upgraded. Remedial action was needed: there was a need for immediate upgrading but also a new plant. The present one was too small, producing less than half of the antihaemophilic

globulin [i.e. Factor VIII] that the country needed. The Chair argued that the production of a new facility could be strongly justified on economic grounds.

15.32. On 9 October 1979, I sent to Dr Harris (and various others), with a request for comments, a draft response to Medicines Division on the BPL manufacturing facilities ([WITN4461018] (cover minute) and [WITN4461019] (draft response)). The draft response noted that the report was discussed at both the JMC and the STC of the Central Blood Laboratories. The DHSS advice to those committees was that the conclusions of the Inspection Action Group should be accepted in principle. It noted that Mr John Flint, Principal Medicines Inspector, had been enlisted to advise a special working group on the priorities. That group had identified priorities for action for short term improvements. These were then listed under 11 headings. It noted the Department's grave concern for the future of NHS blood product production and for NBTS and sought reassurance that the interim measures were acceptable, and to the Inspectorate's agreement to the possibility of a limited increase in production once the improvements had been completed.

15.33. A meeting within the DHSS took place on 10 October 1979, chaired by Mr Wormald and with Drs Oliver and Tovey in attendance, as well as me. The minutes note that I had put together the proposals of 19 September 1979. But the discussions focused on the upgrading of BPL and whether this would involve industry. It was agreed to investigate (as a first step) the facilities that industry could offer and on what terms [WITN4461020].

15.34. From the papers that I have been provided with to review for this statement, I can see that there was further work being undertaken on the economics of redeveloping BPL at the time (see for example [WITN4461021], a minute from Mr Vaughan (Finance Branch), to Mr Dutton dated 26 September 1979 – not copied to me). On 11 Oct 1979, Mr Dutton attempted to give the financial and other information that had been requested by Mr Bayliss ([WITN4461022], copied to me).

15.35. Also, on 11 October 1979, Mr Wormald minuted Dr Harris on the "Future of Production of Blood Products in the UK" (the minute was copied to me). He said that he had chaired a meeting the previous day with Drs Tovey, Walford and

Oliver on a submission to go to Ministers [WITN4461023]. He noted that the 'mixed' option of a partnership between the NHS and commercial partners at BPL was not likely to be viable and set out the options that Ministers were likely to have to choose between. Until the options had been further explored and proposals crystallised, he had difficulties with the text of the draft letter for Medicines Division that I had circulated previously.

Ministerial Submission, December 1979

15.36. The first draft of a Ministerial submission on the options for BPL was prepared by Mr Harley on 17 October 1979 [WITN4461024], with comments quickly sent in by colleagues (for example, [DHSC0003936_046]). There were various iterations of the draft submission, culminating in the submission to Ministers in December 1979 (see below, paragraph 15.41).

15.37. Turning back to events in October, on 22 October 1979, Dr Lane wrote to Dr Harris (DCMO) enclosing a paper from the last meeting of Scientific and Technical Committee on BPL's future needs [CBLA0001014]. He argued the need for a clear policy on the laboratory in order to make financial projections. He believed that there was a need for centralised management and organisation of the Transfusion Service. The figures for five-year forecasts of revenue and capital growth, as well as staffing, as required for the Public Expenditure Survey, should be related to a firm policy on production targets. Financial requirements needed to be understood in the context of both BPL and Regional Services.

15.38. On 29 October 1979, Mr Harley approved and sent off the Departmental response to the Medicines Division ([WITN4461025], copied to me).

15.39. On 5 November 1979, I reported on the Regional Medical Officers' meeting on 1 November that had been addressed by Dr Oliver. Dr Oliver had reported back to me that the general (though not universal) consensus was that RHAs were willing to help fund the capital investment in BPL and Ministers should be made aware of this in the submission [WITN4461026].

15.40. Further meetings were taking place to plan the changes needed immediately at BPL: see for example the note of a meeting dated 6 December 1979, where a decision was made to proceed at once with a list of interim works required at

BPL including those that had been pressed by Mr Bailey (see [WITN4461027], copied to me). Steps were also taken to keep the UKHCDOs informed: see for example the minutes of the meeting of 20 - 21 November 1979, attended by Dr Lane (and me for DHSS) ([CBLA0001028], at internal p.22). At the Joint Management meeting of the 19 December 1979 [CBLA0001041] approval was given for appointments needed to progress the changes required by the Medicines Division. The minutes record that it was estimated that £800,000 would be needed in the 1980/81 year to carry out the works to remedy the worst defects. A bid had been put in for the necessary capital, but there was as yet no certainty that it would be available.

15.41. On 21 December 1979, Dr Harris put the final submission to Ministers: to Mr Patrick Jenkin, the Secretary of State; Dr Gerald Vaughan, Minister of State (Health) and Sir George Young, Parliamentary Under Secretary of State (Health). It set out the issues with regard to the BPL, Elstree, its current problems and its future operation [DHSC0002307_049, DHSC0002307_050]. Recommendations were made for a short-term programme of improvements, albeit one that would not meet in full the requirements of the Medicines Division. Ministers were also asked to decide, in principle, to rebuild the BPL and to explore further the possibilities of rebuilding either within the NHS or in collaboration with industry.

Summary of events by the end of 1979

15.42. In summary, by the end of 1979, the Medicines Inspectorate had reported, condemning the facilities at BPL. This led to the temporary suspension of the 'Stop-gap' scheme and a restructuring of priorities to meet the Inspectorate's recommendations. A submission was sent to Ministers for their agreement to the course of actions summarised in 15.41.

15.43. I have continued the chronology of events from paragraph 17.3.

16. Q16: Impact upon the 'Stop-gap" development of BPL

16.1. I have been asked to describe the impact of the Medicines Inspectorate's report upon the existing 'Stop-gap' proposals.

16.2. The broad impact will be apparent from the account I have set out above. The Stop-gap proposals were mostly about increasing production, although there was an element of upgrading of the facilities involved. However, those proposals did not fully address the requirements of the Medicines Inspectorate, although they did deal with some quality and safety improvements. Steps had to be taken to meet the Medicines Inspectorate requirements at that time; otherwise it would have been necessary to shut BPL down, on grounds of safety of the products, despite Crown Immunity. The Medicines Inspectorate was, very reluctantly, prepared to let production at BPL continue on the condition that its safety recommendations were implemented and on the basis that there would be absolutely no increase in the production of any product. So, safety had – rightly – to take precedence over any attempt at increased production. However, subsequently there was agreement by the Inspectorate that recommended improvements were sufficient to allow an increase in production.

17. Q17: Funding for 'Stop-gap' Proposals

17.1. I have been asked if funding was diverted from the 'Stop-gap' plans to fund remedial action, in light of the Medicines Inspectorate report.

17.2. A full answer to this question would require detailed analysis of the complicated material in Dr Lane's paper of May 1979 [BPLL0001508] and comparison with what is in the Inspectorate report. In due course, once the funding position was clarified, the 'Stop-gap' proposals, as formulated by Dr Maycock, were, in effect, folded-in to the remedial actions and upgrades as required by the Medicines Inspectorate. In fact, significant additional funds both for this purpose and for increases in production were ultimately allocated (see the submission to Ministers of 21 December 1979, briefly summarised at paragraph 15.41 and events in July 1980, see paragraphs 20.6 and 20.7 below). I would suggest that finance colleagues may be better placed to comment on the details.

Events in 1980

17.3. On 3 January 1980, Sir George Young responded to Dr Harris' submission of 21 December, stating [DHSC0002307_002, copied to those who had received the original minute]:

"PS(H) has seen Dr E L Harris' minute dated 21 December 1979 and has commented: "I have looked through this rather quickly. Perhaps a Minister should visit Elstree - it's always easier to understand a problem if one has seen it personally. I think we should aim at cutting out imports and I think the Private Sector could have a role to play in the new set-up."

17.4. The suggestion that a visit would be useful was later agreed to by the Minister of State, Dr Vaughan, and arrangements put in train for the visit that ultimately took place in March 1980.

17.5. On 7 January 1980, Mr Knight provided Dr Vaughan's further response to the submission of 21 December 1979 [DHSC0002307_047):

"MS(H) has agreed to the recommendations 18(a) and 18(c), but not to 18(b). He has asked to be kept in close and regular touch on this. He agrees that it will be necessary for officials to tell interested parties that short-term measures are in hand and that serious consideration is being given to alternative methods (paragraph 17). On paragraph 16, he has commented that he is not sure that donors would require explanation of the basis on which their blood was to be processed by profit-making industry."

17.6. Thus, Dr Vaughan had agreed that BPL should continue to function, until it could be replaced, on the basis of a short-term upgrading, accepting that this would fall short of the upgrading recommended by Medicines Division (decision 18(a)); and agreed to further exploration of the possibilities of rebuilding either within the NHS or in collaboration with industry (18(c)). However, he had not agreed to the principle of rebuilding BPL (decision 18(b)).

17.7. These decisions were passed on by me and Mr Dutton (as joint secretaries) in a minute to the NBTS Scientific and Technical Committee for the Central Blood Laboratories ([WITN4461028], note dated Jan 1980).

17.8. On 14 January 1980, Mr Harley minuted Mr Wormald on action arising out of the Ministerial response to the December submission [WITN4461029]:

"1 Consultations with industry (to be completed in 6 months) on building and running a plant to process raw materials provided by the

NHS. Supply Division to be asked to organize and chair. You may wish to minute Mr Hart; if so I will draft.

2 Preparation within 1 month of technical and policy briefing for Supply Division. Dr Walford to chair a Med SM4/HS2 group with other branches (and STC?) being involved as necessary.

3 Projection of requirements of existing BPL for 1981/82 onwards. Dr Walford to chair a group involving HS23 Works Group, Medicines Division, and members of STC (including Director).

4 Financing the requirements at 3 above. I will deal with this in the JMC's Finance Sub-Committee.

5 Requirements for new BPL if built with public-money. Informal consideration has been started by STC; this can be transferred to a Departmental group (as at 3 above) chaired by Dr Walford.

6 Costing of requirements at 5 above. I will take this on as part of the work of the Finance Sub-Committee.

7 Working up in detail, in consultation with Medicines Division, of the note prepared for Deputy Secretaries/DCMO in connection with the paper submitted to Ministers. That paper listed Medicines Division recommendations for the BPL and showed those in hand, those dependent on resources, and those not expected to be carried out. Dr Walford will work with Dr Lane and Mr Dutton on this."

17.9. The decision that there would be short-term upgrading, falling short of the upgrading recommended by Medicines Division attracted comment at the Scientific and Technical Committee for the CBL, which held its 4th meeting on 23 January 1980 [CBLA0001052_001]. I restated that Ministers' intention that BPL (Elstree) should conform to commercial standards (Medicines Division) despite the existence of Crown Immunity. The Committee is recorded as agreeing that they could not endorse the views attributed to Ministers. As secretaries, Mr Dutton and I explained that there had since been further discussions on the upgrading required and Mr Harley would be able to confirm that there would be a substantial measure of upgrading. Dr Lane

acknowledged that the DHSS had intimated that further money would be provided in the coming year.

17.10. As set out above, in January 1980 it was decided that planning should go ahead for the redevelopment of BPL [DHSC0000862]. Ministers also wished us to explore commercial participation in the redevelopment. I was appointed to chair a Med SM4/HS2 Group, in which other branches and the STC for the Central Blood Laboratories, would also be involved, as necessary, to prepare technical and policy briefings for the negotiations with industry, which were to be led by Supply Division. In February 1980, I prepared a Technical and Policy Brief for Supply Division [CBLA0001074], outlining BPL's work, the products made and supplied (including for research) and the policy requirements that would need discussion and which manufacturers would probably need to accept. The document at this reference also shows some (but not all) of the input that I would have received to draw this, including from Mr Harley and Mr Dutton.

17.11. On 20 Feb 1980, the sixth meeting of the NBTS and Joint Management Committee for the Central Blood Laboratories took place, chaired by Dr Harris and attended by me [CBLA0001068_0002]. The minutes record that work on the immediate upgrade works had started.

17.12. The Department reported that a capital sum in the region of £750K was anticipated to be available in 1980/81 and Dr Lane had been authorised to proceed "with 'Stop-gap' and several other projects".

17.13. There was a need for oversight by a project manager and committee. It was agreed that I would chair the project committee, which would determine the short-term development policy, consulting the STC, and submitting progress reports to the Joint Management Committee as necessary. Dr Lane was worried about even the short-term costs involved which could instead be going towards the cost of a new laboratory. However, short of stopping production, it is difficult to see what the practical alternative would have been.

17.14. On the future of BPL, Professor Mollison said that the STC had received the report of Ministers' decisions, but they were "left with the general feeling that the implications of letting industry become involved in the processing of voluntary donated plasma may not have been adequately explained. The

committee was very anxious about the effect of a commercial partnership on the volunteer donor system. Mr Smart had recently written to Mr Harley expressing the STCs views on the wording of the report of Ministers' decision".

17.15. Dr E.L. Harris said that there should be no misunderstanding about the Ministerial Submission – it fully reflected Medicines Division views, emphasised the gravity of the situation at BPL and attention had been drawn to the paper prepared by the STC. "Faced with constraints on funds, Ministers had to decide what action was practicable and necessary in the light of Medicines Division's requirements and, as often happened in the industrial situation, a suitable compromise would have to be reached between the practical and the ideal". He noted that members could put their views to the Minister on his visit. He made clear that the Secretary of State and the Department assumed responsibility for what went on at BPL, having recognised that there were shortcomings which could not be put right immediately. Professor Mollison and Dr Tovey said they felt reassured by what Dr Harris had explained. DHSS Supply Division was to lead in the consultations with industry. I would chair a group involving STC and JMC members as necessary to prepare briefing for Supply Division, assessing the requirements of the existing BPL in 1981/82 and onwards and considering the requirements of a new BPL if it were built with public funds. The finance sub-committee of the JMC would examine the cost implications.

17.16. On the subject of blood supplies, Dr Tovey reported that Transfusion Directors accepted there had to be distribution of blood products proportionate to plasma and other source material contributions they made to BPL. The committee urged consideration of those centres that had traditionally received preferential treatment and that their needs should be taken into account.

17.17. For the sake of completeness, I note that it was at about this time that proposals for the reorganisation of the management of the Central Blood Laboratories, began to be discussed. I have discussed this in response to Question 22, below.

17.18. On 3 March 1980, I chaired a meeting at which a briefing document on BPL industrial participation was agreed [WITN4461030]. It set out some key

principles and requirements for blood products production if industry was to be involved. It was circulated somewhat later, on 8 April 1980.

18. Q18: Ministerial Visit to BPL

18.1. I have been asked (Q18) to describe the visit made by the Minister, Dr Gerald Vaughan, to BPL in March 1980. Its broad purpose was outlined above. I can see from the papers made available to me that I accompanied the Minister, together with Mr Wormald and Mr Harley, but I have no recollection of the event now and believe that the written records will contain the most accurate account of events. There is a note of discussions held during Dr Vaughan's visit to BPL on 21 March 1980 [DHSC0002307_041]. In summary, MS(H) said that it was agreed:

> *"i. that the voluntary blood-donor system should be maintained;*
>
> *ii. that co-ordination between the BPL and the Regional Transfusion Centres should be improved;*
>
> *iii. that the existing laboratory should be kept going while its future was being considered;*
>
> *iv. that the BPL should be rebuilt either as an entirely NHS concern or in partnership with a British (and not a foreign) company, and that the possibility of making such a partnership attractive to a British firm should be explored urgently; and*
>
> *v. that expenditure on up-grading should be reviewed and minimised pending a decision on the laboratory's future."*

18.2. There is a further note of the Minister's meeting with union representatives at [CBLA0001085_001]. There is positive feedback from Dr Lane and Mr Smart reported in the Minutes of the fifth meeting of the Scientific and Technical Committee for the CBLAs of 23 April 1980 [CBLA0001093_001] and the Joint Management Meeting of 2 May [DHSC0002325_037]. However, it should be noted that paragraph 5 of the minutes of 23 April 1980 also recorded the Ministerial decision following the visit to BPL that, in respect of the measures agreed, "these measures be re-examined to see if there might be scope for

further savings" pending a decision on the laboratory's future (see (v) at paragraph 18.1 above). This would have been a most unwelcome development from Dr Lane's point of view.

18.3. In the fifth meeting of the Scientific and Technical Committee (23 April 1980), Mr Smart had set out reasons why foreign companies were likely to find involvement with BPL unattractive. These Minutes (together with the correction at [BPLL008419]) also record that Professor Mollison proposed that a sub-group of the STC should be set up, chaired by Dr Dunnill, to explore all details of the planning and in particular the technology to be employed in production. International fractionation schemes were to be studied.

18.4. On 21 April 1980, I wrote a report [DHSC0001895_0002] which identified the following critical improvements needed for the short-term operation of the BPL: new building works, cleaning the laboratory, facilities for handling single pack donations, essential new equipment to keep the factory running as now, essential items of new equipment to increase safety and production levels and key staff appointments. Total capital expenditure required was at least £610,000 spread over two years. Extra revenue requirement was in the order of £70,000.

18.5. Further meetings took place with Dr Lane to get agreement on the short-term works needed. Minutes of meetings such as that of 29 April 1983 (for example, [CBLA0003243_001], chaired by Dr E.L. Harris) show the complexity of agreeing on key works needed and the Ministerial concerns about not only public finances at the time, but also the fact that BPL would be replaced entirely in the medium term. There was a need for proposals to be finalised for Ministerial approval, and an appreciation of the risks if the necessary changes were not to receive approval:

> *"Dr Harris explained that although a programme of improvements have [sic] been agreed for BPL and budget provision made accordingly Dr Vaughan had given specific instructions that the proposal should be completely re-examined with a view to cutting the cost very substantially. The Minister was clearly looking at the requirement against the background that there would be a totally new BPL although this decision had not been formally promulgated.*

Although any upgrading was a temporary expedient it was important to appreciate for how long the improvements would require to operate and it was difficult to imagine that the existing BPL would be replaced in much less than six years. Dr Lane agreed with this assessment of the time scale and pointed out that during the period any expenditure would be amply repaid if production was allowed to expand. He thought that whatever the level of production, the processes etc must be adequately safe. Dr Harris explained that it might not be possible to ensure product safety to the extent which the Director of a manufacturing laboratory would naturally wish, but the Secretary of State would carry the responsibility until the new plant came on stream."

18.6. Dr Harris is further recorded as saying:

"Dr Harris thought that rather than compromise the upgrading, the Minister should be persuaded of the advantage of providing the full facilities associated with a production level of 30 million i.u. of Factor VIII and the introduction of the single donor pack."

18.7. Dr Harris minuted Mr Wormald and me on 8 May 1980 [DHSC0002307_042] expressing his concern that following the meeting of 29 April, the submission to Ministers upon the minimum acceptable improvements needed should be finalised as soon as possible. He commented, "If Ministers do not like the results of our reappraisal it is up to them to carry the responsibilities and the subsequent serious consequences". He wanted the costings from Dr Lane to be provided, and the submission to be ready for Dr Vaughan by the end of the month.

18.8. Dr Harris continued to press for progress on finalising the proposals and the submission, expressing concerns at any delay (see for example his further minute to Mr Wormald and me dated 9 June 1980 [WITN4461031]). Ultimately, the submission was finalised at the end of July (see paragraphs 20.3 – 20.6 below), following further work on the revised costings.

18.9. In May 1980, the ad-hoc Protein Fractionation Technology Working Party was established, chaired by Dr Peter Dunnill. I was a member. The Terms of Reference [CBLA0001109] centred around evaluation of the "available and

potential technology by which a new NHS fractionation facility can best process blood plasma to prepare therapeutic and diagnostic products".

18.10. Dr Dunnill himself wrote to Dr Vaughan to press the case for redeveloping BPL at speed, within three years, and expressed serious concerns about the processes being followed to plan this redevelopment of BPL. I have referred to his correspondence at paragraph 20.29 below, as all his letters and the Ministerial responses were appended to a Ministerial submission in June 1981.

19. Q19: Dr Lane's concerns in meeting of 11 June 1980

19.1. A meeting was held on 11 June 1980 to discuss expenditure on the upgrading of BPL. Dr Lane expressed his reservations about limiting capital expenditure to £500,000 in 1980/81 and undertook to provide further details of a revised capital budget that would "provide a basic facility to keep production going and at the same time to match the build-up of resources in Regions." He felt that without that latter expenditure, BPL would run at less than planned capacity for a number of years [CBLA0001112].

19.2. I have been asked (Q19) what consideration was given to Dr Lane's concerns. Dr Lane was – understandably – concerned that the funding proposed was inadequate. He was fighting his corner. Dr Lane's views about the 'envelope' of £500,000 for 1980/81 were being expressed in June 1980, when central funding for the Department for that financial year had already been set.

19.3. I note that Dr Lane expressed similar concerns at a meeting of the Scientific and Technical Committee on 18 June 1980 [CBLA0001119] but I was not present at that meeting.

19.4. Ultimately (see the summary of the submission to Ministers in July) more ambitious short-term improvements allowing for an increase in production and the additional sum requested to finance this were recommended and approved, albeit that additional money could not be found in the 1980/81 financial year.

19.5. It is also apparent (see paragraph 20.13 and following, about events in October - November), that further discussions took place with Dr Lane to consider his funding concerns and the requests that he had for additional spending.

20. Q20: Costing Estimates

20.1. I have been asked to comment (Q20) on a document of June 1980, which sets out costing estimates from Dr Lane and myself about the short-term works needed. I am not able to say, at this remove from events, how I came to the figures I used. I presume they will have been based on information from Dr Lane and from Supply Division but there were also finance, procurement, building and equipment experts in the Department who may have assisted in the production of these figures. The funding that was made available to BPL is addressed above at paragraph 19 and below at 20.4 to 20.9.

Events in 1980 (Continued):

20.2. On 18 June 1980, an Ad-Hoc Meeting of the Regional Transfusion Directors took place, meeting at DHSS. Apologies were sent by me. There was discussion of the reorganisation of the NBTS. The prospect of spare fractionation capacity at PFC (Liberton) was also raised. The meeting thought that any offer of capacity should be made formally by SHHD. There was discussion of the proposal for sale of surplus BPL products abroad.

20.3. In June 1980, work was continuing on the further submission to Ministers that was needed to approve the proposals and additional expenditure. In a minute to Dr Harris about BPL dated 12 June, I outlined three options for BPL. These were options that had been put forward by colleagues in HS2 (and were the options that Mr Harley outlined to the Scientific and Technical Committee on 18 June, see [CBLA0001119], referenced above). I advised that the existing budget allocation could only be cut if a new BPL could be commissioned within 3 years. Otherwise, the existing budget allocation should be increased, adding £300,000 to the capital sum already set aside for BPL - allowing a doubling of production. I argued for increased capital allocation if the upgraded BPL was to be treated as the fore-runner of a new laboratory and stressed the importance of securing adequate plasma supplies [DHSC0002307_008]. F.W Harris (HSSB) responded on 27 June, setting out the conditions that would have to be met if a new facility at BPL were to be commissioned within the next three years [DHSC0002307_014].

20.4. On 24 June 1980, Mr Wormald minuted Mr Harley, noting that he had spoken to Dr Vaughan that morning about authorising expenditure up to £100,000 on additional cold storage in advance of the general submission on short-term upgrading. The Minister agreed to this subject to the DHSS being satisfied that the facility would be re-usable as part of the long-term development/rebuilding of the laboratory [WITN4461032]. On 25 June 1980, Mr Harley then formally authorised the installation of the new modular cold storage at up to £90,000 [WITN4461033]. It is apparent that by 9 July, the most favoured option for the short-term funding was to increase the BPL budget to £1.3m over 1980/81 and 1981/82, "to enable the BPL not only to meet the requirements of the Medicines Inspectors but also to increase production" (Minutes of the Joint Management Committee for the Central Blood Laboratories, 9 July 1980, [CBLA0001137]). In the event it appears that, ultimately, at least twice as much as £1.3m was spent on the short-term improvements to the laboratory. See [WITN4461034] at paragraph 266, which is the draft statement of Dr Lane in the HIV litigation.[2]

20.5. A further note by me on 15 July to Mr Harley stressed that RTCs would not increase their plasma supplies to BPL unless production also increased, allowing extra products to be sent back. Production had to be increased to allow supplies to be increased to the level needed to run a new factory [WITN4461035].

20.6. On 24 July 1980, Mr Wormald provided a covering note to the Minister of State, Dr Vaughan, on the short-term upgrading to BPL [WITN4461036] with a detailed supporting submission paper from Mr Harley (also at [WITN4461036]). The submission noted work done at the plant to date. In relation to the further work needed, it rejected options involving lesser expenditure to argue in favour of approval of capital expenditure totalling £1.3 million over the next 2 years, plus increased revenue of £0.1 million per year from 1981/2. It noted that the proposals would enable a substantial increase in production (Table 1 shows that production of Factor VIII was planned to rise from 15m i.u. in 1980/81 to 30m i.u. in 1983/84). Mr Wormald noted that the success of the extra expenditure (ie the £0.3 million capital and £0.1 million revenue) would depend

[2] A copy of this document was supplied to me by the Inquiry as part of the preparation for this statement; I had not previously seen it.

on persuading RHAs to increase plasma supplies. A few had already offered to do so. *"Others may not find it so easy, but I think we can be fairly optimistic about an increase of the order implied by the proposals. It will be the job of the reconstituted Co-ordinating Committee [i.e the Advisory Committee of the NBTS] (now approved by the Minister) to sort this out, but it will take them some time. If we are to get our pay-off from the BPL expenditure we must get on with it, even though some risk is entailed, and I recommend that we do so. … An important factor here is that RHAs will in any case have to increase their input if we were to have a new BPL on any worthwhile scale. It will be much easier to increase gradually than attempt a sudden major increase when the new laboratory is ready."*

20.7. On 29 July 1980, Mr Knight provided Dr Vaughan's response to the above submission stating: "MS(H) has seen your minute of 24 July and the accompanying submission recommending capital developments at the BPL over the next two years, and increased revenue from 1981/2. He has agreed to the proposals but has asked when and how we announce them. I should be grateful for a note." [WITN4461037].

20.8. The increased funding that had been agreed for short-term upgrading is set out in the Minutes of the Scientific and Technical Committee held on 17 September 1980 [CBLA0001171]. Dr Lane reported that the upgrading work was on schedule. The issue of possible commercial involvement in the longer-term redevelopment was also discussed, with members of the Committee expressing concern about risks such as the possibility of increasing the hepatitis risk from UK products as well as damage to the voluntary blood donor system in the country. They asked that these problems should be brought to the attention of Ministers. On this, please see my memorandum of 15 September 1980 to Mr Harley, discussed in Section 5. But in any event, the option of any commercial involvement was ultimately rejected by Ministers.

20.9. Discussions with potential commercial partners were taking place, via Supply Division.

20.10. On 6 August 1980 there was a written PQ on private industry involvement in BPL which set out the position with regards to the investigation of commercial involvement at that time:

> *"Dr M S Miller (La. East Kilbride)*
>
> *To ask the Secretary of State for Social Services, what are his intentions or plans regarding the introduction of private capital into the National Health Service through partnership schemes between the National Blood Products Laboratories, Elstree, and privately-owned companies; and what stage they have reached.*
>
> *DR GERARD VAUGHAN*
>
> *I am investigating the possibility of private industry collaborating in the redevelopment of the Blood Products Laboratory, but I have not formulated any plans."*

20.11. On 30 September 1980, Dr Dunnill sent me a draft executive summary for the Working Party report [DHSC0002199_102]; the full report subsequently presented to the STC in 1981 is at [DHSC0002213_021]. He argued that a smaller extension to BPL's capacity would be advisable, to permit more rapid building and to cater for uncertain future developments. Dr Dunnill also expressed the view that Liberton should not replace Elstree and that having two plants was advisable, although there should be a move towards national management. The summary which followed set out the challenges to be faced before a new plant could be built, including the need for a very substantial increase in plasma supply. Production differences between PFC and BPL were noted, and the fact that PFC was about to trial fully continuous operation. An additional handwritten note from Mr Godfrey [WITN4461038] noted that the target of 450,000 litres of plasma a year for England and Wales was being amended to 410,000 a year.

20.12. On 3 October 1980, I wrote to Dr Dunnill thanking him for the prompt report. I corrected his impression that the DHSS envisaged Liberton replacing Elstree; ideas for using it revolved around the more limited possibility that it could fractionate the plasma from 2 or 3 of the Northern Regions [WITN4461039].

20.13. It is apparent that, at the time, Dr Lane was continuing to express concerns about underfunding. On 4 November 1980, a note was sent by S Godfrey (HS2A(1)) to Mr Brechin containing thoughts on Dr Lane's underfunding claim about BPL and specifically about the 'four tables of pages' handed out at the meeting of 21 October 'in support of his claim that BPL's capital allocation was insufficient' [WITN4461040]. This discussion can (presumably) be linked to the meeting of 11 June 1980, when Dr Lane undertook to provide further details about his funding concerns or shortfall. The note was copied to me for comments on its contents, although I do not recall being at the meeting of 21 October referred to; this would be consistent with the fact that these were detailed financial discussions, in which I was generally not involved. It was noted that BPL should not have a problem with expenditure in 1980/81 as there had been an underspend, but that problems could arise in 1981/82.

20.14. From a subsequent note from Mrs Yuille (14 November) it is apparent that I was asked to comment on the medical justification for Dr Lane's bids and did so [WITN4461041]. There are further notes on this topic from colleagues, but I feel that the overall issue of financial settlements or budgets for BPL should be discussed with those responsible for these areas of financial control.

20.15. In the light of two submissions to Ministers concerning (i) the general question of a possible takeover of BPL by industry [WITN4461042] and (ii) a follow-up submission of 14 November 1980 concerning the possible takeover by Beechams [WITN4461043], Ministers reached a decision on the issue of commercial involvement in BPL redevelopment. The decision was announced to Parliament on 26 November 1980 via written answer by Gerard Vaughan (Minister for Health):

> *"The Blood Products Laboratory at Elstree is the main centre for developing blood products in England and Wales. The laboratory was built in the 1960s and requires modernisation and expansion. The first stage of modernisation is now under way. This will increase the capacity of the laboratory considerably, but not sufficiently to meet all the needs of the NHS in the future. We have been considering how best to develop the laboratory still further. Among a number of possibilities we have considered bringing in commercial management.*

However the blood donor service in this country is a voluntary service and we are proud of it. After exploratory discussions we have concluded that there is no place for a commercial company in the management of a service which depends on volunteer donors. There is therefore no question of commercial management of the Blood Products Laboratory". [PRSE0000063]

20.16. There was a press release issued to much the same effect on the same day [HCDO0000394_052]. Subsequently there was an Adjournment Debate on 15 December 1980, concerning the Blood Transfusion Service and BPL, in which more details were provided to Parliament by Sir George Young [WITN4461044].

20.17. On 1 December 1980 a meeting took place with SHHD, DHSS, NI and Welsh Office colleagues to discuss UK self-sufficiency in blood products [DHSC0000064]. I attended. Mr Harley reported that Ministers had now decided against commercial management of BPL. Thus, they had to consider how to provide funds for new fractionating plant and how to manage the redevelopment. The challenges of quantifying UK needs for plasma were discussed, and the possible contribution of PFC Liberton, where an experiment with shift-working was to start. I explained that fractionation at new BPL would have to conform to good pharmaceutical manufacturing practice.

20.18. On the same day, the first meeting of the Advisory Committee on the National Blood Transfusion Service took place. The Chair was Dr E.L. Harris, with membership of RHAs and Dr Lane for BPL. The DHSS Secretariat members included Mr S Godfrey, Mrs Yuille and Mr J Harley and me. The minutes [CBLA0001207] provide a summary of the point reached in decision-making during the course of 1980; see below at 20.21.

20.19. On 3 December 1980 [CBLA0001257], I attended a meeting of the Scientific and Technical Committee for the Central Blood Laboratories as joint secretary with Mr Godfrey. Dr Lane provided an update on refurbishment works. The RHA had taken over management of building projects and work was anticipated to be finished in autumn 1982. Staff were reported to be relieved by the Minister's announcement about not involving commercial participation.

20.20. On 22 December 1980, a note from me to Dr Harris attached copies of reports of visits made in November and December by the Medicines Inspectors, Mr Flint and Mr Ayling, to BPL to review the progress made following the original inspection. (It is apparent that visits, although not formal visits, had been made on 26 November and 9 December 1980). I noted that the Inspectors were not satisfied with the progress and had stressed the importance of appointing two key members of staff, namely, a Head of Quality Control and a Factory Manager. Having discussed the matter with Mr Harley and Mr Godfrey, I set out the proposals that had been agreed, for the next steps to be taken, including for the appointment of these two posts [WITN4461045].

Summary of Developments in 1980

20.21. Ministers had instructed officials to begin work on planning and designing a new BPL (see the confirmation in a minute from Mr Knight to Mr Harley on 8 January 1981, [WITN4461046]). More particularly, as the first meeting of the Advisory Committee on the National Blood Transfusion Service had noted:

i) Ministers had agreed a short-term upgrading programme at a cost of £1.3 million;

ii) The possibility of collaborating with private industry had been investigated but Ministers had decided against this (with an announcement and press release on 26 November);

iii) The Department was now considering how a new fractionation facility might be funded and the management arrangements needed;

iv) The policy on self-sufficiency and the continuing rise in demand for Factor VIII in the UK were also under discussion, together with the planned introduction of 'pro-rata' supply of blood products to the RHAs, from April 1981 onwards.

Events in 1981

20.22. It is apparent from documents supplied to me that on 6 February 1981, I attended a meeting of the Joint Management Committee for the Central Blood Laboratories [CBLA0001268]. Dr Lane reported that the major upgrading work

needed in the short-term was about to begin and outlined both progress and problems. He felt fractionation from single-packs, originally planned for Spring 1981, would not be possible until Spring 1982. He expressed his unhappiness with the conclusions of the Medicines Inspectors in late 1980 and responded to their criticisms. Dr Harris pressed for the new appointments that the Inspectors had required to be made (see paragraph 20.20 above). Dr Harris further reported that Ministers had instructed officials to begin work on planning and designing a new BPL, and project management arrangements were discussed, without firm conclusions. It was agreed that whatever option was agreed, a small steering group to provide policy direction would be needed, and Mr Smart of Glaxo Holdings was invited to chair the group. Dr Lane referred to the opinion of Dr Dunnill that if a commercial company were to design and build the new BPL it would be completed more quickly (perhaps by 1984), but it is evident that not all thought that this timetable was feasible (Mr Connor, who commented along those lines, was, I believe, the Department's chief architect). It seems that my personal contribution was limited to speaking to a paper describing Celltech's proposal for a joint venture with BGRL (the Blood Group Reference Laboratory) on the production of monoclonal blood grouping reagents.

20.23. At this time in 1981, considerable work was taking place, led by Dr Gunson, to estimate future needs for plasma supplies. This was an important element for planning the requirements of a new laboratory. I have covered this topic in detail under requests Q23 and Q24, below. The preliminary report of the Working Party was delivered on 1 June 1981.

20.24. The Scientific and Technical Committee met on 4 March 1981 [CBLA0001299], with further discussion of issues such as research, the recent visits by the Medicines Inspectorate and short and long-term BPL development.

20.25. The next meeting of the Joint Management Committee for the Central Blood Laboratories took place on 20 March 1981. (The agenda is at [CBLA0001321] and the minutes are at [CBLA0001315]). Topics included an update on the long-term development of BPL by Dr Lane and the Department, and a discussion of whether the RHA would decide to take on the project management role for this. There would need to be a steering group to provide policy direction, and the Department would pursue this with the RHA.

20.26. A minute to the Minister from Mr Wormald dated 10 April 1981 [WITN4461047] gives a summary of events. Mr Wormald noted that there was a government intention to rebuild BPL but there had been no commitment to date on a particular timetable or how much of the laboratory would be rebuilt. He stated that the preliminary investment appraisal of 1980 had estimated that the costs of redevelopment would be recouped in revenue saving within six years. But the "estimates of costs to RHAs were largely guess-work. We are working on better ones." The minute noted that the first charge to the project and design team would be to consider what minimum rebuilding/refurbishing was immediately essential. The initial appraisal could not start until:-

i) The responsibilities for design had been determined and design consultants appointed;

ii) a project team, with attached experts from industry, had been established;

iii) Dr Dunnill's report on technology had been received and at least provisional decisions on the technology to be used had been taken.

20.27. Mr Wormald noted that Dr Dunnill's report had been submitted to the STC in draft and was now being finalised. I believe this process was completed in May.

20.28. On 18 June 1981, Mr Wormald reported that the Secretary of State, Mr Jenkin, had agreed that RHA capital allocations could be 'top-sliced' to pay for redevelopment of BPL [DHSC0002309_004]. This enabled detailed planning to go ahead, and Mr Wormald set out the challenges, particularly with regard to production and design policies. He attached a submission to be sent to the Minister [WITN4461048], seeking Ministerial agreement to the formation of a sub-committee of the Joint Management Committee for the Central Blood Laboratories to handle the redevelopment of the Blood Products Laboratory. This was the proposal that had been first discussed in February 1981 (see above). It would be chaired by Mr Smart, with representatives from the Department (Mr Harley), RHA and NBTS. The draft terms of reference were set out.

20.29. Dr Dunnill (a potential member)'s previous letters to the Minister were included with the Ministerial submission, including his comments on the imperative of

rebuilding quickly. His observations included the following expression of concern:

> *"The Medicine Division's recommendations [this is a reference to the inspections] follow a series of recommended short-term expedients designed to boost production by tinkering with the present inadequate plant. This has created a trail of overlapping and confused initiatives which are made more difficult to implement by the inevitably slow process of funding in the ministry. It will have been suggested recently that, operating within this regime, it will take up to seven years to accomplish rebuilding. This is unacceptable in terms of safety and will lead to serious wastage of public funds since modifications cannot stand in the final plan." (Letter of 13 May 1980, Appendix 1).*

I have quoted this because it seems to me to be a good summation of the situation as reflected in the papers I have seen. I do remember, too, my own frustration about innumerable and repetitive meetings which generally ended without moving matters forward to any appreciable extent.

20.30. The proposals set out in the submission were agreed by the Minister for Health (Dr Vaughan) on 1 July 1981 [WITN4461049].

20.31. Minutes of the Joint Management Committee for the CBLA held on 19 June 1981 [DHSC0002209_093] show the range and complexity of the issues being considered in order to progress redevelopment. A minute from Mr Harley dated 3 July 1981 summarised the position that had been reached [WITN4461050]. Mr Harley stated that the Department was waiting for RHA proposals on project management and for further information about the costs of collecting different amounts of plasma. It was required to submit for Treasury scrutiny and approval all capital projects costing £4 million or more, normally before any detailed design work had begun. The steps that needed to be taken were set out: they included appointing the members of the Steering Group, and arranging for them to meet and be briefed; pressing the RHA for proposals on project management; and pressing on rapidly with work on plasma costs so that (amongst other things) the Steering Group could be provided with information on which the capacity of the new BPL could be based.

20.32. The first meeting of the Policy Steering Group for the Redevelopment of BPL took place on 24 August 1981, chaired by Mr Smart [WITN4461051]. I was part of the Secretariat (along with Mr Godfrey). The Group was to act on behalf of the Joint Management Committee for the Central Blood Laboratories in planning the redevelopment of BPL. The objective was to redevelop as quickly as possible in order to save NHS expenditure on commercial products. Mr Harley explained that there were two possible sources for capital funding: additional money from Treasury or "top slicing" Health Authorities. The Group agreed a time frame of three years for redevelopment, noting that there was a risk that the rate of technology change would threaten the investment. It is not clear from the papers what information was taken into account to reach that decision, or whether it was realistic, see para 20.22 above. Dr Dunnill confirmed that the report of the Protein Fractionation Technology Working Party remained valid, for a finite period. The Policy Steering Group was also required by Ministers (Lord Elton) to consider whether an existing factory could be reused, rather than building a new facility from scratch (see further [WITN4461052], minute from Dr Harris to Mr Harley, copied to me).

20.33. With regard to the possible contribution of PFC Liberton in fractionating some English plasma (se Q29/30 below), I explained that PFC trials were set for late Autumn but for a two-week period only. It was agreed that Dr Lane and Mr Hibbert should discuss the design implications of processing 24 hours a day. Dr Gunson fed back the initial conclusions of his Working Party on self-sufficiency targets; the Group was refining its costings before reporting back to the NBTS in September. It was agreed that spare capacity must be built into BPL. There was discussion about project management arrangements and the details of development [WITN4461051]. Meetings continued thereafter.

20.34. Concerns continued to be expressed by the Medicines Inspectorate about the limited progress that had been made to remedy deficiencies found in 1979. The Inspectorate recognised that a number of important deficiencies could not be remedied short of major redevelopment but were keen to press Dr Lane to achieve "improvements in the general standard of housekeeping and management" (see Mr Brown's letter to Mr Harley of 25 September 1981, [WITN4461053]).

20.35. The Joint Management Committee for the CBLA continued to discuss a wide range of issues; see (e.g.) the minutes of 23 October 1981 [DHSC0002211_063]. Discussions included the continued work on the BPL upgrading programme, which was proceeding alongside work on the commercially-prepared feasibility study for redevelopment. By this time the Policy Steering Group (above) had met three times. The Group expressed concern about the need for a Ministerial decision on the long-term management arrangements, but had made decisions on a number of matters. It was working to a target of 435,000 kg of plasma being needed to enable England and Wales to be self-sufficient in blood products. The appointment of Matthew Hall Norcain (MHN) was approved by the Joint Management Committee, for the preparation of a Feasibility Study, and a Project Manager appointment was agreed. Treasury approval in principle for the redevelopment had been obtained, although further economic justification needed to be prepared. There was further discussion of the upgrading work that continued to be needed at BPL in the short term.

20.36. A handwritten note from Mr Godfrey dated 3 November 1981 records that Ministers had agreed to the development of the BPL at a capital cost of £17m and Treasury approval in principle had been obtained [WITN4461054]. In the submission to Mr Finsberg which followed on 17 November 1981, Mr Godfrey noted that the short-term measures were to increase the processing capacity at BPL from 70,000 kg of FFP per annum, to 150,000 kg. (This would amount to 30 million i.u., approximately half of the NHS's usage). The self-sufficiency target set by the Advisory Committee was 435,000 kg/annum. To achieve this, changes would need to be made in the supply of plasma from the RTCs [WITN4461055]. Ministers were asked to consult the NHS on their commitment to supply these quantities. A further minute of 25 November provided further detail on the anticipated financial benefits, after 6 years operation of the new plant [WITN4461056].

20.37. Ministerial approval to consult the NHS about plasma supply, as proposed by Mr Godfrey, was given by Mr Finsberg on 26 November 1981. [WITN4461057].

20.38. The minutes of the Scientific and Technical Committee for the Central Blood Laboratories meeting held on 24 November 1981 (which I attended as one of

the joint secretaries) record that Mr Smart reported back that, by this date, the Policy Steering Group had met three times, and set out the progress made including on the technological design [WITN4461058]. In particular, a feasibility study from Matthew Hill, Norcain, had been commissioned and was due by 10 December 1981. Mr Collins of the NW Thames RHA had been appointed Project Manager.

20.39. The fourth meeting of the Policy Steering Group for the Redevelopment of BPL was held on 18 December 1981 [CBLA0001517]. It is apparent that by this time the Group had received a possible scheme for the development of BPL from Matthew Hill Norcain Ltd, at an anticipated cost of £21.6m. However, members of the Group expressed reservations, commenting that the facility proposed was too large and at the "top end" of the development scale. The Group discussed the need to obtain Treasury approval in principle to a "management contracting" approach to the redevelopment, given the need for speed and fast-tracking. It is apparent from the minutes that Mr Harris (Finance Division) was tasked with making progress on these matters and with any approach to HM Treasury.

Summary of events by the end of 1981:

20.40. By the close of 1981:

i) Ministers had agreed to the development of the BPL at a capital cost of £17m and Treasury approval in principle had been obtained;

ii) A Working Party had assessed and defined production targets;

iii) Short-term measures were in hand to increase the processing capacity at BPL from 70,000 kg of FFP per annum, to 150,000kg;

iv) A possible scheme for the development of BPL had been delivered by the contractors Matthew Hill Norcain Ltd; it was estimated it would cost £21.6m.

Events in 1982

20.41. On 12 February 1982, Mr Finsberg visited BPL. A minute from Dr Harris dated 21 January to Mr Finsberg, sent in preparation for the visit, noted that in 1981, BPL's production of Factor VIII had increased to 22m i.u, from a previous best output of 15m i.u. The increases had been achieved at a time of considerable upheaval. The short-term upgrading programme was on target to be completed by the summer [WITN4461059].

20.42. The fifth meeting of the Policy Steering Group for the Redevelopment of BPL was held on 1 March 1982 [DHSC0002215_087]. I can see that I was not in attendance, having sent my apologies. There are a series of detailed discussions on issues such as the design and feasibility study. A proposal was made and accepted for Matthew Hill Norcain Ltd to be appointed as both management contractors and project designers, which was thought to have the benefit of continuity and saving in time. A formal application for outline planning permission had been lodged.

20.43. I went on maternity leave from April 1982 – October 1982. I had some sporadic involvement with Departmental issues whilst away, as I was very occasionally asked by the Principal of HS2, Mr Stan Godfrey (as had been agreed with me before I went on leave) to provide medical or scientific advice. However, I am not well-placed to comment on developments during this period.

20.44. I can see from papers that I have been shown that planning for the establishment of new managerial arrangements for the Central Blood Laboratories continued (see Q22 below). In the autumn of 1982, approval was given by the Minister (Mr Finsberg, I believe) for the building of a new Blood Products Laboratory of a size planned to be large enough to secure self-sufficiency. I have been shown a submission drawn up by Mr Godfrey dated 22 September 1982 (copied to me) that set out the decision for the Minister to take [WITN4461060]. The laboratory was expected to cost £21.03m plus a contingency allowance of £1.5m. The recommendation was approved: see [WITN4461061], which is a note of the meeting held with Mr Finsberg on 7 October 1982, when the proposal was discussed and approved. The note was copied to me but I was not present at the meeting.

20.45. Although I attended a meeting of the Joint Management Committee on my return on 5 October 1982 [CBLA0001631] I do not believe that I had any real involvement in the oversight of the further design work or building works, prior to leaving Med SEB in December 1983. The project was overseen by the new CBLA established on 1 December 1982. Dr E.L. Harris (DCMO) represented the DHSS at meetings of the CBLA, although I attended in his place on occasion.

21. Q21: Funding made available to BPL:

21.1. I have been asked a series of detailed questions about funding allocations to BPL (for what, and when) and to explain how, by whom and by what process the funding allocations for BPL were decided. My role was to provide medical input to the policy division. Funding decisions were not my responsibility (although I might at times have been asked to comment on the medical justification for funding requests). They will have been dealt with by the policy division, HS2 and Finance Division and ultimately agreed by Ministers. I would ask the Inquiry to direct these questions to those with first-hand involvement in these issues.

22. Q22: Establishment of the Central Blood Laboratories Authority ("CBLA")

22.1. The Central Blood Laboratories comprised the Blood Group Reference Laboratory, the Blood Products Laboratory and the Plasma Fractionation Laboratory, Oxford. They were placed under the management of a newly-created Special Health Authority, the CBLA, from 1 December 1982.

22.2. According to the explanatory notes appended to SI 1982 No 1515 of the Order establishing the special health authority, the CBLA was established for the following purpose:

> *The Order provides for the establishment and constitution of a special health authority, to be known as the Central Blood Laboratories Authority, for the purpose of exercising on behalf of the Secretary of State functions relating to the provision of laboratories for the*

preparation of plasma fractions; research and development in blood products; and the manufacture of blood grouping and related reagents.

22.3. To the best of my recollection, I was not closely involved in the establishment of the CBLA, not least because I was on maternity leave from April – October 1982. In any case, this was an administrative rather than medical matter.

22.4. The matter appears to have been considered seriously from early 1981 onwards, when the decisions regarding the redevelopment of BPL led to consideration of the arrangements that would be needed to plan such a major set of works effectively. A detailed minute from Mr Peter Wormald to Mr Nodder (Deputy Secretary and Mr Wormald's line manager) dated 6 April 1981 addressed the topic of the future management of the Central Blood Laboratories and set out the case for a Special Health Authority being created. [WITN4461062]; the paper was further revised by HS and recirculated on 27 May 1981, [WITN4461063]. It received support from Mr Nodder on 29 May 1981 [WITN4461064]. Mr Nodder noted that it would not be possible to undertake a major investment of £17 million or so in BPL, without a "secure top management".

22.5. However, these minutes were, at most, copied to me. I would suggest that those directly involved in this correspondence would be best placed to discuss this policy initiative and its progress.

22.6. The broad parameters of the tasks taken on can be seen from the record of the first informal meeting of the CBLA, which took place on 3 Dec 1982 and which I attended, which set out the tasks for the new CBLA [CBLA0001644]. Although I attended this first informal meeting, Dr Harris attended formal meetings on behalf of the Department and I rarely did.

23. Q23: Estimates for plasma supply, demand for Factor VIII and demand for other blood products.

23.1. The Inquiry has asked how the DHSS obtained estimates for plasma supply, and the demand for Factor VIII and other blood products.

Estimating Demand for Blood Products

23.2. Estimates of demand for Factor VIII and other blood products came mostly from haemophilia centre directors and blood transfusion service directors, together with Dr Lane of BPL, Drs Tovey and Gunson; and Professor Cash and others from the Scottish blood transfusion service, SNBTS.

23.3. I have set out below the detail of the work done in 1981 to estimate demands. Up to that point, the last large-scale consideration of the issue of future demands had been carried out, I believe, in 1977, by the Working Group on Trends in the Demand for Blood Products.

23.4. It is apparent that there was a need for a systematic revision of the targets, not least in the context of planning for BPL redevelopment. This took place in 1981.

23.5. A Working Party of the Advisory Committee on the National Blood Transfusion Service was set up in early 1981 (its formation was agreed at the Advisory Committee Meeting held on 23 February 1981). The Working Party was chaired by Dr Gunson and I was a member [CBLA0001287_001]. The terms of reference were "To advise on supplies of plasma for self-sufficiency in England and Wales".

23.6. Arising out of this, a Joint Meeting of the Representatives of Haemophilia Reference Centres and Blood Transfusion Service Directors was held on 23 April 1981 [DHSC0002207_19]. The minutes give a good account of the projected demands of the various products. The meeting had been specifically convened to consider the foreseeable requirements for blood products used in the treatment of haemophilia.

Demand for Factor VIII and Factor IX concentrates

23.7. At this meeting, it was agreed that the projected figure for Factor VIII usage for the mid-1980s was 100 m i.u. A minimum of 80% of the Factor VIII requirement would need to be in the form of intermediate purity concentrates. A maximum of 10% of the total Factor VIII requirement would be needed as high purity concentrate, mostly for major surgery. It was agreed that the rate of increase in Factor IX usage appeared to be levelling off, probably because many patients

with haemophilia B were now on prophylactic therapy. No significant increase in Factor IX usage over the present 7.5 m i.u was envisaged for the mid-1980s.

Frozen Cryoprecipitate

23.8. There would be a small requirement for its use in patients with von Willebrand's Disease (vWD) and in mild haemophiliacs and some carriers with low levels of Factor VIII, because the small pool size reduced the risk of hepatitis transmission. The amount needed was simply described as a "small amount".

Freeze-dried Cryoprecipitate:

23.9. The advantages of this over frozen cryoprecipitate were easier storage and greater standardisation. This had to be balanced against the risk of hepatitis transmission from the larger pool sizes involved, although the latter risk might be mitigated by using pools derived from an accredited panel of donors with a low hepatitis risk. If it were to be produced, it should comprise no more than 10% of total Factor VIII usage.

23.10. Although the future requirement for albumin and immunoglobulins was not considered at this meeting, other documents [CBLA0001377] confirmed that the foreseeable usage would not require more plasma than would be required for the production of coagulation factors.

Demand for Plasma

23.11. The demand for plasma was set out in the report of the Working Party to Advise on Plasma Supplies for Self-Sufficiency in England and Wales, June 1981, chaired by Dr Gunson [CBLA0001377]. I have described the formation of this Working Party above.

23.12. The main findings of the Working Party were that: 100m i.u Factor VIII were needed by the mid-1980s, the majority (80m i.u) of which should be in the form of intermediate purity concentrates, together with a requirement for a small quantity (10 m i.u) of high-purity concentrates and 10m i.u frozen/freeze-dried cryoprecipitate. At the date of reporting, only 15m i.u Factor VIII were being produced (BPL + PFL, England) with about 10m i.u in the form of frozen cryoprecipitate at RTCs. If sufficient plasma could be obtained to enable production of 100m i.u, that would be adequate to satisfy the anticipated needs

for albumin at 200g/1000 population ('Trends' Working Party Report (Dec 1977). Overall the quantity of plasma required would be 500,000 kg annually. Subsequently, the total volume of plasma required was reduced to 435,000 kg; see the minutes of the Advisory Committee on the NBTS, 28 September 1981, below at paragraph 23.15.

23.13. The Working Party report looked at options for obtaining 500,000 kg of plasma annually. Plasma collection from whole blood would have to increase by increasing the numbers of donations from 2.032 m to an estimated 2.2 m. This would yield 200,000 kg plasma, if plasma could be used from 51% of whole blood donations. Options for securing the remaining 300,000 kg of plasma included increasing whole blood donations by 1.3 m or removing larger amounts of plasma from the donations. This would be difficult to secure, would be very costly, would require new equipment and would lead to an unethical waste of red blood cells.

23.14. Another, feasible option would be to introduce plasmapheresis.[3] Manual plasmapheresis and machine plasmapheresis were considered, with the former requiring 65 plasmapheresis centres to be established and the latter requiring 35 centres in the regions, each requiring the recruitment of donor panels to serve them. The report gave estimated costs of the various options.

23.15. The Working Party in turn reported back to the Advisory Committee on the NBTS on 28 September 1981 [CBLA0001457]. Its estimate of 500,000 kg for the projected plasma needs was reviewed in the light of information received from the Haemophilia Centre Directors and revised down to 435,000 kg. Member endorsed the report and asked that Ministers' agreement be sought for formal consultation with RHAs above plasma supplies to take place.

23.16. As a consequence of this work and the agreement reached, Mr Shaw wrote to the Regional Administrators of the RHAs on 18 December 1981, setting out the

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[3] Plasmapheresis is the process whereby a unit of blood is taken from a donor and the blood is centrifuged to separate the plasma from the red cells and other cellular components. These, with the addition of some saline or other fluid, are then returned to the donor. The plasma is retained to make Fresh Frozen Plasma. Because the red cells are always returned to the donor, the process of removing plasma can be repeated much more frequently than whole blood donation, thus yielding considerably more plasma per donor. The process can be manual or automated.

overall target that had been calculated: at present yields, 435,000 kg of FFP would be needed to enable the redeveloped BPL (expected then to be commissioned by the end of 1984) to meet the NHS's foreseeable needs for blood products. The annex to the letter set out the possible plasma supply 'targets' for 1984/85, related to the population in each Transfusion Centre's catchment area. It was intended that BPL products would be supplied back to the RHAs in direct proportion to their plasma input. The Administrators were asked to supply early estimates of the RHAs' willingness and ability to provide FFP on this basis [WITN4461065].

23.17. See further the minutes of the Advisory Committee on the NBTS in its meeting on 31 March 1982 [DHSC0001136], where Dr Gunson explained that the Working Party had considered recent trends in Factor VIII yield and had concluded that the estimated quantity of plasma required to achieve self-sufficiency in blood products should remain at 435,000 kg per annum. Paragraph 7 of the minutes further records that in the lights of responses from the RHAs, the Committee felt that a phased build-up to 435,000 kg was a reasonable proposition which would enable account to be taken of changes in product yield.

24. Q24: Funding for the Stop-gap measures and Re-Development of BPL.

24.1. I have been asked what estimates were used to make decisions about funding Stop-gap measures and redevelopment of BPL. This was a matter for the Finance Division and HS2, not medical professionals. I do not think that I can assist (see Request 21, which raises the same issues).

25. Q25: Speywood

25.1. I have been asked to describe my knowledge of and/or involvement in the DHSS's consideration of an application by Speywood for financial assistance to support a project for the development of a new blood fractionation process:

25.2. I have reviewed the copious papers on Speywood that I have been sent. These include those listed in the Rule 9 letter, plus numerous other documents sent

to me subsequently by the Inquiry. Over the course of the period to which the documents refer, not only were the DHSS and BPL involved with proposals for funding a specific project and for collaborative working with BPL, but the Department of Industry, the National Enterprise Board, Celltech, Prutec and the Atomic Energy Laboratory at Harwell were also involved at various stages in respect of bids for funding or collaboration for different, albeit related, projects. I am only able to comment on the first Speywood project which came to the Department's attention in November 1978. My own involvement was from October 1979, after I had joined Med SEB.

25.3. The company, Speywood Laboratories, was a small British firm, established in 1974, specialising in the fractionation of porcine plasma to produce porcine Factor VIII for the treatment of haemophiliacs who had developed inhibitors to human Factor VIII products. Speywood had been working on a new method of fractionation of blood using a technology involving precipitation of plasma proteins with varying concentrations of polyelectrolytes (polyethlene glycol, PEG) at varying pH, allowing the purification of different plasma protein fractions. The technology had been developed and patented by Monsanto which had licensed it to Speywood. The technology could be used with human plasma as well as porcine plasma and, when Speywood approached the Department, (in May 1979), for assistance with funding of the project, they had already begun a collaborative experiment with BPL to explore the fractionation process for human plasma.

25.4. One notable advantage claimed for the PEG fractionation process was that there was some experimental evidence, using plasma samples 'spiked' with known amounts of hepatitis B surface antigen (HBsAg), that the HBsAg was reduced or absent in certain resulting plasma fractions [PRSE0003799_0001; BPLL0016008_002; DHSC0003936_062].

25.5. A meeting was held on 7 May 1979 between Speywood and the DHSS (Mr Weston and Mr Buck) [DHSC0003936_082]. There was no Departmental medical representative.

25.6. The meeting note recorded the three projects that Speywood had under consideration. They were only seeking DHSS assistance with the first project

concerning (a) the development of the work already being done on PEG-fractionated porcine plasma in their plant at Wrexham, including additional factory space; and (b) developing their work on PEG fractionation of human plasma, on which they were already working with Richard Lane of BPL.

25.7. DHSS officials present were reported to believe that 'PPDS' (which later papers indicate was a Department of Industry (DoI) funding scheme to support project development) appeared to be appropriate and offered to consider an application for such funding, with the support of STB (the DHSS' Scientific and Technical Branch). Speywood said they expected to make an application for a 25% grant.

25.8. Once the project came to the attention of Dr Wintersgill (Med OS3), he expressed concern, in a minute dated 21 May 1979 to Mr Buck, IED (Industry and Exports Division), [DHSC0003936_074] that no medical input had been sought and that such input was important. He copied his minute to Dr Waiter, my predecessor in Med SEB.

25.9. A formal grant application was made by Speywood on 7 June 1979 [DHSC0003936_077]. The objective of the project, which was set out in [BPLL0016008_151], was to finalise the production scale process for the routine manufacture of human Factor VIII:C. This was with a view to undertaking initial clinical trials in the UK, leading ultimately to an application for a UK product licence.

25.10. I was not involved in this meeting but, to assist the Inquiry, I have taken up the narrative from the submission of the bid in June 1979.

25.11. The bid explained that, using the PEG technology, Speywood had completed, to production scale, porcine Factor VIII:C and, to pilot scale, human Factor VIII:C. Speywood lacked the facilities to scale-up to production scale for human Factor VIII:C and to extend the technology to the separation of albumin, immunoglobulins etc. Their bid for funding, at this stage, was confined to work in relation to human Factor VIII:C.

25.12. The bid set out the benefits envisaged from using the technique to fractionate human plasma which I summarise here as: a highly purified Factor VIII:C product; improved yield; reduced hepatitis risk; reduced liver damage; reduced

injection volume; and a simpler and quicker process (see paragraph C of p2 of the bid document [BPLL0016008_151]).

25.13. The intention was that Speywood's Chief Scientist would work at BPL, with a technician assistant provided by BPL. Speywood would provide most of the equipment and the polyelectrolytes. BPL would supply the cryoprecipitate and various chemicals, laboratory space and sterile filling capacity. In return, it was proposed: BPL to have exclusive rights to use the Speywood process in England and Wales and there were various other commercial proposals including: royalty payments from BPL to Speywood; ownership of the technology by Speywood and access by the company to all the technology discovered by BPL during the programme.

25.14. A meeting was held on 7 August 1979 between the DHSS and the MD of Speywood, David Heath and a Director, David Williams. Dr Richard Lane of BPL was also present, but no one from the Medical Divisions, although Drs Wintersgill and Waiter were copied into the minute note of September 1979 [DHSC0003936_071]. The meeting focused on describing the chemistry of polyelectrolytes and the mechanism by which they could be used to adsorb and desorb (sic) proteins differentially from whole plasma.

25.15. The point of the proposed collaboration with BPL (some aspects of which appear, from the papers, to have already started) was to have access to cryoprecipitate starting material to which the PEG process could be applied, and the necessary quality control measures could be developed. The company seemed to envisage that once such material had been satisfactorily processed by BPL, it could be used on a named patient basis for patients with Factor VIII inhibitors. There was some discussion about clinical trial certificates and applications for product licences but, I would observe now, such a discussion was distinctly premature, given the project was at an early stage of proof of concept for a human Factor VIII product.

25.16. It appears that a similar view was taken by Mr Sloggem of STB4, in his minute of 11 October 1979 to Mr Dutton [DHSC0003936_070]. His view was that the use of polyelectrolytes appeared to offer advantages, and that Speywood/BPL should be given DHSS backing to assess and develop the method to the pilot

scale and for in vitro and animal testing. But he did not think that DHSS should as yet give support for the clinical evaluation or use of the materials produced by PE fractionation until a fuller examination of the project was possible, especially since the needs of the PE project and BPL priorities may not at a given point coincide.

25.17. The papers then show, from a letter from Speywood to Mr Weston, DHSS, [DHSC0003936_050] that there had been much too-ing and fro-ing of their application for funding between various Department of Industry departments (presumably because there was debate about whether the PPDS funds were the most appropriate source of financial assistance). In the event, it appeared that the project was likely to receive PPDS funds.

25.18. My first involvement came in October 1979, in a minute to me from Mr Weston, IED1 [DHSC0003936_049]. From earlier supportive comments about the project received from Drs Wintersgill and Waiter (which do not appear in papers I have seen), he was now seeking my comments on the proposals, in terms of my giving some indication of the potential and importance of isolating other human and animal fractions, which were apparently referred to on p 5 of the firm's submission but had not featured very significantly in the earlier submission. He also warned of his concern about the financial viability of the company.

25.19. Unfortunately, I do not have a copy of a proposal, for this date, with a page 5, nor do I have a copy of my own comments on the proposal. I obviously did comment, very supportively, as Dr Wintersgill's response to Mr Weston made clear [DHSC0003936_044]. Dr Wintersgill noted that I had "already given examples of the possibilities that we can see" and that he endorsed my views in the strongest possible terms. Looking now at the project, I can see why I would have been in favour of it, if the project could show that it yielded the benefits described at paragraph 25.12 above.

25.20. On 28 November 1979 Mr Weston wrote again to me, Dr Wintersgill, and administrative colleagues in the Department and in DoI concerned that, despite the positive comments received, there remained a question mark over the involvement of the Blood Products Laboratory and the extent to which it was

regarded as an integral part of the development programme [DHSC0003936-042].

25.21. In February 1980, Mr Weston's minute confirmed the approval by the DoI of a PPDS grant of £190K, which was the last component on a total financial support package from Government of £890K.

25.22. At some time, between January and May 1981, Speywood appears to have made a presentation to the CSM about Hyate:C (porcine Factor VIII), which had, by that stage been used to treat 26 patients with Factor VIII inhibitors. Its expenditure on the Speywood/BPL project for the first three months of 1981 had been audited by an external firm of chartered accountants and was found to be in order. Its premises in Wrexham which had been leased to enable it to manufacture porcine Factor VIII had also been subject to an initial inspection by Mr Haythornthwaite of the Medicines Inspectorate.

25.23. In May 1981, Speywood had entered into two licensing deals with Monsanto which were agreed by the Department. The nature of the deals with Monsanto were set out in Speywood's report on the PEG Blood Fractionation Project for the first quarter of 1981 [DHSC0003936_027]. The agreement with Monsanto was that porcine PEG products would become exclusive to Speywood worldwide. Human PEG products would become exclusive to Speywood in the Eastern Hemisphere. The latter agreement had caused Speywood to draw up "plans to exploit this opportunity and the NEB are considering Speywood's proposal" [DHSC0003936_027].

25.24. This development was drawn to my attention by Mr Weston on 17 June 1981, simply for my information [DHSC0003936_022]. The NEB was said, in a manuscript note of 7 July [DHSC0003936_018] to be "pretty excited" about the project and had asked the DHSS to set up a meeting. The meeting took place on 22 July 1981. It was chaired by Dr Wintersgill and included representatives of the NEB and Prutec, as well as Speywood. I was present.

25.25. The project that the meeting discussed was described in a Speywood paper [DHSC0003936_019]. It was a £4-5m project to manufacture four plasma fractions from imported US cryoprecipitate. These were: Factor VIII:C; Factor vW; fibronectin and fibrinogen. All the products were described as being 'most

probably free of hepatitis'. The products would be manufactured in a purpose-built facility adjacent to their Wrexham plant. There would also be a long-term research programme with the aim of producing further therapeutic proteins. The target date for making the human fractions factory operational was October 1982. There is also a reference to clinical trials having taken place with the human Factor VIII, but no indication that these trials were carried out in the UK. (Speywood was grant-funding work on the PEG technology with laboratories in New York and Paris).

25.26. There is a draft note of the meeting at [DHSC0003936_009]. The outcome of the meeting was an essentially positive view of the project by the DHSS, with advice to Speywood to involve Dr Fowler of Medicines Division and other relevant officials, informally, at an early stage in relation to the requirements for producing licensable products.

25.27. Following the meeting of 22 July 1981, a further meeting was held at BPL, involving Dr M Harvey of BPL, Mr Williams of Speywood and myself. I wrote the note, dated 13 August 1981 [DHSC0003936_005]. (There is an obvious error in that the date in the heading of the paper is 12 July 1981. From the context, it was probably 12 August). The meeting was to discuss the BPL/Speywood collaboration on PEG fractionation. Its purpose was to investigate a complaint, made by Speywood at the 22 July meeting, that BPL was being dilatory in its collaboration with Speywood. The contract period for the work had long expired and collaboration was continuing on an informal basis.

25.28. After some discussion about the terms of agreement in relation to the BPL product, one of the most important points to emerge from the meeting was that, unknown to Speywood and the DHSS, BPL had been engaging in talks with Monsanto with a view to collaborating on certain development work using polyelectrolytes and were at the stage of considering a draft contract which had been prepared by Monsanto. The terms of the draft contract with Monsanto were unacceptable to BPL and talks were continuing. Mr Williams expressed dismay at the possible involvement of Monsanto and suggested that such a collaboration with Monsanto, if it were to give rise to a product which was patented by them, could result in both Speywood and the Secretary of State

having to pay royalties to Monsanto. It was agreed that a meeting would be arranged between the parties, which the Department would need to attend.

25.29. In response to a minute of 18 August 1981 which I had written to Mr Weston (I do not have a copy of this minute), concerning a letter that I had apparently received from Dr Lane about the proposed NEB investment (which I also do not have), Mr Weston felt that Dr Lane's criticisms were not significant. Mr Weston confirmed that the NEB had told him that a very thorough investment appraisal on the project had been carried out and the company's claims had stood up well in the face of close examination.

25.30. As far as I can tell from the papers, my involvement with the Speywood/BPL collaboration ended at this point. Looking through various other papers provided by the Inquiry but which are undated, one pertinent fact, not apparent from any of the earlier papers, appears from a document which may have been from a presentation to Medicines Division or the CSM. This was that early in the company's history, they had entered into an arrangement with Cutter Laboratories Inc of Berkley, California under which they became UK agents for their brand of Cohn fractionated human Factor VIII, Koate. A variation to the Product Licence had been granted, changing the name from Koate to Humanate and allowing importation in bulk. The product was quality assured in two laboratories, Toxicol and the Oxford Haemophilia Centre and was subject to NIBSC batch release in the usual way. The product had been used and found acceptable in several centres [DHSC0003936_039].

25.31. As a postscript to this account, I thought the Inquiry would be interested to note that, in planning for the re-developed BPL, the Protein Fractionation Technology Working Party, in its report in 1981, concluded that plasma fractionation should continue to be centred on cold ethanol precipitation, following a first cryoprecipitation step. However, the Working Party had reviewed other fractionation technologies, including polyethylene glycol precipitation and solid phase PEG chromatography. They concluded that these, and other methods using precipitants, ion-exchange and chromatography, did not seem to confer outstanding advantages and were not likely to be adopted in the foreseeable future. Should there be a wish to integrate them in the future,

they could be used in the new plant without major change, because they did not need special services and load-bearing floors [DHSC0002213_021_0001].

26. Q26: Commercial Participation

26.1. I have been asked to describe the steps taken by the Department to meet the estimated future requirements for blood products, including exploration of the option of commercial participation in the fractionation of NHS plasma.

26.2. I have outlined above the steps taken to plan the redevelopment of BPL (Q15). The issues considered during the course of the discussions included the question of whether there should be collaboration with commercial enterprises, a matter that had been raised by Sir George Young (the Parliamentary Under-Secretary for Health) in January 1980, and which Dr Vaughan as Minister of State had decided should be explored. It was a potential means of funding, in whole or in part, the redevelopment.

26.3. The records show that various discussions with companies followed the Ministerial decision that the possibility of commercial partnership should be explored. For example, on 12 February 1980, I minuted a call I had received regarding Nordisk's intention to announce a fractionation plant in the UK [WITN4461066]. On 13 Feb 1980, Mr Barrell, Managing Director of Travenol wrote to Dr Vaughan as Minister of State (Health), re-iterating his company's potential interest in investing in commercial fractionation in the UK. [WITN4461067]. There is a further minute dated 18 July 1980 [WITN4461035] regarding the potential interest from Beechams and Fisons. However, Mr G.A. Hart of Supply/IED was leading on the issue, as I have explained above.

26.4. On 6 August 1980 there was a written PQ on private industry involvement in BPL which set out the position at that time:

> *"Dr M S Miller (La. East Kilbride)*
>
> *To ask the Secretary of State for Social Services, what are his intentions or plans regarding the introduction of private capital into the National Health Service through partnership schemes between the National Blood Products Laboratories, Elstree, and privately-owned companies; and what stage they have reached.*

DR GERARD VAUGHAN

I am investigating the possibility of private industry collaborating in the redevelopment of the Blood Products Laboratory, but I have not formulated any plans."

26.5. The obstacles to allowing foreign companies to set up plants in the UK, or collaborating with such companies in the context of NHS production, were clearly spelled out on the minute of 18 August 1980 from Dr Wintersgill (MED OS3), copied to me [WITN4461068]. In particular, it noted that the entry of a foreign company to the UK would mean importation of plasma, which would increase the risk of contamination of UK plasma with hepatitis, and would run counter to the WHO recommendation that countries should be self-sufficient in blood products.

26.6. For my part, I was conscious of the potential contribution of commercial management expertise, bearing in mind that BPL needed to operate as a pharmaceutical factory as opposed to a research laboratory. However, this was distinct from any proposals to allow the importation of plasma, which would raise wider and more difficult issues. My views on this subject were set out in September in a minute to Mr Harley dated 15 September 1980, copied widely, discussing concerns about a possible industry takeover of BPL by Beechams. I noted the risks of imported plasma: 90% of post-transfusion (and blood product infusion) hepatitis in the USA and elsewhere was caused by non-A non-B hepatitis which could not currently be detected by testing of donor blood. Non-A, non-B Hepatitis `can be rapidly fatal' (particularly for those with pre-existing liver disease) or lead to progressive liver damage. If, however Beechams was not allowed to import plasma, it would compete for plasma supplies from UK donors and undermine the voluntary donor principle in the UK. I commented on the potential ability of Liberton (PFC) to take on ¼ to ⅓ of England and Wales' fractionation requirements (the Scots were very willing to consider UK fractionation as a whole, I considered) and my view that the self-sufficiency figures that had been given were underestimating the requirement of FFP for self-sufficiency in England and Wales [WITN4461069].

26.7. The Minutes of the Joint Management Committee meeting held on 2 October 1980 [CBLA0001190] record that Beechams Pharmaceutical was the only

British company interested in redeveloping BPL. A submission was going to Ministers setting out the 'pros and cons' of collaboration. The possible effect on donors would be a major part of the submission.

26.8. By end of November 1980, Ministers decided against commercial involvement; see paragraphs 20.15 and 20.16 above. Redevelopment planning continued without further consideration of commercial involvement.

27. Q27: The importance of plasma supply to achieving self-sufficiency

27.1. I have been asked how important plasma supply was to achieving self-sufficiency. The answer is that it was critical. Without the right amount of plasma, derived from UK donors, self-sufficiency would have been impossible.

28. Q28: Steps taken by DHSS to increase plasma supply

28.1. The Inquiry has asked for a description of the steps taken by the DHSS to increase plasma supply.

a. DHSS influence over RHAs

28.2. I have been asked about the extent, first, to which DHSS could/did influence how RHAs and/or RTCs used their funding to harvest plasma. RTCs required extra funding or support if they were to significantly increase plasma supplies, particularly from plasmapheresis on any scale. However, the DHSS could not instruct RHAs on how their allocation of funding was to be spent, and their priorities for expenditure. In general, the topic of increasing plasma supplies was addressed by discussion and exhortation, rather than instruction. For example, the DHSS pointed out to RHAs that an increase in the supply of NHS concentrates would be liable to result in lower expenditure on commercial imports. Another lever would be the provision of additional earmarked funding, but this was unusual because the philosophy was to devolve decision-making to local level.

28.3. There was a further disconnect between the RHAs/RTCs and the haemophilia clinicians, who had clinical responsibility for their prescribing decisions, including decisions on the use of commercial products. Even if had been

possible to provide enough plasma to make sufficient Factor VIII to satisfy the needs of haemophiliacs for treatment, if there were a clinical preference to prescribe commercial products, it would not have been possible to reach self-sufficiency based on demand.

b. DHSS support for pro-rata supplies of Plasma

28.4. I have been asked about DHSS support for pro-rata supplies.

28.5. Change from the pre-existing system to a pro-rata system was proposed by Dr Lane, as part of his proposals for expanding BPL production. He saw it as an essential means of securing increased supply of high-quality plasma to BPL. See, for example, Dr Lane's paper of September 1979 [WITN4461070]. Dr Lane argued that: "For many years, the relationship between RTCs and BPL has existed only in an irregular manner, raw material supply being on a 'grace and favour' basis from regions". He was pressing for guaranteed supplies to BPL in return for proportionate delivery back of the products manufactured, on a quasi-contractual basis, including specified quality standards for the FFP.

28.6. As the minute of 8 September 1980 from P J Wormald [WITN4461071] makes clear, the DHSS approved of this proposal and encouraged it. It was put forward as a means of taking advantage of the increased capacity of BPL that was to result from the short-term works agreed after the inspection of the Medicines Inspectorate. The upgrading was expected to increase the production capacity for Factor VIII by about 100% (and that of albumin by about 60%). RHAs were asked to commit to the new system in order to ensure that both the quantity and quality of plasma supplied to BPL would improve.

28.7. As the operation of this aspect of the NHS was delegated to the RHAs, their consent was required. In addition, the RHAs would have to use their own funding to increase supply to BPL so as to receive back sufficient Factor VIII and other blood products to meet their needs. Ultimately, the operation of this system was expected to reduce RHAs' expenditure on commercial Factor VIII, and it was therefore anticipated that their additional expenditure would be recouped once the increased production from BPL was available.

28.8. Dr Lane described the proposed pro-rata system again at the first meeting of the Advisory Committee on the NBTS held on 1 December 1980

[CBLA0001207_0001], explaining that the proposal was that it should be introduced by 1 April 1981. This pro-rata system had been accepted in principle by the RHAs and Haemophilia Centre Directors as a rational way to distribute a scarce resource but there remained some issues (e.g. supply for Treloar's School).

28.9. I understand that the system was implemented from 1 April 1981.

c. Cross-charges for Plasma

28.10. I am not sure what is meant by the reference to a "cross-charging" system for plasma; plasma was not cross-charged or distributed during my time in Med SEB. It does seem that there was a cross-charging scheme first put forward to Regional Treasurers in September 1982. A note of a meeting held with the CBLA on 14 June 1983 [WITN4461072] suggested that there had been little enthusiasm for the proposal, but a pilot had been set up in Wessex; results were not yet available. I am reported as saying that there were possible difficulties surrounding cross-charging which had yet to be resolved (Regional purchasing policies and the level of charge to make for products). However, I was not involved in any charging decisions, and I suggest that financial colleagues may be better placed to answer. It may have been introduced at a later date.

d. Support for Plasmapheresis

28.11. Plasmapheresis was a technique for plasma collection and therefore a matter for the RTCs. But DHSS supported plasmapheresis in principle and recognised that RTCs would need additional funding for equipment and even building works to do this on any scale.

28.12. The topic of plasmapheresis was one considered by the Advisory Committee on the National Blood Transfusion Service from its outset: see the minutes of the first meeting on 1 December 1980. The meeting was chaired by Dr E.L. Harris, and I was present as a member of the Secretariat. Under the heading of 'self-sufficiency' the minutes record:

> *2) "One of the ways of increasing plasma supplies would be by plasmapheresis and the UK had to consider the possible role of this method of plasma collection as a means of attaining self-sufficiency.*

The Chairman said that the Department would be preparing a paper for discussion by the Committee. Dr Tovey and Dr Cash offered to provide information on other countries' experience with plasmapheresis."

28.13. The next meeting was on 23 February 1981 [WITN4461073] and details a discussion on the contribution that plasmapheresis might make. I have already explained how it was agreed that a Working Party should be set up under the Chairmanship of Dr Gunson with Dr Tovey and myself amongst its members, to advise on supplies of plasma for self-sufficiency in England and Wales. Plasmapheresis was to be one of the topics considered. Dr Cash and Dr Bell explained that the subject was also being studied in Scotland (and added at the next meeting that it was being carried out in similar detail to the study in England).

28.14. In the meeting held on 22 June 1981:

"13. The Committee endorsed the suggestion that there should be a properly controlled pilot study to evaluate the feasibility of establishing manual plasmapheresis centres. The Chairman asked the Working Party to put forward a formal proposal which could then be considered within the Department, possible [sic] in conjunction with MRC".

28.15. The next meeting took place on 28 September 1981 [CBLA0001457]. The report of the Working Party to advise on Plasma Supplies for self-sufficiency in blood products was presented. Recommendations were put forward for the introduction of plasmapheresis to supplement the quantity of plasma obtained from whole blood donations (see References AC(81)11 and AC(81)18)). The costs of production were estimated. The plans for increasing the plasma supply called for an increase of approximately three-fold in the plasma currently being sent to BPL. The report of the Working Party was accepted by the Advisory Committee and revised targets were prepared for RTCs.

28.16. It is apparent from the minutes that it was envisaged that the recommendations would be followed up by the Regional Transfusion Directors. A Code of Practice had been developed for Automated Plasmapheresis of Volunteer Donors and an equivalent one was to be prepared for manual plasmapheresis.

28.17. At the next meeting 31 March 1982 [DHSC0001136]:-

> *"Dr Gunson reported that encouraging progress had been made in the establishment of a machine plasmapheresis centre in Bradford, where it was hoped to have 6 machines in use by June 1982. North Western RHA planned to set up a manual centre in Lancaster with assistance from DHSS under the Special Medical Development Funding. The centres would provide other Regions with an opportunity to assess the relative merits of manual and machine plasmapheresis for harvesting routine plasma and much practical information would be learnt from their establishment."*

28.18. But by 1983, the need for use of plasmapheresis was reducing, as a result of new techniques for increasing the volume of plasma that could be safely removed from whole blood donations. These included techniques for the storage of red blood cells (RBCs) in SAGM (saline-adenine-glucose-mannitol). A discussion of the positive impact of the technique is recorded in the Working Party's meeting of 8 February 1983 [NHBT0009357_003].

28.19. The UKHCDO meeting of 17 October 1983 [PRSE0004440] suggested that there were problems with regard to the funding of plasmapheresis programmes. But the minutes record no detail and I was not present at that meeting.

e. Any other issues or means of support

28.20. My recollection is that clinicians were not, in general, keen to use plasma-reduced red-cells or packed red cells for treating their patients. As they were the principal 'customers' for RTCs' products, the RTCs could not divert too much plasma from whole blood donations for cryoprecipitate production or to go to BPL. Consideration would have been given to encouraging the use of packed red cells by clinicians, but this would not have been a matter for the DHSS.

29. Q29: PFC (Scotland) consideration of supply to England

29.1. I have answered this request alongside request 30.

30. Q30: PFC (Scotland) decision taken not to pursue PFC fractionating English Plasma

30.1. It seems appropriate to answer requests 29 and 30 together. They concern the consideration given to the possibility that the Protein Fractionation Centre ("PFC") could supply blood products to England and Wales.

30.2. In October 1979, the Minutes of the meeting of the NBTS Scientific and Technical Committee for the Central Blood Laboratories (I attended as one of the joint secretaries), noted that Dr Dunnill was "surprised" that there was not a strong link between BPL and PFC. PFC was not represented on this committee. By contrast, Dr Lane did not think PFC was in a position to provide any significant help.

30.3. In 1 July 1980, at an Ad-Hoc meeting of Regional Transfusion Directors at which I was not present, Dr Bird, a RTD, reported on spare fractionation capacity at PFC. The Director of PFC could fractionate "any plasma which Birmingham RTC might care to send to him". Members agreed that the aim should be to see that BPL Elstree was in a position to fractionate all the Birmingham and other plasma". Mr Dutton (DHSS) was to speak to SHHD to indicate that offers of spare capacity should be made formally between Departments.

30.4. I have noted how in September 1980, I commented on the potential ability of Liberton (PFC) to take on ¼ to ⅓ of England and Wales' fractionation requirements (the Scots were very willing to consider UK fractionation as a whole, I stated, following a recent visit to Liberton with colleagues from HS2). This reflected the information I was given at PFC; in fact, as subsequent events were to show PFC was not capable of providing extra capacity without substantial additional costs and process modifications.

30.5. On 1 December 1980, a meeting was held with officials from SHHD, DHSS, Northern Ireland and Welsh Office to discuss UK self-sufficiency in blood products; I attended. The minutes record that that Scotland was almost self-sufficient. England, Wales and NI were currently supplied by BPL, but it was agreed that PFC could help meet total UK needs. In the short term, PFC could fractionate an extra 500 litres of FFP per week; however, I believe that at the

time BPL was able to process the supplies that were available to it. It was suggested that in the longer term, PFC could cope with up to 1500L per week and perhaps more if funds were made available and provided agreement could be reached on shift working. The DHSS agreed that SHHD's experiment in shift working would be useful. It was possible that ultimately PFC might be able to meet up to half the UK's requirements. This was to be discussed in detail once total requirements had been defined. One possibility was that PFC should fractionate plasma from northern English regions and Northern Ireland.

30.6. The minutes of the CBLA's Joint Management Committee meeting of 10 June 1981 [DHSC0002209_093] record the disappointment of its Scientific and Technical Committee that the experiment involving continuous production at Liberton was not to take place for at least several months.

30.7. The PFC shift-work trials were eventually set for late Autumn 1981 but for a two-week period only, as I explained at the first meeting of the Policy Steering Group for the Redevelopment of BPL [WITN4461051]. I noted that they would centre on the production of SPPS from which it should be possible to extrapolate potential plasma protein fraction production levels. The minutes recalled a discussion of the role of PFC, Liberton and its effect on target capacity:

> *"Dr Walford suggested that, subject to the result of PFC's shift working experiment, it may prove uneconomical to divert resources to Liberton to enable it to fractionate English plasma. PFC's capacity was so small compared to that required to reach self-sufficiency in England and Wales as to be within the acceptable "margin of error" for assessing BPL's capacity."*

30.8. The minutes of the Scientific and Technical Committee for the Central Blood Laboratories meeting held on 24 November 1981 [WITN4461058] (which I attended as one of the joint secretaries) record that Dr Lane reported back on observations of PFC's shift-work experiment. This was a two-week experiment that had taken place recently. Dr Lane plainly had reservations about what had been observed and "doubted whether it would give an accurate indication of PFC's potential capacity." Dr Dunnill felt that useful information would be derived from the exercise, including whether PFC could handle more plasma.

The same minutes record the desire of the Policy Steering Group on the redevelopment of BPL to encourage greater collaboration between BPL and PFC.

30.9. There was further comment on the shift-working experiment in the fourth meeting of the Policy Steering Group for the Redevelopment of BPL on 18 December 1981, where Dr Lane set out his reservations about the Liberton production experiment. In particular, the study had only examined one part of the production process [CBLA0001517]. The Group noted that "...it was essential to obtain a firm commitment from the Scottish Home and Health Department of the amount of plasma from England which PFC, Liberton could fractionate. The Group asked Mr Harley to press SHHD for this information as a matter of urgency."

30.10. One of the documents which has been supplied to me is a late draft of Dr Lane's witness statement dated 10 December 1990[4] [WITN4461074]. At paragraph 334 he describes his reservations in more detail.

> *"It was all very well fractionating plasma on a continuous basis, but the facilities both up and down stream had also to be capable of handling the raw product and end product from the continuous manufacturing process. The experiment at PFC Liberton was inconclusive (as paragraph 7 of the minutes show), and the commitment of the SSHD to PFC Liberton would be critical to the mode of its future use."*

30.11. A lengthy letter from SSHD to Mr Harley followed on 11 January 1982 [WITN4461075] setting out the conditions that would have to be fulfilled before progress could be made. It was said that first, shift-working could not take place regularly until pay issues had been resolved, through the usual Whitley Council machinery that regulated NHS pay at the time. Second, more ancillary facilities would have to be provided (for freeze-drying, packaging etc), and land would be needed for those. The overall capital costs would be about £6 – 7 million and take about 2.5 years to complete. In principle, PFC could process 200,000 litres of English plasma annually – but subject to those conditions,

[4] I understand that this a draft statement only; it was supplied to me by the Inquiry for the purpose of preparing this Statement.

30.12. A paper commenting on the topic was received at the next meeting, on 1 March 1982 [DHSC0002215_087] (I was not in attendance). With regards to the possibility of Scottish fractionation of English supplies, the minutes record:

> *"Mr Harley reported that he had received a response from SHHD which indicated that PFC, Liberton would not be able to fractionate any substantial quantity of English plasma without the introduction of a 3-shift working system. Mr Harley had asked DHSS Personnel Division to consult their Scottish colleagues on the possibility of reaching an agreement on shift-working, but he was not hopeful of receiving even a preliminary answer before late April.*
>
> *The Group agreed therefore that in planning the redevelopment of BPL it should not anticipate any contribution from Liberton."*

30.13. It therefore appears that the potential Scottish contribution was dependent on PFC being able to increase capacity by introducing shift working. However, it also seems that Mr Harley was handling this correspondence. I have referred above to the submission drawn up by Mr Godfrey dated 22 September 1982 (copied to me) that recommended to Ministers that a new BPL should be built [WITN4461060]. The submission "explores, but discounts on financial and other grounds, the possibility of using the Scottish fractionation plant at Liberton to meet some of our needs".

30.14. This seems to have continued to be the understanding into 1983 and until I left; thus in October 1983, Dr Oliver wrote "...it is just not feasible to transfer a significant amount of production to Scotland and there really is no alternative but to continue production at Elstree…" [DHSC0002235_013]. Colleagues may be able to assist with any further information needed on this topic.

31. Q31: Evaluation of attempts at self-sufficiency

31.1. I have been asked for my views on how successful the DHSS's/Government's attempts to achieve self-sufficiency were and to what extent insufficient funding was a reason for the failure to achieve self-sufficiency.

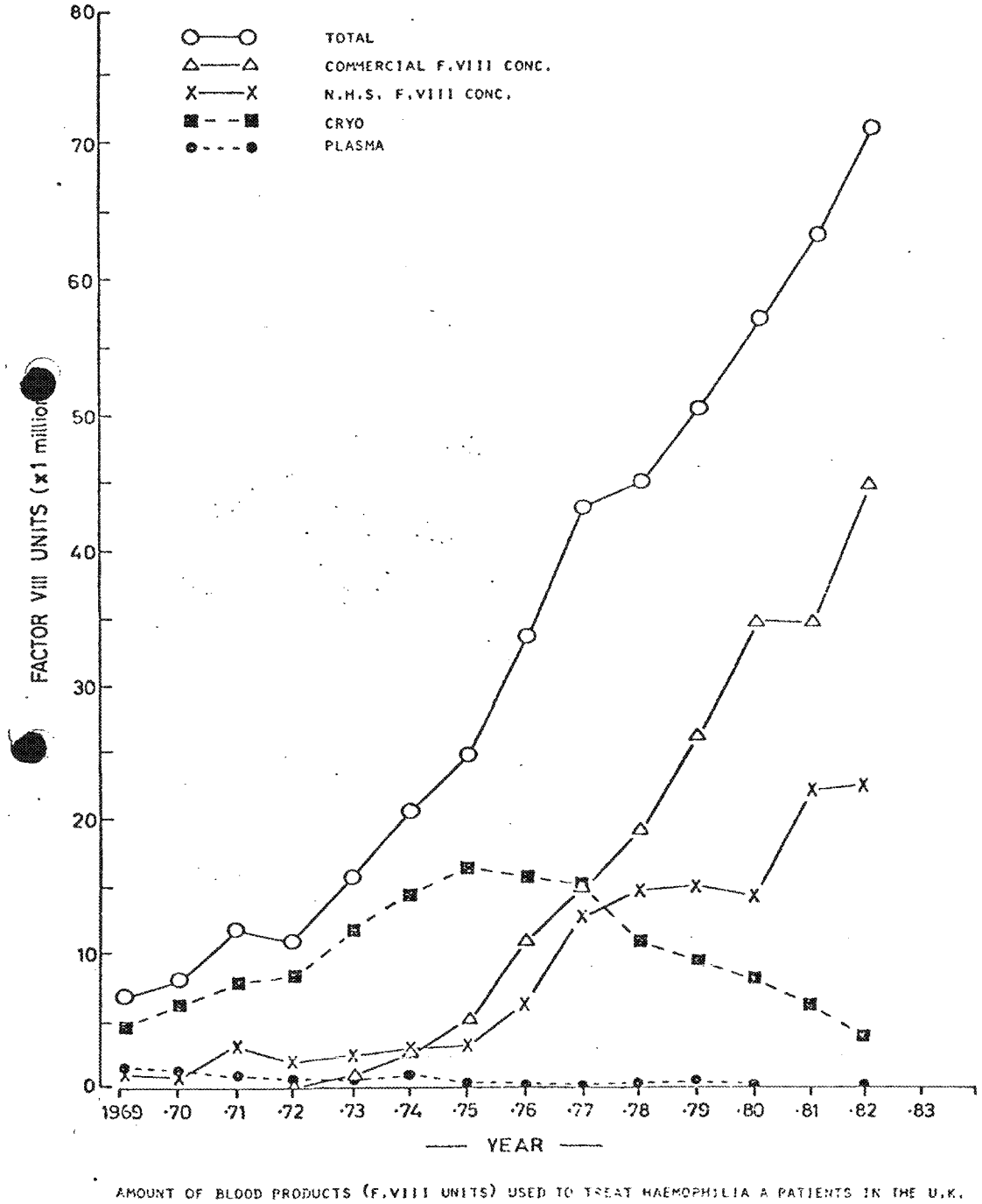
31.2. This is an extremely broad question that ranges over numerous issues, time-periods and changes of Administration, as well as involving many different

organisations (RTCs, RHAs, BPL, DHSS and Haemophilia Centre Directors). The pursuit of self-sufficiency was happening outside my sphere of responsibility which was limited to assisting in (from a medical perspective) the redevelopment of BPL and work on predictions of demand for plasma. Furthermore, I was only involved in this area from September 1979 to December 1983. I hesitate to tackle this large issue because of these limitations. However, since I have been asked for my view, I have set it out below with reference to my time in Med SEB.

31.3. During this time, the UK was nowhere near self-sufficiency, if that is defined as having sufficient plasma from UK voluntary donors to meet all the demands at the time for blood products, without recourse to imported commercial products. I have included in my statement below a copy of the graph prepared by Dr Craske in his annual report for 1982 for the Hepatitis Advisory Group for the UKHCDO [WITN4461076]. This clearly illustrates the pattern of escalating demand and the significant gap between that demand and the ability of BPL and cryoprecipitate to meet it. It also shows the increase in BPL production from 1980 to 1982 as well as the steep fall in the use of cryoprecipitate.

Copy of graph at page 15 of exhibit WITN4461076

FIG. 2.



AMOUNT OF BLOOD PRODUCTS (F.VIII UNITS) USED TO TREAT HAEMOPHILIA A PATIENTS IN THE U.K.

31.4. Self-sufficiency required adequate supplies of UK-derived plasma and appropriate fractionation facilities. Although there was a policy commitment to achieve self-sufficiency, when I joined MED SEB in 1979 the reality was that BPL had been condemned by the Medicines Inspectorate and it would have necessarily taken at least four to five years to plan and execute a redevelopment of such a complex manufacturing plant.

31.5. Furthermore, there was a need to increase substantially the amount of plasma available to BPL. In principle, the RTCs were willing to try to increase the plasma supply but there were major funding and logistic issues, including the need to set up multiple plasmapheresis centres. In any event, the increase in supply could only match an increase in BPL's capacity since the two had to proceed in tandem. Despite all the difficulties faced by BPL in responding both to the Medicines Inspectorate's findings and in planning its redevelopment at the same time, it did manage to achieve a substantial increase in capacity as Dr Craske's graph illustrates. This increase in capacity was, in fact, funded by the DHSS despite all the constraints on its funding. But any more substantial increase in capacity was dependent upon a new BPL.

31.6. There has been a suggestion that spare capacity could have been used at PFC. I was very keen to explore this possibility at the outset (it was in my early scheme of September 1979). But further exploration showed that it was not a realistic possibility primarily because the Centre was never going to adopt the 24-hour shift working for which it had been built and which would have been essential in order to provide sufficient capacity. I was not directly involved in matters to do with PFC, but I believe there were at least two reasons why 24-hour operation was not introduced: first, trades union opposition and the significant cost of shift work; second, in practice, it turned out that the continuous working was dependent upon further and expensive improvements. Please see my answer to question 30.

31.7. I strongly believe that a lack of funding was the major impediment to making progress swiftly, as far as the redevelopment of BPL and increase in plasma supplies from the NBTS were concerned. Had money been less constrained in 1979, it would have been possible to expedite planning for a new BPL whilst simultaneously making more extensive improvements to the existing plant.

Those improvements could have run in tandem with efforts, supported by the necessary funding, to increase substantially the plasma supply. It would still in my view (although I am no expert) have taken at least four to five years to plan, build and commission a new factory; but a new BPL might have been available sooner.

Section 3: Relationships between the DHSS and others

32. Q32: The role of the DHSS with regard to Blood and Blood Products

32.1. I have been asked to describe the DHSS's role (during my tenure) in relation to the licensing and regulation of blood and blood products, and to set out the principal organisations, committees or other bodies involved in the licensing and regulation of blood and blood products.

32.2. I have briefly outlined the process for licensing of blood products above (see my time in Medicines Division, paragraphs 2.14 - 2.16 above) and I have provided some additional detail at 32.3 - 32.5 below. However, I have no reference material on this issue (with the exception of the minute from Dr Holgate, see below) and I have had to rely on my memory. The account below is accurate to the best of my recollection.

32.3. The Medicines Act 1968 provided the legal framework for the control of medicines in the UK. It required medicines to be licensed (to have a Product Licence) before being allowed onto the UK market. The importation and manufacture of biological products, such as blood products, was further controlled under the Therapeutic Substances Act (1958).

32.4. The Committee on the Safety of Medicines (CSM) was a committee of the statutory Medicines Commission (established under the Medicines Act). The CSM made recommendations to the Licensing Authority (comprising the Secretaries of State for Health and Agriculture, and the Secretary of State for Scotland) as to the granting or withholding of approval of a licence for a new drug, or a variation to the licence for an existing drug, or approval or refusal for a clinical trial or clinical trial exemption certificate. In practice, the Licensing Authority exercised its powers through the DHSS Medicines Division, on the advice of the CSM. A pharmaceutical company could appeal a decision of the CSM to the Medicines Commission, in which case a different Medical Assessor from Medicines Division would be assigned to support the Commission during

the hearings. The CSM's decision, if not appealed, was invariably accepted by the Licensing Authority. The decision of a Medicine's Commission appeal was likewise final.

32.5. For biological products, such as vaccines and blood products, each batch was subject to a process called 'batch release'. The National Institute for Biological Standards and Control (NIBSC) tested each batch to ensure it conformed in its composition to the specification against which it was awarded its Product Licence, including, amongst a host of other analyses, its potency. For example, in relation to Factor VIII concentrate, this was the concentration of Factor VIII in international units (i.u) per ml. Batches were also analysed to ensure they were free from potentially toxic or otherwise undesirable material. Every batch was subject to a protocol for review by NIBSC. Until NIBSC was satisfied with the quality and safety of the batch, it could not be released. If there was concern about a batch, a Batch Release Certificate would not be issued. This meant that the product could not be marketed in the UK. My recollection is that if a batch was not released, this was known as being subject to a 'Stop Order.' NIBSC was also empowered to require manufacturers to include particular labelling requirements and warnings on vials and packaging.

32.6. Blood itself was not subject to the batch release regime, since each unit of blood is *sui-generis* and cannot be standardised. If blood was a raw material in a manufactured product, then it was caught under the Medicines (Control of Substances for Manufacture) Order[5] (see Dr Holgate's minute of 14 March 1978, [WITN4461077]).

33. Q33: The Licensing of BPL and PFC Blood Products

33.1. The Inquiry has asked for an explanation of how BPL and PFC blood products were licensed, or if not licensed, what regulatory oversight was in place to ensure the safety of these products in 1979. I have been reminded of a minute to Mr Harley, November 1979 [DHSC0003715_126].

33.2. To the best of my recollection, BPL and PFC products were not licensed in precisely the same way as commercial blood products. Whilst the manufacture

[5] SI 1971 no 1200.

of blood products at these facilities did come under the aegis of the Medicines Act 1968, they had 'Crown Exemption' under the Therapeutic Substances Act (again, see the minutes from Dr John Holgate, 14 March and 9 September 1980, below at 33.5). However, the policy established under Sir Keith Joseph was that, although the NHS did not need manufacturing licences, NHS manufacturing facilities should comply with the standards Medicines Division would require commercial manufacturers to observe (see Dr E. L Harris's submission to Ministers, 21 December 1979 [WITN4461078] and the Health Circular HSC(IS)144 of May 1975 referred to, which related to the scrutiny of RTCs [WITN4461079]).

33.3. In order to assist the Inquiry, I asked the Government Legal Department if they could establish, from the NIBSC, whether my recollections concerning the licensing of BPL, PFL and PFC products were correct. They supplied me with copies of two Reports from NIBSC, for 1978 - 1980 [WITN4461080] and 1983-1984 [WITN4461081] respectively. It is clear from the NIBSC Report for 1978 - 1980 that a new Blood Products Division was established in 1976 and that by the date of the report, NIBSC was examining protocols and samples of blood products from not only commercial fractionators but the laboratories at Elstree, Oxford and Edinburgh. A "fruitful dialogue" was said to have been established and the NHS products "have been found to be generally of excellent quality."[6]

33.4. The NIBSC report for April 1983 to March 1984 stated: "Although NHS fractionation laboratories are not technically under licensing control in England and Wales (unlike Scotland), samples and protocols of Factor VIII, Factor IX and albumin are sent to the Division from the Blood Products Laboratory (BPL), Elstree." But colleagues at NIBSC would be better placed to supply details of the nature of the control exercised and whether it encompassed the use of product licences and Batch Release systems.

33.5. In November 1979, in my minute to Mr Harley [DHSC0003715_126] I urged the importance of ensuring, for the future, that BPL and PFC products be subject to Product Licensing ("or its administrative equivalent"). This comment appears to imply that, at that time, they were not required to have product licences. But

[6] Report, p29.

I cannot now be sure. In a later minute to Mr Harley of 8 September 1980, I described the manner in which the system was being run, in practice, and the 'sea-change' that was occurring with regard to control over UK blood fractionators (following the Medicines Inspectors' adverse report on BPL). By way of further explanation of the controls then available, I attached a note, dated 14 March 1978, from Dr Holgate (Head of Biological Products, Medicines Division), which I said might need bringing up to date. A further note from Dr Holgate dated 9 September 1980 was provided. [WITN4461071, p5 – 10].

33.6. In their interim report, I note that the Penrose Inquiry, in Chapter 12, 'Licensing', provides an overview of the Regulatory Framework under the Medicines Act 1968. This Chapter also explains (paragraph 12.23) the doctrine of Crown Immunity. It was because BPL was covered by Crown Immunity, the Medicines Inspectorate's adverse report on manufacturing conditions at BPL stated that, were BPL a commercial manufacturing facility, they would have closed it down – but they did not do so.

33.7. As an aside, it is interesting to note Dr Holgate's suggestion in his 9 September 1980 minute that what he called "Crown Exemption" might not, in actual fact, have been applicable to BPL since, at the time the legislation came into force "the legal responsibility for BPL rested with the Lister Institute and not (as now) with the Regional Hospital Board" (He was meaning to refer, I would suppose, to the North West Thames Regional Health Authority).

34. Q34: DHSS understanding of fractionation

34.1. The Inquiry has asked what the DHSS's understanding was of the differences in fractionation processes amongst various manufacturers of FVIII products, in 1980.

34.2. The Licensing Authority (and therefore relevant staff within Medicines Division) will have been supplied with details of the fractionation processes used by various manufacturers when they applied for licences. This information was commercially confidential.

34.3. Within the wider DHSS, I doubt there was any significant degree of understanding of any fractionation methods, let alone the different fractionation

methods of different manufacturers. There will have been a greater understanding amongst relevant staff in Medicines Division. My own understanding of the fractionation processes at BPL I would describe as 'elementary' but adequate to the task of acting as interlocutor between Dr Lane and the Department at the time I was in Medicines Division.

35. Q35: DHSS policy for sharing information in product licences.

35.1. I have been asked about DHSS's policy with respect to sharing information contained in product licences and product licence applications pertaining to fractionation methods, with outside groups, such as UKHCDO.

35.2. Please see my answer to Question 34 above. It was not open to DHSS to share commercially confidential information obtained in its role as the Licensing Authority.

35.3. I am uncertain of the relevance of the UKHCDO minutes of 17 October 1983 [PRSE0004440], to which the Inquiry has referred me. That meeting (to which I sent apologies) did not discuss issues relevant to information contained in product licences or applications and, even had I been present at the meeting, I would not have been in a position to provide any such information.

36. Q36: Relationship between the DHSS and the National Blood Transfusion Service (NBTS).

36.1. The Inquiry has asked for a description of the working relationship between the DHSS and the National Blood Transfusion Service (NBTS), including:

> *a. the lines of communication between the DHSS and NBTS, including how information was shared between the organisations,*
>
> *b. the principles and policy objectives which underpinned the relationship between the DHSS and the NBTS;*
>
> *c. the internal structure at the DHSS for managing the relationship with the NBTS, including the role of the DHSS official(s) present at any NBTS meetings;*

d. any areas of overlapping responsibility between the DHSS and the NBTS, and how these were navigated;

e. how information received by the DHSS from the NBTS was communicated to ministers, including the standard information ministers would be briefed on when first taking office;

f. how ministers were kept up to date with developments in the NBTS.

36.2. The NBTS was not a corporate or unified entity, as such; there was no constitution, governance or overarching management structure. It consisted of some 14 Regional Transfusion Centres (RTCs), managed individually by their Regional Transfusion Directors (RTDs). The RTCs were funded by their Regional Health Authorities (RHAs) - some more generously than others, there was no standard model - and the RTDs were variously accountable to the Regional Medical Officer or another RHA officer. There was no management relationship between RTDs and the DHSS.

36.3. The DHSS had no managerial authority over the NBTS or its constituent RTDs. RHAs were accountable, through their Chairs, to the Secretary of State (SoS) but their accountability encompassed all of their Region's NHS activities and their RTCs would have been unlikely to be a prominent feature in any of their accountability meetings, unless there were a specific issue to be addressed.

36.4. Whilst RTDs met collectively in RTD meetings, which were generally attended by DHSS officials, there was no overarching management structure. Discussions at national level relating to blood transfusion took place in the Central Committee for the National Blood Transfusion Service. Although the meetings were held at the Department, all the members of this committee, including the Chair, were external to the DHSS, which supplied the secretariat. I note I attended one of these meetings, on 23 January 1978, as a representative of Medicines Division. The last meeting of this Committee appears to have been in the Autumn of 1978. It was replaced, in effect, by the Advisory Committee on the Blood Transfusion Service (see below).

36.5. In addition to the means discussed above, information was passed to the DHSS by the Consultant Adviser to the DHSS (Dr Tovey and then Dr Gunson).

36.6. There was no central coordination between the RTDs and the Central Blood Laboratories. This was a constant and understandable concern of Dr Lane. Without appropriate coordination between RTDs and BPL, in particular, there would be great difficulty in achieving national self-sufficiency in the supply of the plasma needed to provide all the FVIII and albumin required.

36.7. With the approval of Ministers (see Request 38) a new committee was set up in 1980 whose role was to try to address that lack of coordination. Its title was the Advisory Committee on the Blood Transfusion Service. The Committee was chaired by the DCMO, Dr E.L. Harris and its members included representatives from the Regions and Dr Gunson. I was a member of the secretariat.

36.8. The first meeting of the Advisory Committee of the NBTS was held on 1 December 1980. Its role was: "To advise the Department of Health and Social Security and the Welsh Office on the coordination of the development and work of Regional Transfusion Centres and the Central Blood Laboratories in England and Wales and the English and Welsh Blood Transfusion Service with those of Scotland and Northern Ireland".

36.9. It is worth noting that it was at this meeting that there was a discussion of a proposal for the pro-rata distribution of blood products to Regions from BPL in proportion to the amount and quality of the plasma they sent to BPL. The proposal made by Dr Lane, was that this system be introduced from 1 April 1981. This proposal was accepted, in principle, by RHAs, but there remained some problems, for example the needs of special units. Subsequently, the papers I have seen show a draft letter from Mr P Wormald to Regional Administrators (copied to Regional Treasurers) seeking their comments on the pro-rata proposal and asking them to confirm their willingness to increase plasma supplies to BPL from 1981/82. [WITN4461071]

36.10. To help in completing this picture, I can draw attention to a report by the NHS Management Consultancy Services in October 1987, entitled: The National Blood Transfusion Service in England and Wales: An Organisational Study. The Inquiry may find this report of considerable assistance in understanding the structure, function, organisation and funding of what, despite its name,

remained not a national service, but a "loosely federated collection of Regional Transfusion Centres" (paragraph 1.3 on page i, [WITN4461082]).

36.11. With regard to the role of Ministers, information to Ministers about the NBTS would be sent on specific issues requiring decision or when briefing was required in relation to particular problems that had arisen (see Q38 for a specific example). On first taking office, the Minister with specific responsibility for the service would receive a full briefing on all issues relevant to that Minister's portfolio. I do not have access to such briefings now.

37. Q37: Funding for Blood Services

37.1. I have been asked to explain how the blood services were funded at this time (i.e. in the late 1970s and early 1980s), and, if there were changes in the funding arrangements over this period, to describe them. I have been asked to address the following specific issues:

> *a. Did the DHSS decide how much money should be allocated to RTCs, or was that a decision for the relevant RHA?*
>
> *b. Once central funds were allocated to RTCs, how much autonomy did they have over the expenditure of funds?*
>
> *c. What if any role did the DHSS have in deciding and/or advising how monies should be expended?*

37.2. I am afraid I am not in a position to answer this question. I was not involved, at the time, in matters relating to the funding of the RHAs or RTCs. This is a question that would be better answered by an administrative colleague from Finance Division and/or by a member of the Directorate in the NHS Management Executive responsible for Regional Health Authorities.

38. Q38: Knowledge of proposed reorganisation

38.1. I have been asked to describe my knowledge of, and involvement in, a proposed plan for the reorganisation of the National Blood Transfusion Service set out in a letter and plan from Dr Tovey dated 28 February 1980 [DHSC0002197_089].

38.2. On 28 February 1980, Dr Geoffrey Tovey (Consultant Adviser in Blood Transfusion), wrote to Dr RM Oliver, setting out the views of "all consultants in the NBTS" that there was a need for more effective central co-ordination of the Blood Transfusion Service. He outlined the disadvantages of the current system and argued that a Central Co-Ordinating Committee was needed. The accompanying paper noted the aspiration to increase co-ordination with colleagues in Scotland; inviting Scottish colleagues to attend as observers would be a first step towards that end. I was not copied-in to Dr Tovey's minute to Dr Oliver and I do not know whether I would have seen this document at the time.

38.3. I note that the 179th meeting of the Regional Transfusion Directors on 25 June 1980, [WITN4461083] was chaired by Dr Tovey. I attended as one of the observers from the DHSS, together with Dr E.L. Harrris and Mr Harley, Mr Dutton, Mrs Yuille and Mrs Tunnard. Dr Harris spoke on the future of the NBTS. According to the minutes, he stated that: "...the Regional Transfusion Service would not be affected in any major way by the re-structuring of the National Health Service. However, the effects of the cuts in central spending would be felt throughout the service, including the Transfusion Service." He updated the Directors about the future of BPL and the Ministerial visit (covered in Section 2 above). On the specific topic of re-structuring, he stated:

> *".. it had now been recognised that there was a need to set up as soon as possible an advisory committee for the NBTS as proposed by the Chairman, which would receive plans and exchange ideas on the aims and development of the Transfusion Service, including the Central Laboratories and generally advise on co-ordination. It would be a small but effective committee and would in effect replace the Central Committee for the NBTS. Membership would include representation from Transfusion Directors, from the RHAs and the Central Laboratories."*

38.4. The proposal was shortly to be put to Ministers. The Directors are minuted as wishing to ensure that the committee would consider not only the supply of blood products and plasma but wider questions of policy for the NBTS.

38.5. Further details are set out in a submission [see WITN4461084] and sent to the Minister (Dr Vaughan) on 10 July 1980 by Dr Oliver [see WITN4461085]. The submission was based on an informal agreement that apparently had been reached between the Minister and the CMO, that the new committee would replace the existing Central Committee for the NBTS (which had existed since 1975). The paper was intended to seek formal approval from the Minister. The Terms of Reference would be the same. It noted that at present, Scotland was not a member, but presumably that could be amended at a later date. The submission noted that the existing Committee had not met since autumn 1978, having been unable to provide the requisite quality of advice, and there was now a greater need than ever for an effective committee to advise on the coordination of all the supra-regional functions of the NBTS. Proposals had been put forward by the RT Directors through their Chairman Dr Tovey (consultant adviser in Blood Transfusion). The Minister was asked to approve these changes.

38.6. The handwritten comments on the covering note to the submission [WITN4461085] confirm that the Minister approved the changes on 17 July 1980.

38.7. A paper for the Joint Management Committee of the CBL ahead of its meeting on 22 October 1980 noted the agreement to the Central Committee for the NBTS being replaced by a smaller Advisory Committee whose membership would be representative of, and restricted to, those most concerned with the Blood Transfusion Service and RHAs. The first meeting was to be on 1 December 1980. [WITN4461086]. Dr Harris was to be the chair with a selection of RHA members (including Dr Gunson and Dr Jenkins) and Dr Lane and Dr Tovey (consultant adviser in Blood Transfusion to DHSS). The secretariat was to be made up of Mr Godfrey and myself.

39. Q39: Letter between Dr Wood and Dr Lane dated 10 March 1980

39.1. The Inquiry has drawn attention to a letter [BPLL0010130] between Dr Wood of the South London Blood Transfusion Service and Dr Lane of BPL dated 10 March 1980. In this, Dr Wood stated he had sent me and Dr Tovey at the DHSS

his initial draft "more in hope than expectation but it might penetrate the labyrinth of the DHSS!". I have been asked:

> *a. To your knowledge, was Dr Wood's perception of the DHSS, as set out in this letter, shared with others who had dealings with the DHSS?*
>
> *b. Do you consider Dr Wood's comment to be fair?*
>
> *c. Did you/the DHSS agree with the view set out in Dr Wood's draft document, namely that "the imposition of strict liability on the Transfusion Service will undermine the relationships of donor and doctor, and those of the professions and the Department of Health, which finances the Service. It will eventually destroy the NBTS as we know it"?*

39.2. I do not know whether others may have shared Dr Wood's views about the labyrinthine nature of the Department, but it appears that he felt that I, at least, was sufficiently accessible to be sent a document that was intended to be directed elsewhere. I cannot say, at this remove, what view, if any, I may have taken on the subject matter of his draft, nor what may have been the view of the DHSS.

40. Q40: Proposal that Factor VIII should be held by RTCs

40.1. I have been asked about the Minutes of the Advisory Committee on the NBTS, Third Meeting (22 June 1981, [WITN4461087]), which record a proposal that all supplies of Factor VIII should be held by RTCs. I attended as part of the Secretariat (together with Mr Godfrey and Mrs Yuille). Under the minutes of the Haemophilia Centre Directors, a discussion is recorded, first, about self-sufficiency and the probable rise in demand in Factor VIII in the UK. The minutes then continue:

> *"4. Dr Walford reported that the suggestion that all supplies of Factor VIII should be held by RTCs had also been raised [at the meeting with the Directors of the Haemophilia Centres], but Haemophilia Centre Directors' reactions had not been favourable. They feared that such an arrangement might mean that they would be unable to obtain commercial supplies of their choice, although it was explained that*

Haemophilia Centres' requirements for all forms of Factor VIII would indeed continue to be met as at present.

5. Dr Bird [West Midlands RHA] and Dr Darnborough [East Anglian RHA] explained that central supply arrangements were working well in their Regions and that there was always full consultation with Haemophilia Centre Directors before supplies of Factor VIII were ordered. Members thought that in time Haemophilia Centre Directors would reconsider that matter and eventually, perhaps after NHS reorganisation, it might be appropriate for all blood products to be held and issued by the RTCs. Meanwhile it was agreed that the Secretariat should draw up a list of those Regions already operating a central supply system for Factor VIII."

40.2. I attended the next meeting of the Advisory Committee on 28 September 1981 [WITN4461088], on the same basis. Dr Tovey reported on the discussions with the Haemophilia Centre Directors and the Regional Transfusion Directors which had taken place on 15 September 1981. The minutes of that meeting [WITN4461089] were included, for information, in the papers for the Advisory Committee as paper AC(81)21. The Advisory Committee minutes continue: "Haemophilia Centre Directors were aware of the need for close liaison with RTDs on the provision and usage of Factor VIII and accepted the need to provide accurate picture [sic] of the extent to which Factor VIII was being purchased within their Regions. It had been agreed that Haemophilia Centre Directors would keep RTDs informed on commercial purchases, probably by means of a monthly return although details were left to the Directors to work out locally" [WITN4461090].

40.3. The history is explained fairly well by these minutes. It is an illustration of the importance attached by Haemophilia Centre Directors to their clinical freedom, including – here – in respect of purchasing decisions relating to particular brands of commercial Factor VIII. This was a freedom they had which they did not wish to lose.

41. Q41: Concerns about Record Keeping

41.1. The Inquiry has drawn attention to my letter of 3 March 1982 to Dr Wagstaff of Trent RTC and correspondence that followed [CBLA0003306_001, CBLA0012794, CBLA0012795, DHSC0001136, NHBT0010083, DHSC0002215_098 and DHSC0002215_099]. I have been asked to explain the concerns about record keeping which led to this letter being sent and describe the steps taken by the DHSS and/or NBTS to secure improvements in the system of record keeping.

41.2. This correspondence refers to the Department's attempts to investigate allegations in the press about misuse of blood at the National Heart and Chest Hospital. I enclosed, with my letter to Dr Wagstaff (Chairman of the RTDs' meeting), the answer given to a Parliamentary Question on the subject, by the Secretary of State, Norman Fowler. A Committee of Inquiry, set up by the hospital's Board of Governors, had revealed serious procedural defects at the hospital. The Report also suggested that there was a need for improved record-keeping procedures in the blood transfusion service. The nub of the problem was that RTCs did not keep adequate records which would allow them to trace the ultimate fate of a unit of donated blood. To do this would have required hospital blood banks to maintain records of the end user of the blood, including the fate of out-of-date blood, and to make regular returns of this information to the relevant RTC.

41.3. Without such records, it was impossible, for example, for the relevant RTC to follow-up on a donation that had apparently caused an adverse reaction in the recipient and it was impossible to know whether time-expired units, unsuitable for donation had been returned to the RTC for onward transmission for fractionation by BPL (e.g. for plasma protein fraction production), which would also have resulted in loss of revenue for the RHA under the pro-rata system for the provision of blood products to Regions by BPL. The other concern would be that, without adequate records, the system was open to abuse; namely the unauthorised and possibly illegal supply of blood outside of the NHS.

41.4. I asked Dr Wagstaff, as a matter of urgency, to investigate this matter, with his fellow-Directors, with a view to preparing a report on record keeping in the

NBTS and hospital blood banks, for the Advisory Committee on the NBTS which was scheduled to meet on 31 March.

41.5. A report was prepared jointly by Drs Wagstaff and Gunson, to the Advisory Committee on the NBTS, based on a survey they had conducted of records kept by the RTCs. There had been insufficient time to obtain detailed information about record keeping from individual blood banks.

41.6. The minutes of the Advisory Committee record that, after discussion, it was agreed that:

i) the DHSS Management Services Division should be consulted about options for record-keeping systems for blood and blood products;

ii) Mr Baker would discuss within Northern region the practicalities of introducing a monthly summary of blood use, to be completed by hospital blood banks for the information of the RTC and, in the light of (i) and (ii) above;

iii) DHSS guidelines on supplies of blood to hospitals should be updated. The opportunity should be taken to draw attention to the booklet "notes on Transfusion" which was being revised by RTDs.

41.7. It was noted that computerised record keeping, with links between the RTCs and hospital blood banks, would provide better control, but the resource implications of installing such a system had to be assessed and balanced against the potential benefits.

41.8. I do not have any documentation which would allow me to describe what improvements may ultimately have been introduced, but that may be available from the updated DHSS guidelines referred to in (iii) above.

42. Q42: Working Relationship between the DHSS and BPL

42.1. I have been asked to describe the working relationship between the DHSS and BPL, with reference to a number of specific topics, set out below.

a) The lines of communication between the DHSS and BPL, including how information was shared between the organisations.

42.2. There were several lines of communication between the DHSS and BPL. First, there was the Joint Management Committee for the Central Blood Laboratories, chaired by Dr E. L. Harris, DCMO. Its Scientific and Technical Committee was chaired by an external expert, Professor Mollison, but the DHSS provided the secretariat (I was joint secretary with Mr S Godfrey). The CMO's Consultant Adviser, Dr Tovey was also a member. There was much interaction at that Committee between Dr Lane and the Committee and free exchange of information between the members and the Secretariat

42.3. Second, I had a role liaising with Dr Lane on technical issues and visited him at BPL quite frequently, reporting back from those meetings to colleagues, particularly in HS2.

42.4. Following the adverse report from the Medicines Inspectorate and the need for detailed planning on remedial action, contacts between Dr Lane and the DHSS (Med SEB and HS2 particularly) intensified. I also chaired a working party involving Dr Lane, to prepare technical and policy briefings for Supply Division for their negotiations with industry; and a project committee overseeing the project management for the interim upgrade of BPL. I have outlined these matters in Section 2.

42.5. Dr Lane would also write to me, and others, at the Department from time to time.

42.6. Once the Joint Management Committee for the Central Blood Laboratories was abolished and replaced by the Central Blood Laboratories Authority, Departmental attendance at the meetings of the Authority was not allowed, except by the DCMO, Dr Harris. However, the Scientific and Technical Committee of the former Joint Management Committee became a sub-committee of the CBLA, so communications between the Department and Dr Lane were not disrupted.

b) the principles and policy objectives which underpinned the relationship between the DHSS and BPL

42.7. BPL was a manufacturing facility wholly owned and funded by the Government (DHSS) and, therefore accountable to the Secretary of State. The same was the case for the Blood Group Reference Laboratory (BGRL) which provided reference blood group typing services to the whole of the NHS.

42.8. The DHSS was not set up in any way to manage BPL on a day-to-day basis and therefore jointly provided the managerial oversight of the Laboratories with the North West Thames Regional Health Authority.

42.9. This arrangement did not work very effectively, which was the stimulus to establishing the Central Blood Laboratories Authority. The members of the Authority were all independent of the Department. Nevertheless, the Authority was still, ultimately, funded by the DHSS.

42.10. My view is that both in principle and in policy terms, it was essential that BPL remained accountable to the SoS, albeit through the CBLA, since its role was inextricably bound up with that of the National Blood Transfusion Service, without which it would have no raw material for its products. Safeguarding the NHSBT and ensuring blood donation in this country remained a voluntary service was a fundamental 'non-negotiable' for the Government.

c) the internal structure at the DHSS for managing the relationship with BPL, including the role of the DHSS official(s) at any BPL meeting;

42.11. I believe I have largely answered this question at (a) above. Whilst officials did not routinely attend BPL meetings, there were many ad-hoc meetings between Dr Lane and officials, including meetings with, and inspections by, the Medicines Inspectorate.

d) how information received from BPL was communicated to ministers, including the standard information ministers would be briefed on when first taking office;

42.12. Information to Ministers about BPL was on specific issues requiring decision or when briefing was required in relation to particular problems that had arisen.

On first taking office, the Minister with specific responsibility for BPL would receive a full briefing on all issues relevant to that Minister's portfolio.

e) how ministers were kept up to date with developments at BPL.

42.13. Ministers were kept up-to-date on developments in relation to BPL where policy issues or significant problems had arisen or where funding decisions, outwith BPL's normal allocation, were required. In general, HS Division was responsible for initiating briefings or preparing submissions for the Minister (or Ministers), if the issue was likely to be the subject of media reporting or public concern.

43. Q43: Visit by Lord Glenarthur to BPL, July 1983

43.1. I have been asked to set out what I can recall of a visit to BPL by Lord Glenarthur (Joint Parliamentary Under-Secretary of State) on 21 July 1983, accompanied by me (see 75.1 of the enclosed minutes of the CBLA meeting on 27 July 1983 [CBLA0001732]). I have been asked about the purpose of the visit and what was discussed.

43.2. I have no memory of the visit by Lord Glenarthur, except that it occurred. I can see from the minute of the CBLA meeting on 27 July 1983 [CBLA0001732] that the Minister was also accompanied by Dr E.L Harris and Mr John Harley (HS2). The minutes also report that Lord Glenarthur toured the manufacturing unit and enjoyed his visit. I have not been supplied with any other documents relating to the visit.

44. Q44: Relationship between the DHSS and UKHCDO

44.1. I have been asked to: "describe the working relationship between the DHSS and the UK Haemophilia Centre Doctors Organisation ("UKHCDO")."

44.2. During my time in Med SEB, the acronym UKHCDO stood for the 'UK Haemophilia Centre Directors' Organisation'. This is a rather important distinction, because the organisation was much smaller than it subsequently became, once it had been broadened out to include all haemophilia centre doctors. I had no dealings with the larger organisation, which was set up as a registered charity in 1991.

a) the lines of communication between the DHSS and the UKHCDO, including how information was shared between the organisations;

44.3. As a member of Med SEB, I attended meetings of the UKHCDO as a DHSS observer and was free to contribute to their discussion and to relay any information of interest to them from the Department, and to report back, similarly, items of interest to the Department. I did not attend the more specialised meetings of the Haemophilia Reference Centre Directors, other than by invitation or, on occasion when I specifically asked to attend to hear, or communicate about, an important issue.

b) the principles and policy objectives which underpinned the relationship between the DHSS and the UKHCDO;

44.4. The UKHCDO represented, for the DHSS, the group with relevant expertise in a rare disease which consumed a very significant resource in terms of the activities of the BPL and the NBTS, as well as of the budgets of RHAs in terms of the provision of hospital and rehabilitation and other services for haemophiliacs and the need to purchase commercial concentrates.

c) the internal structure at the DHSS for managing the relationship with UKHCDO including the role of the DHSS official(s) at any UKHCDO meeting;

44.5. There was no line of management or other form of control that the DHSS could operate in relation to the UKHCDO. Ensuring that there was dialogue with the organisation was the only effective way of exerting some influence, should it be needed.

d) how the DHSS ensured the UKHCDO was informed and kept up to date about the risk of infection from blood and blood products;

44.6. In general, the Haemophilia Centre Directors (HCDs) were likely to know about or become aware of the risks of infection or the appearance of new infections from blood and blood products as soon, or even sooner, than the DHSS was notified of them. If there was a newly detected infection risk from a specific batch of blood product, the Licensing Authority would take the necessary action, including notifying users. The NBTS played a major role in the detection of new infectious hazards to the blood supply, and local RTCs would be in communication with all their users, including HCDs. The Communicable

Disease Surveillance Centre was responsible for the surveillance of blood-borne infections and reported their findings in the CDR and to the DHSS. If the DHSS needed to ensure that clinicians were alerted to such an issue, the information would go to the whole of the NHS, not simply to HCDs.

44.7. In the particular case of post-transfusion hepatitis, HCDs had a particular interest, given that haemophiliacs could be the recipients of multiple blood transfusions as well as being exposed to large donor pool factor concentrates. The HCDs were also in continuing contact with their patients for much of their lives, so were able to study the natural history of post-transfusion hepatitis in a way not possible for clinicians in many other specialties. Hence, the UKHCDOs had established their own Working Party on Hepatitis, chaired by Dr Craske, virologist at Manchester PHL, who carried out surveillance of post-transfusion hepatitis and liaised both nationally and internationally with experts in the field. It is fair to say that the DHSS relied upon the regular reports produced by Dr Craske for the UKHCDOs, for much of our knowledge of post-transfusion hepatitis.

e) f) how information received from the UKHCDO was communicated to Ministers, including the standard information ministers would be briefed on when first taking office, and how Ministers were kept up to date with developments from the UKHCDO.

44.8. The UKHCDO was not directly accountable to Ministers, nor was it in any way responsible to the DHSS. Therefore, any information regarding the UKHCDO that was provided to Ministers was likely to be in relation to a specific issue where their views might need to be cited in a submission, for example, in relation, to the central supply and distribution of coagulation factor concentrates. Whilst it is possible that the existence of the UKHCDO might be mentioned in the induction briefing for the relevant Minister, I suspect it will not have been briefed about in any detail.

45. Q45: Relationship between the DHSS and commercial pharmaceutical organisations:

45.1. I have set out this request out in full:

Please describe the relationships between the DHSS and pharmaceutical companies involved in the manufacture, importation and/or supply of blood products. In particular, please address the following:

a. the lines of communication between the DHSS and pharmaceutical companies and the processes by which pharmaceutical companies conveyed their priorities, interests and capabilities to the DHSS;

b. the internal structure at the DHSS for managing the relationships with pharmaceutical companies;

c. the frequency with which DHSS officials met with pharmaceutical companies and the types of issues discussed;

d. how information received from pharmaceutical companies was communicated to ministers.

45.2. I do not consider myself sufficiently informed to answer this question. I had relatively few dealings with pharmaceutical companies, either in Medicines Division or in Med SEB. I believe that there will be those now in the Medicines and Healthcare products Regulatory Agency, or former colleagues from Medicines Division and Supply Division, who will be better able to assist.

46. Q46: Co-operation between DHSS's staff and private organisations.

46.1. I have set out this request in full:

By letter dated 24 June 1981 solicitors representing Cutter Laboratories Ltd wrote to the DHSS (letter enclosed DHSC0041319_203 and DHSC0041319_204) asking for "A statement as to the policy of the Department in relation to open or secret co-operation between its staff and private concerns; particularly where such cooperation is calculated to secure financial and other advantages for such concerns to the detriment of competitors". Please set out what the DHSS's policy and practice was in relation to co-operation (open or secret) between its staff and private organisations.

46.2. I have no memory of this correspondence and, on reviewing it, I note that while it was copied to me, it was addressed to Mr Sharpe of Supply Division, who passed it to Mr Harley, HS2, to respond. Mr Harley's manuscript note on Mr Sharpe's minute asks Mr Godfrey (HS2) to let me know that HS division will be dealing with the matter. Therefore, apart from having received a copy of the correspondence, I was not involved with the issues and do not feel qualified to answer; colleagues from HS may be able to assist.

Section 4: Relationships between DHSS officials and ministers, and the role of ministers

47. Q47: Decision making structure and processes:

47.1. I have been asked to describe the decision-making structures and processes were in place (and with what oversight) during my time at the DHSS to ensure:

> *a. comprehensive assessment of the risks arising from the use of blood and blood products;*
>
> *b. timely, co-ordinated and/or structured decision-making as to the nature and extent of any risks;*
>
> *c. timely, co-ordinated and/or structured decision-making as to any steps that should be taken to reduce or mitigate such risks; and*
>
> *d. adequate information sharing in relation to such matters between DHSS officials and ministers.*

47.2. Responsibility for the assessment of risks arising from blood and blood products did not rest with any one entity or organisation. The following is a list, not necessarily exhaustive, of the bodies I recall having particular areas of responsibility in relation to the assessment and management of such risks. I am not, here, including the responsibilities of the local NHS and local public health authorities.

Blood and blood components:

47.3. The responsibility for risk assessment and monitoring of the safety of blood and blood components rested with the National Blood Transfusion Service and the Regional Transfusion Directors.

Blood-borne infections:

47.4. The responsibility for the identification of blood-borne infections rested with the Communicable Disease Surveillance Centre (CDSC) of the PHLS, reporting to the DHSS (Med IMCD); CDSC provided evidence of the nature and extent of the hazard and the consequential risks and the PHLS provided public health microbiology specialist testing and support.

Biological products:

47.5. The responsibility for risk assessment of biological products such as coagulation factor concentrates rested with the manufacturers and the oversight was by the Licensing Authority, to which manufacturers had a duty to report problems with the quality or safety of their products. Problems might also be identified by NIBSC who could take action by refusing to issue a Batch Release Certificate. The Licensing Authority also maintained an adverse reactions to drugs monitoring system and a post-licensing enhanced monitoring system.

Risks to health service staff from contaminated blood, blood components and blood products:

47.6. The responsibility for monitoring risks to health care staff from infected blood or blood products rested with the employers and the HSE. The DHSS could issue guidance to the NHS, as necessary.

Committees advising the DHSS:

47.7. A series of committees advised the DHSS on risks related to blood and blood products, e.g. the Committee on Safety of Medicines (for blood products); the Advisory Committee on the NBTS; the Advisory Group on Hepatitis; the Advisory Group on testing for the presence of Hepatitis B surface antigen and its antibody; the Advisory Committee on Dangerous Pathogens etc. It may be

worth noting that, during my time in Med SEB, there was no overarching advisory committee on blood safety, such as the Committee on the Virological Safety of Blood which was set up, some years later, to advise the Government on blood safety issues.

47.8. Unless there were an identified hazard, with risks to the public health, which required a national response, the wider DHSS generally did not become involved in decision-making or risk mitigation, as this was best done by the responsible organisation, or through the Licensing Authority (administered through Medicines Division). In the event that a hazard was identified with potential national or serious ramifications for the public health, the DHSS would become involved and would work with Regional and local public health officials and the PHLS to take the necessary action and offer guidance to the responsible bodies. In such circumstance, Ministers would be promptly informed, briefed, submissions provided and would be asked to take decisions, as necessary.

48. Q48: Information exchange within the DHSS

48.1. The Inquiry has asked who was responsible within the DHSS, and what was the procedure within the DHSS:

> *a. for ensuring that the Department was kept informed of the growing awareness (internationally and/or domestically) about the risks arising from blood and blood products and the various national and international responses to such risks?*
>
> *b. for briefing ministers about the risks from blood and blood products, including any risks posed by the purchase of commercially supplied blood products?*
>
> *c. for ensuring that ministers were informed of changes in the understanding of relative risk?*

48.2. In England, the Chief Medical Officer's Consultant Adviser in Blood Transfusion was an important resource for ensuring the CMO was kept abreast of both international and domestic concerns and responses in relation to blood or blood products. The Consultant Adviser attended meetings of the World Health

Organisation (WHO), Council of Europe and other international bodies and conferences and reported back to the CMO on the key discussions. The International Relations Division was also involved in gathering information about international developments. The CDSC had good links with CDC Atlanta and with WHO and their counterparts in Europe and passed intelligence on to the DHSS.

48.3. Domestically, Medicines Division, Med SEB, Med IMCD and HS divisions would keep abreast of developments through contacts with, the PHLS and CDSC, the relevant specialist bodies, including the RTDs and the HCDs and by keeping a watching brief for relevant articles in the medical journals. In terms of blood products, the Director of the BPL was an important source of information.

48.4. If an emerging and significant issue was identified or a known problem was becoming of greater public health importance, Ministers were notified and briefed. Written briefing was generally provided by the relevant policy division, with input from medical colleagues and, in the case of an urgent public health problem arising, a meeting would be arranged as a matter of priority through the Minister's Private Office. In such cases, the CMO or a DCMO would usually be involved. Briefing might also be prepared for the Prime Minister, if the situation warranted it.

49. Q49: The extent that DHSS officials were forthright with Ministers.

49.1. I have been asked the extent that DHSS official were forthright with Ministers.

49.2. During my time in post in Med SEB, I had relatively few meetings with Ministers, although I quite often had to provide written briefing or prepare, or contribute to, submissions. So, my experience with regard to face-to-face briefings on communicable disease issues, stems mainly from when I was SPMO in Med IMCD. In my experience, it was never difficult engaging Ministers' attention in relation to communicable disease risks to the public health and it was top of officials' minds to ensure that Ministers were briefed as the issues emerged. Ministers took very seriously the advice offered by senior medical staff in the Department and I do not recall any instance in which the advice from the CMO

or one of his deputies was ignored. Obviously - and rightly - Ministers cross-questioned officials in relation to the facts and opinions offered, but there was no incentive other than to be forthright in these exchanges.

50. Q50: Ministers' decisions

50.1. I have been asked which decisions relating to blood and blood products were taken personally by Ministers.

50.2. I believe the Ministerial role in relation to decisions about risks from blood and blood products was no different from their role in relation to other significant public health risks. In my experience, the default position of officials would always be to seek Ministerial agreement to a course of action that had been fully explained in a written submission which presented a series of options for Ministerial decision.

50.3. A relevant example relates to the role Ministers played in agreeing that an information leaflet be provided for blood donors to ask them to self-exclude if they were in one of the higher-risk groups for AIDS. Ministerial agreement was required not only to the leaflet itself but also to its mode of distribution to donors. Ministers disagreed with officials' advice that the leaflet should be distributed with the call-up cards. Officials sought to argue that it would be less effective in deterring donors simply to leave the notices to be picked up at the donor session, but did not win that argument. I have described this in more detail in Section 6.

51. Q51: Identity of Ministers concerned with blood products

51.1. I have been asked to identify the Ministers I worked with in relation to the issues covered by the Inquiry. These were: Dr Vaughan, Mr Finsberg, Lord Glenarthur, Mr Kenneth Clarke and Mr Fowler.

52. Q52: Meeting on 11 June 1980

52.1. The Inquiry has noted that in a meeting about the development of BPL on 11 June 1980, Dr Lane warned that he advised strongly against providing

£500,000 in capital for 1980/81, and asked that his views should be squarely put to ministers.

52.2. I have been asked who was responsible for communicating this view to Ministers and to what extent was this view communicated to Ministers; and what the response of Ministers was.

52.3. I have addressed Dr Lane's views and the Ministerial submission which followed, in Section 2. The information that was put to Ministers can be seen there. Generally, the response to Dr Lane's concerns included: (i) agreement to an immediate additional £90,000 to be spent on cold storage facilities; and (ii) agreement to a revised plan which included, in addition to the £500,000 capital expenditure allowed for both 1980/81 and 1981/82, an additional £300,000 in the second year.

52.4. I do not know whether Dr Lane's comments were conveyed to Ministers. It would have been John Harley's responsibility to do that if he felt it necessary, but I presume he felt that the Department was proposing to Ministers that there should be additional funding, over and above the £500K which Dr Lane had felt to be inadequate, so that Dr Lane's concerns had, in fact, been addressed.

53. Q53: Hepatitis Advisory Group

53.1. The Inquiry has noted that on 27 June 1980, Phyllis Furnell sent me a memorandum [DHSC0000884] stating that ministers had agreed to the setting up of the Hepatitis Advisory Group with the 'strict proviso that there should be no other committees concerned with Hepatitis in operation'.

53.2. I have been asked to describe the respective roles of ministers and DHSS officials in:

a. setting up advisory groups;

b. determining their terms of reference; and

c. imposing any conditions on their functioning.

53.3. If officials concluded that there was a need for a new Advisory Group to be set up, this would be a matter to be agreed by Ministers. A submission would be prepared explaining why this new group was needed, what committee(s)

already existed and might be replaced or subsumed by the new committee; draft terms of reference would be proposed and an indication given of the membership and suggestions for a possible Chair. The submission would generally also cover the issue of the cost of setting up and running the Committee and which Division would be responsible for overseeing its operations.

54. Q54: Party Political Positions

54.1. I have been asked to describe any ways in which party political positions such as any manifesto pledges or public ministerial statements influenced the position taken by ministers, or had an effect on the decision-making process or actions taken by the DHSS, with regard to the safety of blood and blood products, the risks of viral transmission and the response to such risks.

54.2. I cannot comment on political matters. These would be matters for discussion between Ministers and their Special Advisers.

Section 5: Viral Risks Associated with Blood and Blood Products

55. Q55: Knowledge of hepatitis and the risks of infection associated with blood and blood products

55.1. I have been asked about my own knowledge and understanding of hepatitis and that of the DHSS about the risks of infection associated with blood and blood products and the relative risks of infection from commercially sourced versus domestically produced blood products.

55.2. My responsibility for blood products in the DHSS began in 1977 when, as a Senior Medical Officer in the Medicines Division, I was given the job of assessor to the Committee on Safety of Medicines, through its Sub-committee on Biological Products, for the assessment of applications for licensing of biological products, including blood products.

55.3. As a haematologist, trained also in blood transfusion, I was well aware of the risks of infection associated with blood and blood products. Learning about the infection risks, as well as other risks, such as the risk of blood group incompatibility, was a fundamental part of my training.

55.4. In 1978 I was invited by the publishers, Excerpta Medica, to write a chapter on '*Blood and Blood Products*" for the reference work '*Meyler's Side Effects of Drugs, Ninth Edition*' 1980 [WITN4461002] and a chapter on '*Blood and Blood Products*' in the '*Side Effects of Drugs Annual 4*' (1980) [WITN4461003]. These chapters were review articles, in which I reviewed recently published academic papers, principally about hepatitis, submitted to me by Excerpta Medica. The publications in which my chapters appeared were reference works intended for medical libraries.

55.5. These two chapters can be taken as illustrating the state of my knowledge regarding hepatitis B and non-A, non-B hepatitis at the time (1979) and their role in blood transfusion or coagulation factor infusion-associated hepatitis. It was this knowledge that I brought with me to my new post, as Principal Medical Officer, in Med SEB in September 1979.

55.6. In *Meyler's Side Effects of Drugs* pp 654-656, I describe the state of knowledge of the transmission of post-transfusion hepatitis associated with hepatitis A, hepatitis B and non-A, non-B viruses, recognising that other viruses, such as cytomegalovirus and the Epstein Barr virus could also cause transfusion-transmitted hepatitis, although this was not their principal clinical manifestation.

Hepatitis A

55.7. In relation to hepatitis A, the literature confirmed that this was very rarely associated with post-transfusion hepatitis.

Hepatitis B (HBV)

55.8. This section described the reduction from 30% to 10% of all cases of post-transfusion hepatitis that could be attributed to HBV, following the introduction of sensitive tests for screening of donor blood for Hepatitis B surface antigen (HBsAg). Despite the systematic screening for HBsAg, the risk of post-transfusion hepatitis remained greater for certain pooled plasma derivatives such as fibrinogen, antihaemophilic factor (Factor VIII), and prothrombin-complex concentrates than for single donations. This was partly explicable by the fact that that those fractions were often prepared from paid-donor plasma, in which the incidence of HBsAg-positivity was 10 times that in plasma from a non-commercial source; and antibody against the hepatitis B core antigen (anti-HBc) was found in HBsAg-negative sera from a commercial source five times more frequently than in HBsAg-negative sera from unpaid donors. A further explanation for the higher infectivity of these products of fractionation could be attributed to the unequal distribution of the infective particles in the different Cohn fractions, with most of the virus particles being retained in Fraction III from which the prothrombin-complex concentrates were derived. Other products, such as albumin were derived from a different Cohn fraction and were also subject to terminal pasteurisation. At the time of writing, there was no vaccine available against HBV.

55.9. In the *Side Effects of Drugs Annual*, pp 230-231, I described the significance of the finding of antibody-positivity to the hepatitis core antigen (anti-HBc). This antibody regularly developed after infection with HBV and the highest titres of this antibody were found in people who became chronic carriers of HBsAg.

However, the anti-HBc could persist even in sera in which HBsAg and anti-HBs were no longer detectable, giving rise to concerns that additional screening tests for the presence of anti-HBc would be necessary, particularly in plasma for fractionation, given that even potentially undetectable levels of virus in the starting plasma might be selectively retained in the relevant Cohn fractions (see above). Additional screening tests for the presence of the soluble antigen HBe and for DNA polymerase (an enzyme closely associated with replication of the virus) had been suggested.

55.10. I went on to describe a paper[7] about the potentially serious liver damage that had arisen in a group of 13 asymptomatic haemophiliacs in whom hepatitis B infection had resulted in persistently abnormal liver function tests. Eight of the 13 were found histologically to have chronic active hepatitis, but five had severe liver disease and despite the presence of anti-HBs, hepatitis virus could be detected in the liver cells of 8 of the 12 patients. The authors concluded that, "Throughout the world, a large number of asymptomatic haemophilic patients who have received numerous transfusions must have histological liver disease. In some it must be severe". The paper went on to observe that, in addition, the implications of non-A, non-B virus (or viruses) in haemophilia had yet to be evaluated. "To return to less effective therapy for haemophilic bleeding would represent a step backward"... and the paper went on to say that a major effort was needed to develop "a clean product rapidly for the treatment of the next generation of haemophiliacs".

Non-A, Non-B Hepatitis

55.11. In *Meyler's Side Effects of Drugs* (p.566) I described the fact that some 60-90% of post-transfusion hepatitis in the USA was unrelated to either hepatitis A or B and at least one other hepatitis virus was suspected. Three recent studies had provided convincing evidence for a transmissible agent of non-A, non-B hepatitis. One of the studies involved the inoculation of volunteer subjects with stored sera from donors who were thought to have transmitted hepatitis. The other two studies involved the inoculation of infected human sera into

[7] Spero,J.A., et al (1978) Asymptomatic structural liver disease in haemophilia. New Engl. J. Med., 298, 1373 [CGRA0000487].

chimpanzees. The same study – as well as two other studies – demonstrated the existence of a chronic carrier state in humans, "the existence of which had seemed essential in order to account for the large numbers of non-A, non-B hepatitis cases that were derived from apparently healthy donors". Such chronic carriers, like HBsAg carriers, were thought to be about 10 times more prevalent amongst paid than amongst unpaid donors.

55.12. In the *Side Effects of Drugs Annual* (p 231), I described the increasing evidence for the severity of non-A, non-B hepatitis and its progression to chronic liver disease. Two fatal cases and one non-fatal case of non-A, non-B hepatitis had occurred in patients with liver disease who had received the same batch of prothrombin-complex concentrate prior to liver biopsy. The agent responsible was found to be transmissible to chimpanzees.[8] A further death, apparently from non-A, non-B hepatitis was found amongst a series of patients with liver disease who had received four different batches of concentrate. In light of these reports, the Committee on Safety of Medicines had suspended all clinical trials of prothrombin-complex concentrates for indications other than the treatment of haemophilia B. This section concludes that the need to limit the non-essential exposure to coagulation factor concentrates is reinforced by reports that non-A, non-B hepatitis may progress to chronic liver disease. In one of these reports,[9] histologically verified non-A, non-B hepatitis was shown to progress both histologically and clinically to chronic active hepatitis within a two-year period.[10]

Relative Risks of Commercial and Domestic Products

55.13. At the time there was a general view that UK plasma from voluntary donors carried less risk than US plasma from paid donors. Whilst undoubtedly that was true, what was less well appreciated at the time (at least by me), was that once the pool size of a coagulation factor concentrate was increased beyond a certain point, it became inevitable that recipients would become infected with

[8] Wyke, R.J. et al (1979): Transmission of non-A, non-B hepatitis to chimpanzees by factor-IX concentrates after fatal complications in patients with chronic liver disease. Lancet, 1, 520 [BPLL0016050_003].
[9] Iwarson,S. et al (1979); Progression of hepatitis non-A, non-B to chronic active hepatitis. A histological follow-up of two cases. J. Clin. Path., 32, 351 [PRSE0002174].
[10] The papers I was asked to review did not include the paper by Preston *et al* (1978) to which the Inquiry has previously referred.

non-A, non-B hepatitis, whether these pooled products were made from domestic or US paid donor sources. See Fletcher *et al,* BMJ 1983, 287, 1754-1757 [WITN4461091] and Kernoff *et al*, British Journal of Haematology 1985 60, 469 – 479 [PRSE0003439].

DHSS Perceptions of Risk

55.14. In terms of what, to the best of my knowledge, the DHSS knew of these risks from blood and blood products, I can say, with confidence, that the issue of post-transfusion hepatitis from hepatitis B virus was well known and testing of donor blood with tests of increasing sensitivity and specificity were being employed. As a result, the risks of transmission of hepatitis B from donor blood were much reduced and the risks from blood products were also reduced, although by no means entirely eliminated.

55.15. I have described what I believe to be the DHSS's knowledge of non-A, non-B hepatitis in my answer Q56 below.

56. Q56: Development of knowledge of hepatitis over time.

56.1. I have then been asked how, if at all, did that knowledge and understanding (of hepatitis risks) change or develop over time. This is a very broad question. To the extent that it refers to how the "collective" DHSS knowledge and understanding of hepatitis risks developed, I do not believe that I am well-equipped to answer, although I have described the committees or other resources used by the DHSS to gather information, below. I think it fair to say, however, that the risks of post-transfusion hepatitis from Hepatitis B – and the potential for this infection to give rise to chronic liver disease - were well known by colleagues dealing with blood transfusion policy.

56.2. Non-A, non-B post-transfusion hepatitis was also a problem known to the DHSS and, indeed, the Committee on Safety of Medicines had taken action, through the Licensing Authority (DHSS), to restrict clinical trials of prothrombin-concentrate for indications other than haemophilia B, in the light of the findings reported by Wyke *et al* (see above). However, it is my belief that, during my time in Med SEB, there was much less appreciation, amongst my colleagues, of the risks of serious liver disease arising from non-A, non-B hepatitis.

56.3. That was perhaps understandable since I am not sure that even amongst haematologists, or haemophilia clinicians, the potential severity of non-A, non-B hepatitis was generally recognised at the time. Indeed, very much in line with evidence that the Inquiry has received from several Haemophilia Centre Directors, non-A, non-B hepatitis was generally thought to be a fairly benign condition at that time. This accorded with what they were observing about the health of their own patients, coupled with the extremely long incubation period before liver damage generally became manifest. Post-transfusion hepatitis, or transaminitis without jaundice, were generally not thought to have serious consequences.

56.4. The most authoritative textbook on liver disease at the time was by Professor Sheila Sherlock. The relevant extracts from her book were set out in the report by Lord Penrose, as follows:-

> *"The 6th edition of Diseases of the Liver and Biliary System" by Professor Sheila Sherlock was published in 1981. Excerpts from the book are quoted in the Preliminary Report at paragraphs 6.110-6.114. Significant points made were:*
>
> *NANB Hepatitis was largely spread by blood and accounted for about 75% of PTH and possibly 15-20% of sporadic hepatitis; and*
>
> *Haemophilia patients receiving factor concentrates obtained from commercial sources were particularly at risk.*
>
> *The NANB Hepatitis agent had not been 'conclusively identified' and its identity remained uncertain; and*
>
> *The clinical course of the disease progressed to a 'mild, chronic hepatitis' in about a quarter of patients but this usually improved with time although cirrhosis could develop.[96]*
>
> *Professor Sherlock commented that:*
>
> *"Non-A, non-B hepatitis often progresses to a mild chronic hepatitis. The prognosis of this is, at the moment, uncertain but probably benign". [259]*

56.5. For haemophilia clinicians in the UK and for the DHSS more generally, understanding of the risks only emerged gradually, primarily through the surveillance work done by John Craske, Chair of the UKHCDO Hepatitis Working Party.

56.6. The Report for 1980-1981 of the Haemophilia Centre Directors' Hepatitis Working Party, chaired by Dr Craske describes the results of the surveillance of both Hepatitis B and non-A, non-B for that year. The report was issued in October 1981 [CBLA0001466]. The DHSS did not attend this working party, but were aware of its work, not least as it was reported to UKHCDO meetings.

56.7. The report for 1980-1981 described the third and final year of a retrospective study financed by the DHSS.

56.8. Although the report is not entirely clear, the chief finding appeared to be that 70-80% of cases of overt non-A, non-B hepatitis were associated with the first dose of concentrate that the patient received. Dr Craske concluded that: "Most of the patients treated with any batch of concentrate will be immune to non-A, non-B hepatitis, since batches of concentrate of any brand are contaminated with one (or more) serotypes of these agents."

56.9. The natural history of the disease was still unknown: "The question of the significance of chronic hepatitis observed by several groups of workers in liver biopsies of patients with chronically elevated transaminases is still unanswered …Most patients in this group are still entirely symptomless."

56.10. Further surveillance into changes in incidence of non-A, non-B hepatitis related to changes of types of treatment and blood products was recommended; and research was needed into the incidence of sub-clinical hepatitis.

56.11. The final section of the report on recent hepatitis research stated:

> *"Recently published evidence concerning the use of ultra-violet light and β-proprio-lactone to inactivate hepatitis viruses in factor IX preparations claimed that 90% or more of infectivity due to non-A, non-B viruses had been removed. It is likely that commercial factor IX preparations treated by this method will become available with claims that they are associated with a low risk of transmitting hepatitis. The only way that infectivity for non-A, non-B hepatitis can be shown other*

than human inoculation is by inoculation into chimpanzees. Since very few of these animals are available, it is difficult to see how every batch treated by this method will have quality control assurance with respect to non-A, non-B viruses. This information should be borne in mind when considering purchase of these preparations.'

56.12. This statement was relevant to the concerns about how to determine the effectiveness of virucidal treatments of blood products in preventing non-A, non-B infection.

56.13. I have also described my own involvement in matters related to hepatitis risks and blood products in detail in answer to the further questions below.

57. Q57: Systems and Processes at DHSS to inform itself of risks

57.1. I have been asked to describe the systems and processes in place for the DHSS to inform itself about the risks from blood and blood products.

57.2. It is difficult to give a comprehensive answer to this question. But broadly, and focussing upon the issue of blood and blood products, routes for information gathering included:-

i) The DHSS employed medical staff, at that time in a parallel hierarchy to administrators, at whose head was the Chief Medical Officer or CMO, who were tasked with evaluating medical issues and interpreting them to administrators and Ministers as necessary. Given the breadth of issues that had to be covered, the DHSS medical advisers were usually generalists rather than specialists, but they were also supplemented, in some specialties, by Consultant Advisers to the CMO. In the area of blood and blood products, I have referred to the role of Dr Tovey and Dr Gunson, as CMO's Consultant Advisers in Blood Transfusion, in Section 2 of this statement.

ii) The Department and its officials were advised by both regular Standing Committees and also Ad-Hoc Committees or Working Parties, which gathered together key professionals with expertise in particular issues (e.g., on Hepatitis).

iii) Organisations and administrative structures within the NHS were frequently not merely staffed but directed by clinicians, rather than by managers, or by a combination of them both, and officials from the Department attended key meetings. So, for example the Regional Transfusion Directors were clinicians, with relevant expertise in Blood Transfusion Medicine. I have given an account of the frequent meetings with the Regional Transfusion Directors as well as officials and clinicians from organisations like the Blood Products Laboratory that took place in relation to issues such as the re-development of BPL and the estimates for future plasma volumes needed to achieve self-sufficiency.

iv) Medical and administrative civil servants both interacted closely with clinical professionals in the NHS through regular attendance at meetings of key clinical professional associations (in this context, the UKHCDO being an example), or through attendance at professional conferences or other gatherings;

v) Clinicians could and did raise concerns directly with the Department, whether by writing directly to the CMO or anyone else within it.

57.3. See further my comments in respect of Q73, in Section 6 (AIDS) below, which addresses similar issues.

58. Q58: Enquiries or Investigations by DHSS

58.1. I have been asked what enquiries and/or investigations the DHSS carried out or commissioned in respect of the risks posed by the purchase of commercially supplied blood products and what information was obtained as a result.

58.2. During the period that I was in Med SEB, the risk of hepatitis B in imported commercial (and NHS) blood products was primarily addressed by the increasingly sensitive tests that were being developed for the screening of donor blood for Hepatitis B surface antigen (HBsAg), antibody to the surface antigen (anti-HBs) and antibody to the core antigen (anti-HBc). I have described (below) the work of the Advisory Group on Testing for the Presence of Hepatitis B Antigen and its Antibody, which was the principal initiative seeking further improvement in the testing regimes employed at the time.

58.3. Hepatitis B risks from commercial products would have also been a matter for the Licensing Authority and NIBSC, which set requirements for the evidence to be provided concerning the safety of such products.

58.4. At the time, knowledge or investigation of the risk of non-A, non-B Hepatitis in blood or blood products was limited by the fact that there was no test capable of identifying this postulated virus (or viruses). In general, developments on these issues were delivered by research efforts, whether led by clinicians or by fractionators in the public or commercial sectors (given that non-A, non-B hepatitis was a risk not only for commercially purchased products but also those manufactured by the NHS). I have described the Working Groups, etc., at which the DHSS had a presence. I do not have access to information about the funding of specific research bids by the DHSS or by the MRC, but it is obvious from the records of these groups that the Department was one of the potential sources of funding. One example of the scope for funding by the Department, can be seen from my comments, in December 1980, on the research work of Dr Craske: *"Studies of the Epidemiology and Chronic Sequelae of FVIII and IX – Associated Hepatitis in the United Kingdom*". I noted that I had heard Dr Craske deliver several talks covering the content of the study. I also supported proposed work by Dr Craske on the potential use of 'small pool' products for the mildly affected with minimal previous exposure to blood products [DHSC0001121]. I am afraid that I have no papers to show whether or not this work was actually funded, but it is an example of the type of research that the DHSS would then fund, in comparison with research funded by the MRC, which tended to be of a less 'applied' nature.

59. Q59: Advisory Groups - Hepatitis

59.1. I have been asked to describe the work of, and my involvement in, a series of advisory committees or groups concerned with the risk of hepatitis. I have described each in turn below.

The DHSS Advisory Group on testing for the presence of HBsAg and its antibody

59.2. The DHSS Advisory Group on testing for the presence of Hepatitis B Surface Antigen and its antibody advised on methods and policy with regard to the screening of blood donations and the preparation of national standards.

59.3. It is apparent from the *Third Report of the Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibody* (1981) [PRSE0000862] that the Group followed on from the work contained in: (i) the First Report of May 1972, which first recommended the testing of all blood donations for the presence of the Australia (hepatitis-associated) antigen and its antibody; and (ii) the Second Report, which in September 1975 recommended a revised method of testing of what was by now referred to as Hepatitis B. However, I had no involvement in any of this earlier work and have no knowledge of it.

59.4. I can see from the Third Report that the Group was then re-established in November 1979, with the purpose of considering whether any alterations in the methods used for testing donations were desirable in consequence of developments in knowledge and technique which had occurred since the second report.

59.5. The Group met at various times after November 1979 and its report was published in summer 1981. As far as I can tell, the first meeting I attended was on 6 March 1980, when I attended with Dr Sibellas [CBLA0007195], but I have not had access to all sets of minutes. The membership is apparent from the Report: it was chaired by Dr Jenkins of BTS and included expert transfusionists and virologists in its membership. I attended but was not the Medical Secretary; that was Dr Furnell.

59.6. The group met at various times until its report was finalised in mid-1981.

59.7. On 17 September 1980, for example [CBLA0001167], the minutes recorded information about the creation of the Advisory Group on Hepatitis ("HAG"). Professor Zuckerman reported the findings of a paper for the MRC Research Committee (notably that non-A, non-B hepatitis was not sexually transmitted) and the need to collect information on post-transfusion non-A, non-B hepatitis.

He supported collaboration with commercial companies to develop tests, an idea which was to be put to the DHSS. There was lengthy discussion of BPL's RIA test, separately addressed in this statement at Q67.

59.8. The Report, published in summer 1981, recorded that the Group considered the merits of the various screening tests for HBsAG: Radioimmunoassay (RIA); Enzyme-linked Immunoabsorbent Assay (ELISA) and Reverse Passive Haemagglutination (RPHA). Dr Lane reported that BPL had developed its own RIA test, which was also in use in certain RTCs. However, a commercial manufacturer, Burroughs-Wellcome, was claiming unfair competition. The Committee noted the levels of HBsAG positivity amongst UK blood donors (between 1 in 3,500 and 1 in 5,000). At paragraph 22, the report stated that non-A, non-B hepatitis viruses were a common cause of post-transfusion hepatitis in the USA and were thought to have been responsible for cases in the UK. Hepatitis due to these viruses was common amongst haemophiliacs and followed the use of imported and (occasionally) UK Factor VIII and Factor IX. There were no screening tests for non-A, non-B hepatitis, and research was recommended into the extent and severity of post-transfusion hepatitis caused by it.

59.9. The recommendations included (but were not limited to) the following:

i) all donations destined to contribute to protein fractionation at NHS fractionation centres should be tested by techniques with a sensitivity of at least 2 BSU/ml of HBsAg;

ii) all [RTCs] should screen as many new donors as possible for anti-HBs and panels of suitable anti-HBs donors should be built up;

iii) there should be no general screening of donations for anti-HBc (the antibody to the core antigen);

iv) liver function tests should not be used for general screening of blood donors;

v) hospitals should be encouraged to report all cases of post transfusion jaundice and where these could be due to non-A, non-B hepatitis, the facts should be reported to the appropriate adviser in blood transfusion at the DHSS or SHHD;

vi) research should be undertaken in the United Kingdom to determine the extent and severity of post transfusion hepatitis due to non-A, non-B hepatitis viruses; and a committee of experts should be established to assess the suitability of any new tests for hepatitis markers.

The MRC Blood Transfusion Research Committee Working Party on Post-Transfusions Hepatitis ("PTH").

59.10. The MRC Working Party had its first meeting on 14 February 1980; I was in attendance [WITN4461092]. It was a group chaired by Dr Gunson; Dr Craske was the Secretary.

59.11. The minutes note that the MRC Working Party had arisen out of an ad-hoc meeting, in February 1979, at the request of the DHSS, as a result of discussions in the DHSS's own Advisory Group on Hepatitis (the HAG). (The reference to an ad-hoc meeting may be a reference to a MRC meeting which took place on 12 February 1979: [WITN4461093]. I was not in attendance, but I note there was a discussion about the state of knowledge about non-A, non-B hepatitis).

59.12. At the meeting in February 1980, it was agreed that the purpose of the MRC Working Party was to promote research to assess the nature and size of the problem of Post Transfusion Hepatitis (PTH) in the UK, with particular reference to changes in transfusion practice e.g. the use of components prepared from pooled plasma from large numbers of donors and the introduction of commercial products from abroad. Studies should include (1) an assessment of any further need for research into hepatitis B, e.g. the need for a vaccine; (2) investigations to assess the incidence of non-A, non-B hepatitis in the UK, particularly the risk of introducing the infection by blood transfusions and (3) the position of research to characterise the agents(s) associated with this form of hepatitis and to derive diagnostic tests.

59.13. The meeting noted that other bodies were involved in the field of post-transfusion hepatitis. For example, the DHSS Advisory Group on Testing for the Presence of HBsAg and its Antibody advised on methods and policy with regard to the screening of blood donations and the preparation of national standards. It was noted that a new DHSS Hepatitis Advisory Group [HAG],

Chair Sir Robert Williams (Director of PHLS) would shortly be formed to advise on the public health aspects of hepatitis. (This met for the first time in October 1980 [WITN4461094]). It was to have a sub-committee to advise it on technical aspects of tests for viral hepatitis

59.14. It is apparent that the MRC Working Party reported to the MRC's Blood Transfusion Research Committee, which may also have had discussions of relevance. However, I only have limited access to minutes of the meetings which followed, whether of the PTH Working Party or the Blood Transfusion Research Committee. I have been shown the Minutes of the meeting held on 25 June 1981 [NHBT0000068_049]; this was apparently the second meeting. Dr Zuckerman summarised the research work undertaken in the last 2 years to try and identify and characterise the viruses associated with non-A non-B hepatitis. Dr Craske summarised data from the surveillance of reports of hepatitis made by the Haemophilia Centre Directors, including association with different concentrates, and set out priorities for research. The next date of a meeting was set for "early in 1982".

59.15. A decision was taken in March 1982 to disband the Working Party (see the Minutes of the Blood Transfusion Research Committee [CBLA0001558]). The minutes record that it was unanimously agreed that "this working party was in a field in which many other groups, both inside and outside the MRC, were active". It was agreed that it should be disbanded and that any matters in the field of post-transfusion hepatitis (PTH) that arose should be passed to an appropriate advisory body.

The (new) DHSS Hepatitis Advisory Group [HAG]

59.16. The genesis of the Advisory Group seems to have been in a decision by Dr Evans (DCMO) in July 1979 that the Department should obtain "professional advice on the various problems of hepatitis, particularly those related to the hepatitis BsAg carriers." See the minute from Dr Geffen to Dr Evans dated 24 July 1979 [NHBT0000186_006], copied to Dr Sibellas and Dr Waiter; this was before I had taken up post in MED SEB. On 6 November 1979 [DHSC0002195_062], Dr Geffen picked the topic up and explored various issues following some preliminary discussions, including with SHHD. He

explored the issue of how the new body would sit within the existing committee structures. His minute was not copied to me, but has recently been sent to me.

59.17. There were further discussions held between the CMO, Dr Harris (DCMO) and Dr Evans (DCMO) in early February 1980 [DHSC0000857], when it was agreed that "the numerous problems arising in relation to hepatitis need to be brought together into one Advisory Group on Hepatitis," rather than be dealt with by scattered groups in an ad-hoc fashion. A minute from Dr Evans to Dr. Geffen (SPMO, Med IMCD) dated 13 February (this time copied to me) addressed how such a group might potentially function. The terms of reference should be wide enough to cover medical advice on all aspects of communicable hepatitis, and in particular would be asked to provide specialist advice to blood transfusion experts. Dr Geffen was asked to prepare a note so that CMO could inform Ministers of what was proposed. A further minute followed from him on 18 February 1980 [DHSC0000859] and I discussed the allocation of roles between the HAG and the Advisory Group on Testing on 28 February 1980, with the suggestion that the latter should be asked to focus on the testing issue [DHSC0000865].

59.18. A submission to Ministers setting out the proposals, undated, is at [WITN4461095]. See the answer to Q53, where the Minister's response (27 June 1980) is recorded.

59.19. A further undated note [WITN4461096] set out the wide range of problems associated with hepatitis risks (including both hepatitis B and non-A, non-B hepatitis) and confirmed the terms of reference:

> *"To provide medical advice to the Chief Medical Officers of the health departments of the United Kingdom on all aspects of communicable hepatitis."*

59.20. On 3 October 1980, the DHSS Hepatitis Advisory Group met for the first time (see the minutes [WITN4461097]). It was chaired by Sir Robert Williams, with a core membership of independent experts on hepatitis. The Medical Secretary was Dr Mary Sibellas (Med IMCD). Dr E L Harris, Dr T Geffen, Dr H M Hughes, Mr R Tringham and I were all present from DHSS. The Group agreed the terms of reference and also that the Advisory Group on Testing for the Presence of

Hepatitis B Antigen and its Antibody should become a sub-Committee of the Hepatitis Advisory Group.

59.21. The minutes also recorded the recommendations arising out of the Advisory Group on Testing's third report (yet to be approved), considering developments on laboratory testing for the presence of Hepatitis B antigen and its antibody. This has been noted above.

59.22. I reported that BPL material for an RIA test for HBsAg was ready for distribution but representations had been received from manufacturers complaining of unfair competition and the matter was under active consideration.

59.23. A second meeting was then held on 5 December 1980 which I also attended [WITN4461098]. The meeting discussed the supply and distribution of Hepatitis B Immunoglobulin and Hepatitis B vaccines. It was noted that no vaccine produced in the UK would be available before the middle of 1982. There was a discussion of the French vaccine, undergoing clinical trials and another being developed in Holland. The Chairman noted that until a UK vaccine was available, supplies would have to be obtained from abroad.

59.24. There was a reminder from Dr Lane about the need to make any tests for the markers of non-A, non-B hepatitis available as soon as possible when they were developed, and the Chairman asked Dr Lane to keep the Committee informed about these.

59.25. The third meeting of the Advisory Group on Hepatitis took place on 11 May 1981 [WITN4461099]. I attended. The *Third Report of the Advisory Group on Testing for Hepatitis B Surface Antigen and its Antibody* was endorsed.

59.26. The acceptability of blood donors was discussed. I pointed out that the DHSS had issued guidance on the selection of blood donors in a 1980 publication entitled *'Standards for the Collection and Processing of Blood and Blood Components and the Manufacture of Sterile Fluids'*. Part of that guidance was that staff working in a hepatitis unit or family members in close contact with a carrier of Hepatitis B would be excluded from donation. Members accepted that the published advice would stand and withdrew their recommendations.

59.27. Progress towards the development of a vaccine for Hepatitis B was discussed, with papers from Dr Craske and Dr Beale, who had attended for this discussion. It was noted that there were problems with whichever option was chosen.

59.28. It was agreed there was an urgent need to develop a British vaccine. Initial efficacy and safety testing of the micelle vaccine developed at the London School of Hygiene and Tropical Medicine was to be completed by July 1981. Vaccines produced from Alexander cell lines appeared to be free from infection on testing in chimpanzees but were unlikely to be available before September 1982. The Merck vaccine was the most extensively tested and evaluated but there were difficulties in the supply of suitable donors. The efficacy of the Purcell vaccine was likely to be less than the Merck and there was some evidence that it could give rise to non-A, non-B Hepatitis. One solution was to develop a licence and market Merck vaccine in the UK until a British vaccine was developed. An important constraint to production was the organisation of chimpanzee testing which was necessary for every batch of vaccine produced by the Merck or the Purcell method. There was discussion, led by Dr Craske, of priority groups of patients and health service workers likely to benefit from immunisation in light of the high cost of the vaccine. The Chairman said there was clearly an urgent need for a vaccine and in view of the problems with production and testing it was important that the Department should concentrate on drawing up a protocol on how they wanted to proceed. I updated the group on the BPL test for Hepatitis B. The cost of the reagents had been set at 20p per test.

59.29. Regular meetings continued, and by 1983, were linking consideration of AIDS issues with those of hepatitis (see for example the minutes of the meeting of 18 October 1983 [BPLL0008168]). I have tried to pick up relevant issues from those meetings as and when relevant to the topics in this statement.

Other Groups

59.30. I have been asked if there were other groups concerned with hepatitis with which the DHSS was involved. The chief body that I am aware of was the UKHCDO's Hepatitis Working Party, chaired by Dr John Craske. I have referred to this above (at paragraph 56.5 and following) but it was not a group

attended by DHSS officials. I was however aware of its work, not least by attending UKHDCO meetings.

60. Q60: Publication of Third Report of the Advisory Group on Testing

60.1. I have been asked to explain what action was taken within and by the DHSS following the publication of the "*Third Report of the Advisory Group on Testing for the Presence of Hepatitis B surface Antigen and its Antibody*" [PRSE0000862]. I have also been asked (Q61) whether any of the report's recommendations were acted upon, and if so by whom.

60.2. I have summarised the work of the Group above (paragraph 59). I do not think that I was personally involved in any follow-up to this Report. I can see from [WITN4461100] that copies were sent out from Health Services Division in July 1981 to Transfusion Directors, Regional Medical and Scientific Officers, Hepatitis Testing References Centres, the SHHD, the Welsh Office, the Department of Health in Northern Ireland and a number of bodies who had an interest, such as the Medical Research Council. There is every reason to suppose that the recommendations in relation to testing, confirmatory testing and quality assurance would have been implemented. Certainly, the papers make clear that BPL was scrupulous in using the most sensitive test, the RIA and increasing numbers of RTCs did so. In fact, BPL was able to manufacture its own RIA test, which (when given permission by the DHSS to do so) it marketed to the RTCs.

61. Q61: Recommendations in the Third Report of the Advisory Group on Testing

61.1. I have responded to Q61 alongside Q60.

62. Q62: Understanding of the risk of non-A, non-B Hepatitis

62.1. I have been asked what my understanding, and that of the DHSS, was of non-A, non-B hepatitis and the potential harm it posed to those infected by it.

62.2. I have described my own knowledge in response to Q55.

62.3. I have answered concerning the knowledge of colleagues within the DHSS in response to Q56, at paragraphs 56.1 to 56.13 above.

62.4. I have been referred to my minute dated 15 September 1980. This is addressed in detail below at paragraphs 65.1, 65.2.

63. Q63: Communication regarding risk of non-A, non-B Hepatitis

63.1. The Inquiry has asked for an explanation of what, if any, steps were taken (and when and by whom) to ensure that the serious nature of non-A, non-B hepatitis (as summarised in my minute of 15 September 1980, [WITN0282008]) was known to, and understood by:-

a. Ministers;

b. clinicians;

c. NHS bodies;

d. patients who were or might be treated with blood or blood products;

e. the public.

63.2. I do not believe that, at the time, the potential severity of non-A, non-B hepatitis was in any way well known, outside of a body of relevant researchers and hepatologists. I have addressed this in response to Q55 above.

63.3. Haemophilia Centre Directors, through their Working Group on hepatitis, led by Dr John Craske, were receiving research reports about hepatitis associated with blood products, as were Regional Transfusion Directors, not least through the Consultant Adviser on Blood Transfusion.

63.4. As for information to patients:

i) The DHSS would not have regarded itself as having a role in advising clinicians what to tell their patients about hepatitis risks, as that was a matter which lay within the boundaries of the individual clinician/patient relationship; however

ii) The Licensing Authority's regulation of blood products covered the issue of product information. I am not able to state what information would

have been conveyed by labels on blood products or patient information leaflets, but believe they would have mentioned the risk of hepatitis, albeit without specifying the particular hepatitis viruses involved. The Inquiry should be able to obtain information directly from its statutory successor.

iii) There were posters and other information available where patients were having blood tests, which described the risks of hepatitis, and sharps bins were ubiquitous, covered with yellow stickers warning about the risk of infection from needle-stick and sharps injuries.

63.5. Ministers were certainly alerted to the problem of post-transfusion hepatitis in general, but I do not know if the potential for chronic liver damage and severe disease from non-A, non-B hepatitis was particularly stressed.

64. Q64: Steps taken by the DHSS to reduce risks from non-A, non-B hepatitis.

64.1. I have been asked to provide a detailed, chronological account of any steps taken by the DHSS, during the time I worked there, to reduce the risk of people being infected with non-A, non-B hepatitis in consequence of treatment with blood and blood products.

64.2. I have already described, in Section 2 of this statement, the steps taken to achieve self-sufficiency in blood products and to redevelop BPL.

64.3. Given that self-sufficiency had not yet been achieved, the further question to be addressed was what immediate or other steps could be taken to reduce the risks of transmission of non-A, non-B from blood or blood products. But in respect of this, the lead responsibility for reducing non-A, non-B risks did not rest with the DHSS. The challenge was to find effective ways of eliminating a virus; this was not work that the DHSS could possibly carry out, although it encouraged and funded relevant research. Hence the responsibility lay with the NBTS and with the manufacturers of blood products, whether NHS or commercial, working in conjunction with researchers.

64.4. Because the virus (or viruses) causing non-A, non-B hepatitis had not been identified, and no reliable test for its existence had been devised, it was not possible to exclude non-A, non-B carriers through the screening of donors.

64.5. The most effective way to reduce risks would have been through devising methods to eliminate the virus itself from coagulation factor concentrates, and various methods to do this were under investigation or active development. These included the use of ultra-violet light and β-propiolactone, but, above all, the effective use of heat-treatment. However, none of these methods could deal with the problem of non-A, non-B hepatitis in whole blood/plasma or cryoprecipitate.

64.6. In late 1982 and 1983, my last year with responsibility for blood and blood products in Med SEB, I became aware that a number of commercial firms manufacturing Factor VIII concentrates were using various forms of heat or chemical treatment in an attempt to inactivate hepatitis viruses. I was also aware that both BPL and PFC Liberton were investigating the potential of various methods to inactivate hepatitis viruses in blood products.

65. Q65: Minute of 15 September 1980

65.1. The Inquiry has asked about my minute of 15 September 1980, and its statement that the Department of Health had a "moral obligation to ensure collaboration with industry does not increase health hazards not only to recipients of blood products, but also to the community as a whole" [WITN0282008].

65.2. It was because of my concern that the potential seriousness of non-A, non-B hepatitis might not be well understood in the Department, that I wrote in a minute to Mr Harley (HS2) on 15 September 1980 [WITN0282008] that:

> *"I must emphasise that 90% of all post-transfusion (and blood-product infusion) hepatitis in the USA and elsewhere is caused by non-A, non-B hepatitis viruses which (unlike hepatitis B) cannot, at present, be detected by testing donor blood. This form of hepatitis can be rapidly fatal (particularly when acquired by patients with pre-existing liver disease) or can lead to progressive liver damage. It can also result in*

a chronic carrier state, thus increasing the 'pool' of these viruses in the community. In my view, the Department has a moral obligation to ensure that any collaboration with industry does not increase the health hazards, not only to recipients of blood products, but also to the community as a whole."

65.3. I had already published the evidence which led me to make these statements in the two publications for Excerpta Medica, to which I have referred at Q55 above.

65.4. I wrote the minute to Mr Harley, which I copied widely, to explain why I thought that a potential commercial fractionator (potentially, Beechams) should not be allowed to import plasma from the USA to fractionate in the same plant as would be used to fractionate UK plasma, because of the risk of contamination of the UK blood products.

65.5. At the time, a proposal to allow Beechams involvement was under consideration. See, for the details:

i) Beechams' proposal of 28 August 1980 [WITN4461101; WITN4461102];

ii) Mr Wormald's note of 19 September 1980, in which he told Mr Harley that it had been agreed that an informal meeting would be held by him with Beechams to explore the proposal [WITN4461103] – he asked colleagues including myself for notes on the issues that should be raised at such a meeting;

iii) the reference, in Mr Wormald's draft letter of 9 October 1980, to a meeting between Mr Wormald, Graham Hart and Beechams representatives then held on 7 October 1980 [WITN4461104];

iv) Mr Wormald's draft response to Beechams, which included a redraft of the outline proposals sent by Beechams in August, under cover of a minute of 9 October 1980, in which he (Mr Wormald) asked for comments [WITN4461105] (draft letter); [WITN4461101] (redrafted outline of proposals) and [WITN4461106] (minute from Mr Wormald asking Mr Hart, Dr Oliver, Mr Harley and myself for comments on his drafts);

v) Ministerial submission prepared by Mr Wormald and dated 14 October 1980 [WITN4461043], cover letter; submission at [WITN4461042], on

the option of commercial involvement, and which pressed Ministers for a decision "in principle" about whether this was to be regarded as a viable way forward or whether commercial involvement should be rejected in favour of the redevelopment of BPL with public funds. The covering letter to the submission noted that there was no desire to negotiate with:

"the foreign blood fractionation companies, who will certainly present problems much more severe than Beecham".

It canvassed a wide range of issues, including hepatitis risk:

"if our domestic supply cannot be increased, either we shall have to have increasing recourse to expensive foreign material, with all the difficulties which that entails, including its higher hepatitis risks; or we shall have to pay our donors… Beecham propose that if the NHS cannot supply enough plasma to supply their factory they should import to make up the deficiency. Apart from the hepatitis risk (present of course now in the commercial products which Authorities now buy)…"

65.6. The underlying submission made it apparent that the proposal would separate NHS and non-NHS product into separate factories because of these risks:-

"13a. No commercially purchased plasma will carry as little hepatitis risk as our own. It is impossible to screen for some forms of hepatitis. Infected plant cannot be readily disinfected. It follows that the same plant cannot be used for NHS and non-NHS plasma unless we are prepared to accept an increased risk of infection of NHS material. (The extent of such risk is not known.) The logical conclusion is separate plant for NHS and non-NHS plasma. The degree of duplication would be very substantial. Beecham are willing to provide this … They have made it clear that they would pass the full cost on to us…"

65.7. Fortunately, Ministers decided against non-British commercial involvement in the redevelopment of BPL. On 26 November 1980, Dr Vaughan made an announcement that there would be "no commercial management of BPL". In the House of Commons, he gave an answer to (what appears to have been an arranged PQ). He said that after exploratory discussions, it had been decided that there was no place for a commercial company in the management of a

service which relied on voluntary donations [WITN4461107]. On the same day [also WITN4461107] after visiting a blood donor session, Dr Vaughan stated:

> *"There have been rumours that we intend to hand the laboratory over to a commercial company to run. This is not so. We thought it only right to examine a number of different ways of developing the laboratory, including possibly bringing in commercial management. But we have decided against this."*

65.8. This Ministerial decision not to involve industry addressed the subject matter of my minute, which was the increased risk to health posed by such collaboration.

66. Q66: Dr James Smith's Report on the inactivation of Hepatitis in BPL products

66.1. The Inquiry has noted that at a meeting of the Scientific and Technical Committee for the Central Blood Laboratories on 24 November 1981 [CBLA0001506], Dr Smith of BPL made a short report on the inactivation of hepatitis in BPL blood products and listed a number of possible means of reducing the risk of infection associated with blood and blood products.

66.2. I have been asked what consideration was given by the DHSS to each of the means described by Dr Smith.

66.3. These were technical issues and the DHSS did not have a role in evaluating the merits of each of the technical solutions mentioned by Dr Smith. Any locus the DHSS might have had would be limited to responding to any request for funding of specific projects. If any new products or variations to existing products emerged from these potential solutions, they would be considered by the Licensing Authority, in the light of the recommendations of the CSM, in the normal way.

67. Q67: Radioimmunoassay test for hepatitis B

67.1. I have been asked to explain what happened in relation to the distribution of BPL's radioimmunoassay test for hepatitis B, and, specifically, whether there was a delay and if so what the reasons were.

67.2. From the documents made available to me, it seems that I was present at various meetings at which the subject of access to the BPL's radio immunoassay test (RIA) test was discussed, but Supply Division led on the issue. I have little or nothing to add to the papers that I have been shown. But I have set out what they suggest, for the assistance of the Inquiry.

67.3. The NBTS's Scientific and Technical Committee met on 18 June 1980: Mr Harley and Mr Dutton attended but I did not. The minutes [CBLA0001119] record, on the subject of the BPL RIA test:

> *"Mr Dutton reported that the Ministry of Defence patents experts were currently examining Abbott Laboratories allegations that the BPL had infringed their patent. A report from the Ministry was expected shortly. Discussion turned to the subject of an RIA test which Boroughs – Wellcome were developing."*

67.4. By 9 July 1980, this challenge had been seen off but another emerged. The Minutes of the NBTS joint management committee for the Central Blood Laboratories meeting [CBLA0001137] held on 9 July 1980 (which I did attend): record, under the heading of the topic of progress with the distribution of the BPL's RIA test:

> *"Dr Lane said that he was pleased that the Ministry of Defence had written in such firm terms to Abbott Laboratories about the alleged patent infringement. However, the news that Boroughs-Wellcome were developing an RIA test similar to the BPL's and had asked where they stood, meant that he could not start general distribution of the kits until Supply division had considered the situation. Members endorsed the Chairman's suggestion that he should write to Supply division to express the Committee's grave concern about the position which had arisen, and advise Supply division of the importance of distributing the BPL test as soon as possible."*

67.5. Dr Harris (the Chairman) duly wrote to Mr GA Hart on 17 July 1980 [DHSC0003618_038], letter copied to me and others]. He expressed concern about the "virtual embargo" placed upon the distribution of the BPL's RIA test as a result of the representations; the needs of the NHS must be paramount and those needs would be most closely and economically met by the BPL

product. The final costings for BPL were not yet available but it seemed that they would be substantially cheaper than the Burroughs-Wellcome test; furthermore the BPL test had been fully evaluated unlike the commercial alternative. The Chairman noted that it appeared that Ministers were to be consulted before allowing BPL to proceed.

67.6. Minutes of the meeting of the NBTS Scientific and Technical Committee for the Central Blood Laboratories held on 17 September 1980 [CBLA0001171] show that I was in attendance as one of the two joint secretaries, the other being Mr Godfrey). Dr Lane outlined that no progress had been made on the question of whether the BPL could continue to supply the RIA test to RTCs. He noted that if the RTCs were obliged to continue to use tests of lower sensitivity, this would mean that BPL would have to retest all the incoming plasma by RIA. I reported the letter from Dr Harris, and that PHLS was currently evaluating the Wellcome test, and once comparable scientific, technical and costing data were available on both tests, Ministers' views would be sought.

67.7. There is a similar report of events in the minutes of the [CBLA0001167_001], which took place on the same day and was also attended by Dr Lane (and me). Members again felt strongly that there should be no barriers to the use of the BPL test.

67.8. It appears from these minutes that, from BPL's perspective, the issue was of potential delay, duplication and wasted effort (and revenue) rather than safety, as BPL would retest supplies arriving at the laboratory using its more sensitive test. A letter from Dr Harris dated 19 February 1981 also reveals that certain RTCs had been receiving the BPL test free of charge for the purpose of evaluation only; the 20p/test sales were to replace this.

67.9. The Minutes of the Joint Management Committee meeting held on 22 October 1980 [CBLA0001190] record that I, together with a member of Supply Division's Scientific and Technical Branch had visited Burroughs-Wellcome and BPL to examine their respective tests. "A recent Departmental meeting to discuss ways forward had decided that the best compromise would be to allow BPL to market its test at a cost of 20p … from 1 March 1981 – or earlier, if Burroughs-Wellcome had entered the market before that date. In this way Burroughs-Wellcome

would be set a firm date … Members endorsed this suggestion." Dr Lane said that he would need c.£75,000 to start producing the test.

67.10. The next meeting of the Scientific and Technical committee took place on 3 December 1980 [WITN4461108] and record:

> *"Dr Walford explained that since the Committee's last meeting the Department had agreed that from 1 March 1981 – or earlier depending on whether the Burroughs-Wellcome test and equipment were ready – BPL should be allowed to market its test to RTC's at a cost of 20p per test. The cost per test had been made as comprehensive and competitive as possible and took account of greenfield development costs and included a profit margin. Burroughs-Wellcome had now been informed of the Department's decision to market the BPL test next year. Mr Smart suggested that the price should also have contained an element to reflect the costs of the central administration of the BPL analogous to commercial "head office costs". Dr Lane's request for funds to start production of the test was being considered by the Department."*

67.11. Minutes of the meeting [CBLA0001268] held on 6 February 1981 of the NBTS Joint Management Committee for the Central Blood Laboratories report similar feedback. I reported that BPL was to market its test to RTC's from 1 March at a cost of 20p per test. Mr Brechin (DHSS) foresaw no difficulties in financing the test in the current financial year; eventually the test would become self-financing. Dr Lane said that the virology laboratory for the large-scale production of the test was due to be commissioned in March. He had already received requests for the test from throughout the blood transfusion service including Scotland and Northern Ireland.

67.12. The minutes of the Advisory Committee of the NBTS held on 23 February 1981 [WITN4461073] show that the Regional Transfusion Directors were unhappy at having to pay 20p/test, when in their view the actual cost of the test was approximately half of that. The Centres would have to pay approximately £7 - £10,000 (presumably per annum) for the test, which would be an additional financial burden. The subject would be raised with the Department. A letter

from Dr Harris to Mr Hart dated 26 February 1981 [WITN4461109] again relayed these concerns to the Department.

67.13. There is a letter dated 25 February 1981 to Mr Punt, Regional Treasurer of Trent RHA [WITN4461110] from Mr Fletcher (DHSS) explaining the Department's position. The letter implies that the release of the BPL test was delayed until 1 March 1981, but it is not clear for how long. Overall, it is not clear to me from the papers how long any "embargo" on the sale of the BPL product lasted, or its effect given that: (i) BPL itself retested any products received; (ii) some of the RTCs had access to the more sensitive test for evaluation purposes and (iii) it appears from Dr Lane's comments that a laboratory had to be commissioned in order to scale up production of the test. However, any delay was undesirable.

67.14. There are further papers which suggest further discussions between BPL and Wellcome about the prospect of a collaboration between the public and private sector; see for example the letter from Mr Finsberg to Mr Smart (Director of Glaxo Holdings and member of the Scientific and Technical Committee for the Central Blood Laboratories) dated 14 December 1981 [WITN4461111] but it is not clear to me whether this raises any matters which will be of interest to the IBI.

68. Q68: Hepatitis B vaccine

68.1. I have been asked a series of questions relating to the use of the Hepatitis B vaccine. They relate to three separate matters:

i) My knowledge of, and involvement in, decisions as to the roll-out of the Hepatitis B vaccine, in particular the decision as to which groups would be offered the vaccine, see the CMO's letter on the topic;

ii) Safety concerns raised with the Department's Chief Nursing Officer (CNO) by the Royal College of Nursing (RCN); and

iii) A suggestion that the Hepatitis B vaccine could be protective against AIDS.

Rollout of the Hepatitis B vaccine

68.2. The first document to which I have been referred is the CMO/CNO's Guidance of 15 October 1982 on the use of the Hepatitis B vaccine. The contents of this document are self-explanatory and were guided by the advice received by the Joint Committee on Vaccination and Immunisation [WITN4461112]. Although I attended meetings where this was discussed (e.g. the Advisory Group on Hepatitis meeting of 5 October 1982 [WITN4461113] and was copied into a Ministerial submission on the topic [WITN4461114], the lead responsibility was held by Med IMCD and by Dr Field as SPMO.

68.3. I have been reminded of a minute which I wrote to Dr Sibellas on 17 December 1982, obviously responding to a query from her about the interpretation of the CMO's Guidance [DHSC0003821_064]. I do not have a copy of her query, so it is difficult to comment further. I have referred back to the "last meeting of the Advisory Group". I think this must be a reference to the meeting of the Advisory Group on Hepatitis that I have referred to above.

Concerns about Safety Raised by the RCN

68.4. In July 1983, a concern about infection with AIDS as a result of Hepatitis B was raised with the Department's Chief Nursing Officer (CNO) by the Royal College of Nursing (RCN). I have been shown a copy of a letter from the RCN, raising the issue of staff worries about the potential of hepatitis B specific immunoglobulin to transmit AIDS [DHSC0002231_074]. It appears that I was asked to provide information for a response.

68.5. Whilst the main thrust of the letter concerned the use of the hepatitis B vaccine, the question I was asked to address was not about the vaccine but about hepatitis B specific immunoglobulin used, for example, in babies born to mothers with hepatitis B or in someone with known exposure to hepatitis B infection. I did this in a minute dated 10 August 1983 [DHSC0002231_021], quoting exactly a statement from a WHO consultative Group in July 1983 and reported in the Lancet on August 6 that there was no evidence of the transmission of AIDS or other infections by immunoglobulins, including specific immunoglobulins, such as hepatitis B immunoglobulin, provided they had been

prepared by universally accepted methods. I did not provide any comments on the question of the safety of the vaccine

68.6. The handwritten notes [DHSC0002231_072] then show the process of drafting a letter in response by my colleagues that followed after the information had been supplied. I am not clear why the reply from the CNO to the RCN of 24 August [DHSC0002231_064] states that "the current expert opinion [is] that the evidence of risk of AIDS after hepatitis vaccine B was very small". The hepatitis B vaccine was treated extensively with virucidal steps during the manufacturing process, with pepsin, extremely low pH2 and heat, then urea and heat then formalin and heat, which makes that statement rather surprising. On 14 December 1984, the CDC Atlanta published the definitive evidence confirming lack of transmission of AIDS by the hepatitis B vaccine (MMWR 33 (49); 685-7).[11]

Vaccine Demand as a result of AIDS fears

68.7. On 16 October 1983, the papers refer to a completely different concern. I have been reminded of a minute that I wrote to Dr M. Sibellas (copying in Dr Oliver, Dr Field and others) [DHSC0003823_197]. In this, I referred to articles in the Lancet that postulated that the agent of AIDS might be carried within the Hepatitis B surface antigen (which might imply that there would be increased demand for protection against Hepatitis B, rather than reluctance as had been the previous issue in July).

68.8. I commented that whether or not the hypothesis was true, *"we must be prepared for a "run" on the Hepatitis B vaccine"*. I queried whether the DHSS should be taking immediate and exceptional steps to secure supplies for the UK. I also queried whether staff would refuse to handle blood from patients with Hepatitis B, jaundice or liver disease, unless they (staff) had been vaccinated, and asked for views.

68.9. A meeting to discuss the issue was held shortly afterwards, on 19 October 1983 [DHSC0003821_016]. It was agreed that there was no supporting evidence

[11] https://wonder.cdc.gov/wonder/prevguid/p0000357/p0000357.asp

behind the Lancet's article, but Supply Division should check stocks with a view to considering whether Ministers should be advised.

68.10. Dr Field (who was not at the meeting) also responded at length in a note written on 20 October 1982: [DHSC0003821_019]. He noted that although the concerns expressed were valid, the original 45,000 doses originally made available had not been taken up (perhaps because the ASTMS had advised members not to accept it). He asked whether enquiries about stocks could be made discreetly, but noted that there would be both "political and financial implications" in persuading the manufacturer (MSD) to guarantee additional supplies in the UK – which was what my proposal would amount to, he commented.

68.11. Enquiries must have been made, as a minute of 1 November 1983 conveyed the information that supplies were, in essence, plentiful but "subject to the caveat that if there was to be a worldwide upsurge in demand", rationing might need to be introduced [DHSC0003821_018]. Essentially, this concern 'fizzled out' without a surge in demand (the science behind the concern was not supported) and nothing more was required.

69. Q69: Licensing of hepatitis reduced products

69.1. I have been asked to address the DHSS's position in relation to "hepatitis reduced" products being introduced into the UK market, and any steps taken in this regard. I have addressed the subject of 'hepatitis reduced' products as part of the discussion of heat-treated products, under Section 6, since by the time that claims for the efficacy of these products were being made, they began to be made in the context of the emerging threat of AIDS as well.

69.2. I have been further referred to Dr Craske's letter to me dated 10 January 1983 [DHSC0002353_021] and his accompanying draft letter to the Lancet [OXUH0001618]) and the note on imports of blood products prepared by me on 10 May 1983). I have addressed Dr Craske's letter to me dated 10 January 1983 in Section 6 in response to Q79.

69.3. Finally, I have been referred to Mr Winstanley's note on the licensing conditions imposed on imports of blood products, prepared in conjunction with me on 10

May 1983 [DHSC0002227_035]. This was a simple statement of the factual position, which also drew attention to the discretionary provision in the legislation allowing a doctor to prescribe an unlicensed medicinal product, provided this was done on a "named patient basis". Although not spelled-out in this note, a doctor prescribing an unlicensed medicinal product on that basis had to be prepared to justify his/her actions, including, if necessary, to the General Medical Council. It was a minute sent to Mr Finsberg's Private Office.

Section 6: Knowledge of risk of HIV and AIDS from blood and blood products

70. Q70: Knowledge and Understanding of HIV and AIDS during my time as PMO and SPMO

70.1. I have been asked to describe my knowledge and understanding of HIV (HTLV-III) and AIDS during my time as a Principal Medical Officer and Senior Principal Medical Officer, including how that knowledge and understanding developed over time.

70.2. Although the Inquiry has used the composite term HIV/AIDS for this section, all the questions relate to my time as PMO in Med SEB. During this period (1979-83) the agent causing AIDS was quite unknown and even the existence of a viral agent transmissible by blood was still very much in question. I left Med SEB at the beginning of December 1983 and was, thereafter, not involved with the subject until 1988, when I became SPMO in Med IMCD. My answers to questions about HIV and AIDS during my time in Med IMCD are in Section 7.

70.3. Sometime around the middle of 1983, an agent called LAV (Lymphadenopathy-Associated Virus) was described by Luc Montaignier in France, but it was not identified as the cause of AIDS. It was not until April 1984 that Robert Gallo, in the USA, described a virus that he called HTLV-III (Human T-cell Lymphotrophic Virus). After a period of controversy, LAV/HTLV-III were recognised to be virtually the same entity and also the agent responsible for causing AIDS.

70.4. Having left Med SEB, I had no further responsibility for blood and blood products for over four years until I became Senior Principal Medical Officer in Med IMCD in 1988. By that time, not only had HIV been identified, but a screening test for HIV antibodies had been developed as well as a test for the p24 antigen and a PCR test for the virus itself. Donated blood could, therefore, be screened for HIV and coagulation concentrates were heat-treated to inactivate the virus.

70.5. As far as AIDS was concerned, I first became aware, sometime in 1981, of an illness in the USA characterised by the occurrence of Kaposi's sarcoma and a constellation of opportunistic infections, most notably, Pneumocystis carinii pneumonia (PCP), which had been reported in the Morbidity and Mortality Report (MMWR) from the US Centers of Disease Control (CDC), Atlanta. The first report I saw described 5 cases, in Los Angeles, of Pneumocystis carinii pneumonia in homosexual men. I now know that this edition of the MMWR was published in June 1981, but there would have been no reason for me to see the report then, and I cannot say now when I would have received it. I did not receive the MMWR reports directly; they came to me from Med IMCD, whose role involved the monitoring of infectious and communicable diseases, through the Communicable Disease Surveillance Centre (CDSC). However, since this report did not refer to haemophiliacs or recipients of blood transfusion there was no reason why it should have been sent to me.

70.6. During my time in Med SEB, additional cases were reported in the MMWR. These cases were occurring predominantly in white homosexual men, but injecting drug users and immigrants to America from Haiti were also reported to be affected. The illness described in these reports became known as the Acquired Immune Deficiency Syndrome (AIDS). The reported fatality rate was approximately 40%. To the best of my recollection, in 1981 at least, and for the first half of 1982, there was not a great deal of information to be gleaned from the UK medical literature or in the lay press about this new American disease.

70.7. Whilst I was on maternity leave, (from 5 April 1982 - 4 October 1982) the first MMWR report of three cases of AIDS in people with haemophilia A who had no other risk factors was published (16 July 1982) . As I was on leave, I would not have been aware of the report at the time. Further cases in US haemophiliacs were subsequently reported, but Kaposi's sarcoma, one of the defining manifestations of AIDS, was not observed in haemophiliacs.

70.8. From documents now supplied to me, I can see that in mid-July 1982 Dr Gunson, the CMO's consultant adviser in blood transfusion reported to Mr S Godfrey (HS1A) that there could be considerable publicity in the coming weeks concerning the safety of American Factor VIII. By a note dated 16 July 1982, Mr Godfrey passed on this information to Dr Holgate in Medicines Division.

70.9. Although Mr Godfrey's description of the reported problem was, by his own admission, somewhat garbled, the safety issue about American Factor VIII was clearly in relation to AIDS [DHSC0002219_009]. A response was sent by Dr Holgate on 20 July 1982 [WITN4461115]. I did not have any involvement in this correspondence at the time, for the reasons I have explained. I note that Dr Holgate proposed referring the matter to his colleague in Medicines Division, Dr Fowler, and promised that either he or Dr Fowler would keep Mr Godfrey in touch with any developments. Medicines Division would have been the correct part of the Department to be involved at this stage since the issue appeared to relate to a medicinal product. I have not been provided with any papers from which I could see whether any follow-up discussion took place either in relation to this discussion or more broadly in relation to the report in the July MMWR of AIDS in a small number of haemophiliacs in the USA.

70.10. I cannot remember any specific discussion of the issue of AIDS in US haemophiliacs when I returned from maternity leave, but I would, undoubtedly, have had catch-up briefing sessions with Dr Petronella Clarke, who was standing-in for me in my absence, and from Dr Oliver and, indeed, also from Mr Godfrey.

71. Q71: First awareness of possible association between AIDS and blood and blood products

71.1. I have then been asked how and when I first become aware that there might be an association between AIDS and blood/blood products.

71.2. Apart from the fact AIDS was occurring in haemophiliacs in the USA who had received coagulation factor concentrates, I believe it will have been at the end of 1982 or early in 1983 that I read about the presumed case of AIDS in a baby who had required blood and platelet transfusions at birth and had later developed an AIDS-like illness. One of the platelet donors had subsequently been diagnosed with AIDS. This was the 'San Francisco' baby that has previously been described to the Inquiry. It is fair to say that this case, added to the mounting reports of cases in haemophiliacs in the USA, was instrumental in my feeling that it was likely that AIDS was transmissible through blood, as

well as through sex. I remained perplexed as to why Haitian immigrants who were neither homosexual nor injecting drug abusers, nor were reported to have had blood transfusions, seemed to be in another, significant, risk group for the illness.

71.3. As the papers show, from January 1983 onwards, the Department's awareness of the potential for transmission of AIDS through blood and blood products grew incrementally. We were aware, for example, of the steps taken by the UK Haemophilia Centre Directors Organisation (UKHCDO) to establish a surveillance system through their Hepatitis Working Party chaired by Dr John Craske, a virologist from Manchester Public Health Laboratory (see Minutes of the 11th Meeting of UKHCDO Hepatitis Working Party, 19 January 1983, [HCDO0000558]). I provide more details of the internal discussions below.

71.4. Despite what I would call 'mainstream' acceptance, by the DHSS, that AIDS was most likely to be caused by an infectious agent transmissible through blood, it seems that, even by the middle of 1983, not all doctors in DHSS were necessarily persuaded of this. For example, amongst the papers brought to my attention by the Inquiry, there is a paper by Dr Keith Fowler, a medical assessor to the Committee on Safety of Medicines, which was included as a paper to assist the Sub-Committee on Biologicals' deliberation on AIDS. [DHSC0002229_059]. Dr Fowler's view was that the "most convincing hypothesis for the aetiology of AIDS" was that propounded by Sonnabend J. et al in the Journal of the American Medical Association, May 6, 1983, vol. 249, 2370-4 [OXUH0002239_005], which dealt with the immunosuppressive effects of repeated exposure to allogeneic sperm. Dr Fowler went on to extrapolate from this theory of antigenic suppression of T-cell immunity, to pose the question: "Is it not possible that "haemophiliac" AIDS may be a function of the concentrate itself, rather than a specific agent transmitted by homosexuals with, or "incubating", AIDS?".

71.5. There was a similar debate occurring in the USA. The Inquiry might wish to refer to the report "HIV and the Blood Supply: An Analysis of Crisis Decision-

Making" from the Institute of Medicine (1995)[12] which gives a full account of the differing views about the causation of AIDS at this time, as well as the policy response.

72. Q72: Advice DHSS received on risk of HIV/AIDS from blood and blood products

72.1. I have been asked to describe, in as much detail as possible, the advice the DHSS received, when and from whom, about the risks of HIV infection/AIDS transmission associated with blood and blood products. In answering this very broad question, I have necessarily focussed on the sources of information with which I was familiar.

72.2. During my time in Med SEB, the transmissible agent, LAV/HTLV-III/HIV, had not been identified as the cause of AIDS. As far as AIDS was concerned, there were various sources of information or advice to the DHSS:

i) One source, as I have described, was from the CDSC, via Med IMCD. CDSC also had good connections with CDC Atlanta.

ii) Another was the CMO's Consultant Adviser in Blood Transfusion, Dr Gunson, who also attended, and reported back from, various international conferences related to blood transfusion and blood safety, including the Council of Europe. Dr Gunson regularly briefed the CMO privately, as I have explained in Section 1.

iii) Dr Lane, Director of BPL, and Dr Craske, Chair of the Haemophilia Centre Directors' Hepatitis Working Party were also important sources of information. As examples, I have referred below to Dr Craske's paper of 1 March 1983 [HCDO0000517_002] and Dr Lane's report to the April CBLA meeting dated 22nd April 1983 [CBLA0001697]. That report provided an early indication of the production difficulties that would be experienced, by BPL, were there to be a demand to switch from

[12] This is the 1995 report of the "Committee to Study HIV Transmission through Blood and Blood Products", approved by the Governing Board of the National Research Council in the USA. It sets out a comprehensive account of the events leading to the contamination of the US blood supply and "a critical assessment of the difficult decisions that were made in the context of the uncertainty of the period."

intermediate purity concentrate production to (frozen) cryoprecipitate. His paper also ruled out, on logistic production grounds, the potential of BPL to produce small-pool freeze-dried cryoprecipitate.

iv) Other experts would be in contact with the DHSS and raise issues: see the important letter and report from Dr Galbraith, PHLS (9 May 1983) proposing the temporary withdrawal of all American products made from blood donation after 1978 [CBLA0000043_040]; and the meeting I had with Dr Tedder, Middlesex Hospital Medical School and Dr Mortimer, of the PHLS (20 May) [DHSC0003824_164].

v) Information was presented at meetings of the CBLA. See for example the minutes of the meeting of 27 April 1983 [BPLL0003987_002], where Dr Lane and Dr Gunson both addressed the topic of AIDS. The minutes merely record that a copy of the report from Dr Lane on the topic of AIDS (CBLA83/23) was received and noted. However, this was an important paper and the Inquiry's attention is drawn to it [CBLA0001697_001]. I refer to it below (paragraph 85.1). I was not a regular CBLA attendee, but Dr E.L. Harris (DCMO) did attend, as did DHSS administrators: first Mr Godfrey, succeeded by Mr Winstanley in spring 1983 (see the minutes I have referred to).

vi) I made it my business to secure invitations to attend meetings of the Haemophilia Reference Centre Directors (which DHSS representatives did not normally attend) after we learned of the first case of AIDS in a UK man with haemophilia and I also attended meetings of the Regional Transfusion Directors, aiming in both cases to understand the position of these specialist groups in relation to the emerging news about AIDS. I would report back from these meetings to DHSS colleagues and would share any information the DHSS held with those attending the meetings.

vii) I attended the Advisory Committee on the NBTS, as its joint secretary and some meetings of the Regional Transfusion Directors (RTDs).

viii) I regularly attended meetings of the UKHCDO.

ix) I was also in occasional correspondence with Professor Arthur Bloom, Chair of the HCDO. For example, [BPLL0001351_047] is a letter from

me to Professor Bloom on 19 January 1983 requesting an update on discussions about AIDS in US haemophiliacs, at a recent meeting of the Haemophilia Centre Directors.

x) Occasional correspondence from manufacturers of commercial Factor VIII: see, for example, the letter to me of 9 May 1983 from the Managing Director of Travenol [WITN4461116]; this was one of the first intimations I had that a commercial manufacturer was attempting to heat-treat Factor VIII concentrate in the hope of killing any viruses which might be causing AIDS. It was already known that they were working on developing heat and other treatments to inactivate non-A, non-B hepatitis viruses.

xi) Information was also received from the Medical Research Council; see, for example, the minutes of the MRC's Working Party on AIDS, 10 October 1983, in relation to the current theories concerning the aetiology of AIDS [PRSE0000389].

xii) With regard to the safety of blood products, the DHSS, as the Licensing Authority, was advised by the Committee on the Safety of Medicines, through its Sub-Committee on Biological Products (CSM(B)). The National Institute for Biological Standards and Control (NIBSC) was part of the licensing regime, and its Director was Dr Joseph Smith. He attended, together with one of his colleagues, the meeting of DHSS officials on 3 June 1983 which reviewed the actions needed on AIDS [DHSC0002229_030] which is described in full at Q96.

72.3. I sought to keep abreast of the medical literature, mostly the BMJ (which I had at home) and the Lancet (on circulation around the Medical divisions). It was not particularly easy to get hold of the New England Journal of Medicine, or other American journals because this required a special request to the DHSS library and, more often than not, the journal would be out on loan. In any case, by the time a peer-reviewed publication reached a prestigious journal, the issues being written about were inevitably months "in the rear-view mirror". It is almost impossible to conceive, now, in this age of instant internet access, how constrained we were in obtaining adequate or, in particular, timely information from abroad. Indeed, I found myself regularly being alerted to some

new development by articles in the lay press, that were circulated by the DHSS Information Division.

72.4. I have tried to summarise, above, some of the sources of the information available to the DHSS. The nature of the advice or information that was being received I have set out below, in a detailed chronological account of events, which includes my responses to the Inquiry's specific questions.

73. Q73 and Q74: Enquiries and Investigations undertaken by DHSS into HIV/AIDS and Blood Products, and the provision of information by the DHSS

73.1. I have been asked to describe the enquiries and investigations undertaken or commissioned by the DHSS in respect of the risks of transmission of HIV/AIDS and the information that was obtained as a result of those enquiries and investigations.

73.2. This is an extremely broad question to which I can only respond with an account of my own involvement in, and knowledge of, the evolving situation with regard to AIDS.

73.3. I have also been asked to explain what if any steps were taken (and when and by whom) to ensure that the risks of transmission of HIV/AIDS from blood/blood products was known to and understood by: (a) Ministers; (b) clinicians; (c) NHS bodies; (d) patients who might be treated with blood or blood products, and (e) the public.

73.4. Again, I have tried to deal with these questions in the course of providing a chronological account of events.

73.5. To provide context, it may be helpful if I explain the position of the DHSS during my time in relation to the provision of advice to clinicians. This was not seen as being the proper preserve of the Department. It would have been very unusual for the Department to become involved in providing clinical advice to doctors, still less to patients. Guidance to doctors would have been seen as the province of the relevant professional bodies.

73.6. This is in distinction to the use of the CMO "Dear Doctor" letters which were used to draw attention to wider public health concerns involving the medical community at large.

73.7. In general, clinicians were expected to be informed of potential adverse effects from a particular treatment through their own reading, their specialist networks (e.g. the UKHCDO) and from specialist medical societies and Medical Royal Colleges etc.

73.8. The Department did not hold itself out as having specific clinical expertise and Departmental doctors certainly would not try to second-guess the experts in the field. Essentially, the Chief Medical Officer and his medical staff sought advice from statutory groups, such as the Standing Medical Advisory Committee, or from recognised groups of medical specialists and used their advice to help in the formulation of policy. In the case of issues relating to haemophilia, a rare condition, the UKHCDO would be an important source of information they would turn to. In turn, we would look to the Haemophilia Centre Directors and other haematologists to advise their patients.

73.9. Product licensing, including the issue of information accompanying products, was the responsibility of the Licensing Authority. The Authority acted upon advice from the Committee on Safety of Medicines, established under Medicines Act 1968. NHS bodies would not necessarily have been informed by the Licensing Authority of the hazard of transmission of AIDS from US Factor VIII concentrates, given that no products were being withdrawn and there was no specific action that the NHS authorities were being asked to take in the light of this possibility.

73.10. One area where I can provide a definitive account of how advice was being offered to a specific group, is in relation to the leaflet which was prepared to alert blood donors to the existence of AIDS and its likely association with blood transfusion and the need for donors, who might belong to one of the defined risk groups, to refrain from donating their blood (please see my response to Q76 below from paragraph 86.50 onwards).

73.11. Later, after I left Med SEB, and as the overall numbers of cases of AIDS in the country continued to increase rapidly, warnings were issued to the general

public by the Department via the well-known media public information campaigns and television advertisements.

73.12. As the potential problem with AIDS and commercial Factor VIII began to emerge, Ministers were kept informed and were involved with decision-making through face-to-face briefings and written submissions. These were led by administrative colleagues, with contributions from medical colleagues as requested and, as far as I can now see, started with the briefing for the Prime Minister and the Parliamentary Under Secretary of State for Health, Mr Finsberg, on 3 May 1983 [DHSC0001651].

74. Q74: See Above

75. Q75: Chronology of steps taken by the DHSS to reduce risks from HIV/AIDS

75.1. I have been asked to provide a full and chronological account, in as much detail as I can, of the decisions and actions taken by the DHSS to reduce the risk of people being infected with HIV/AIDS in consequence of treatment with blood or blood products. I have interpreted this question to refer to my own experience, which stretches up to December 1983 only; after that, others took over my role.

75.2. I have set out a detailed account of my involvement in the DHSS response to HIV/AIDS below, starting with the events of 1983 considered at paragraph 78.7. This includes the work that I, in conjunction with colleagues in Medicines Division undertook in relation to stocks of imported Factor VIII concentrate. I have also tried to answer the Inquiry's specific questions in the course of setting out that chronological narrative.

75.3. The account below also includes my involvement in the issue of a leaflet, to discourage donors in higher-risk groups from donating blood.

75.4. As requests 77 and 78 ask about heat-treated products, I have addressed this topic first, although it straddles the broader chronology.

76. Q76: The Blood Donor Leaflet

76.1. Q76 is addressed below at 86.50

77. Q77: Heat Treated Products

77.1. I have been asked to describe the DHSS's:

i) consideration of the advantages and disadvantages of heat-treated products; and

ii) decision-making process and decisions regarding the introduction of heat-treated products.

77.2. By late 1982, I had become aware that manufacturers of commercial Factor VIII concentrates were working on heat-treating their products with the aim of inactivating hepatitis viruses. I took steps to inform myself about this (see for example my minute to Dr Fowler dated 22 December 1982, asking if any Factor VIII concentrate claiming a reduced risk of hepatitis had been submitted for product licensing) [WITN4461117]. As the problem of AIDS began to surface and, working on the assumption that it might be caused by a blood-borne virus, finding a means to inactivate any viruses in coagulation factor concentrates appears to have accelerated the manufacturers' efforts to bring heat-treated concentrates to the market (see, for example, the letter to me from the Managing Director of Travenol of 9 May 1983, [WITN4461116]).

77.3. Haemophilia Centre Directors were being approached by manufacturers to trial heat-treated products, which were not licensed in this country, on a named-patient basis, as a means of reducing the risk of non-A non-B hepatitis. The UKHCDO was concerned that the efficacy of heat-treatment was unproven and needed to be investigated in clinical trials, rather than used on a named-patient basis for treating individual patients. So (for example) on 22 March 1983, Drs Craske, Rizza and Bloom wrote to Haemophilia Centre Directors (HCDs) about trials of 'hepatitis reduced' Factor VIII, outlining the protocol for a clinical trial of such products [PRSE0003530]. On 24 June 1983, Drs Bloom and Rizza wrote to all HCDs urging them not to use the heat-treated products outside the framework of a clinical trial [HCDO0000270_004].

77.4. At the same time, both BPL and PFC Liberton were working on viral inactivation methods for their factor concentrates, using different methodologies. Information about developments reached me via, for example, attendance at the NBTS's Working Party on Plasma Supply. Thus, on 8 February 1983, Dr

James Smith of BPL reviewed the various techniques that might create hepatitis-reduced Factor VIII and the implications for supply: "It was agreed that whatever method was used there would be a deleterious effect on yield of Factor VIII", perhaps as much as 25% [WITN4461118].

(a) Advantages and disadvantages

77.5. As far as non-A, non-B hepatitis was concerned, a reliable and safe viral inactivation method for coagulation factor concentrates would have been a highly advantageous development, from the point of view of patients, in terms of reducing risks to their health. In modern parlance, it would have been a 'game-changer'. As a second-order issue, the prevention of post-transfusion hepatitis, with its acute and chronic sequelae, would also have been cost-sparing for the NHS (although there would be additional costs of manufacture by BPL and/or purchase of virus-safe commercial products).

77.6. The disadvantages included the loss of yield of coagulation factors in the final product, requiring an increase in the supplies of plasma for a given production target. There was also concern that heating these proteins might damage them in some way, such that they provoked more adverse reactions in recipients, were less effective by virtue of a shorter half-life in the circulation, or encouraged the development of antibodies. Undoubtedly, virally-inactivated products would cost more, whether manufactured by BPL/Liberton or by commercial manufacturers. Whilst that would have been a material consideration for Regional Health Authorities, who were the purchasers of commercial product and who paid for the plasma production by RTCs, I do not recall that it featured significantly in the DHSS's considerations at the time; I believe the Department was keen for BPL to try to undertake the necessary research and development, given the huge potential benefits to patients' health (see also my reply to Q 78).

(b) Decision-making process and decisions regarding the introduction of heat-treated products.

77.7. I left Med SEB before any decisions were needed or taken in relation to the introduction of heat-treated products. As to the processes that might have been involved before coming to a decision, the most material factor in reaching a

decision would have been proof of their efficacy and safety from controlled clinical trials and, in consequence their approval for licensing by the UK Licensing Authority, on the advice of the Committee on Safety of Medicines. Decisions on purchasing commercial heat-treated products (to make up any continuing shortfall in BPL's products) would then have been up to RHAs.

78. Q78: Consideration of costs

78.1. I have been asked what role concerns about costs played in the DHSS's decision-making processes regarding heat-treated products, by reference to a letter from Dr Gunson to me dated 29 June 1983 [DHSC0002229_056].

78.2. Dr Gunson wrote to me on that date, very concerned about the claims being made about commercial heat-treated products. His personal view was that the "F.D.A. is extrapolating heat-treatment with respect to AIDS too far since the agent may not be killed by the treatment." He referred to recent news that chimpanzees who had received heat-treated concentrate still went on to develop hepatitis and noted "It would be unfortunate if a false sense of security arose from the use of this material which might lessen the degree to which professional donors [in the US presumably] were medically examined." So, his primary points were about safety and efficacy.

78.3. He also noted that the commercial product would be "double" the costs of the untreated product. He wrote that: "if demands are made for its use by either Haemophilia Directors or possibly the patients themselves, if they hear or read about it, this would play havoc with the RHA's finances." Dr Gunson explained that he was due to attend the first part of the meeting of the CSM on 13 July and asked if I felt that this was a relevant issue to raise with the Medicines Commission (i.e., the Committee on the Safety of Medicines, CSM).

78.4. In my response to Dr Gunson, of 1 July 1983 [PRSE0001887], I wrote that I, too, had heard the news about the chimpanzees developing hepatitis after receiving heat-treated Factor VIII concentrate and that this was the sort of information that the Licensing Authority would obviously need in considering applications for a product licence. I went on to explain that it was not part of the CSM's remit to be concerned with costs, only with quality, safety and

efficacy. However, I thought that, in the event that unjustified demands for heat-treated products were being made (unjustified in that they were of unproven benefit), the additional costs to RHAs would be a reason for them to resist those demands, until the efficacy of the products had been proven through properly conducted controlled clinical trials. I said: "your comments about the potentially major financial consequences for health authorities, in the event of unjustified demands for this material being made, could be used to support the argument for the need for properly controlled clinical trials before such material is introduced into this country."

78.5. I wrote this well aware of the need for such proper clinical trials, on patient safety grounds. By this time, there were real concerns that products would be introduced without such controls: see for example paragraph 77.3 above where I refer to the letter sent on 24 June 1983 from Drs Bloom and Rizza to all HCDs, urging them not to use the heat-treated products outside the framework of a clinical trial.

78.6. I left Med SEB before any controlled clinical trials took place.

Continuation of Chronology: 1983

78.7. I have set out a chronological account of my involvement in matters relating to AIDS in 1981 and 1982 above, trying to answer the Inquiry's specific questions in the course of that narrative. I now pick-up the narrative for 1983, providing a chronological account and including my responses to the Inquiry's specific questions, as before.

79. Q79: Dr Craske's proposal 10 January 1983

79.1. The first question addressed to me is about the proposal outlined in Dr Craske's letter of 10 January 1983 [DHSC0002353_021] (the draft Lancet article is at [OXUH0001618]). I have been asked if this resolved (as Dr Craske suggested) "the problem related to the investigation of factor VIII related" AIDS?

79.2. As I read Dr Craske's letter – and as I assume I will have read it then – the subjects of the first and second paragraphs are unconnected. In the first paragraph, Dr Craske simply informed me of his intention to submit an article

to the Lancet concerning non-A, non-B hepatitis after a first infusion of Factor VIII. He noted that drug companies were planning to introduce 'hepatitis-reduced' products and was concerned that there should be proper clinical trials (an issue I have discussed above).

79.3. In the second paragraph, I believe that what he was referring to when speaking of the "problem related to the investigation of Factor VIII related AIDS" was simply about resolving the issue of whether, and how, any reports of AIDS related to US Factor VIII should be reported to the US CDC, as the CDC had requested. The resolution was that he, Dr Craske, on receipt of the reports from HCDs, would report them both to CDC and CDSC. That does - and I believe did - seem to me to resolve the reporting problem that he was addressing.

80. Q80 and Q81: Observer Article dated 16 January 1983 and Letter dated 19 January 1983

80.1. Amongst the papers provided to me by the Inquiry, there is reference to an Observer article of 16 January 1983, headlined "Mystery Disease Threat" [DHSC0002223_085]. After giving a description of the "mystery" illness, the article mentioned that the issue was to be discussed at a forthcoming meeting of HCDs.

80.2. The article had certainly prompted interest in the Department and, when the article was brought to my attention, I undertook (see my note in manuscript on the photocopied article), to write to Professor Bloom to try to find out what the views of Haemophilia Centre Directors were about AIDS. I duly wrote to him on 19 January 1983 [BPLL0001351_047], but suggested he telephone me with the information. From the papers provided by the Inquiry, it is likely that the article was referring to the meeting of the UKHCDO's Hepatitis Working Party, which also took place on 19 January 1983 [HCDO0000558], the same date as my letter to Professor Bloom. I return to this below.

Note of 18 January 1983

80.3. I have been asked (Q80) about my reported views at the time, as expressed in a note dated 18 January 1983 [DHSC0002223_088], from Dr Sweeney to Miss Fraenkel, which also arose out of the Observer article. I am quoted in the note

as confirming that the "value to severe haemophiliacs of clotting factors 8 and 9 [sic] far outweigh the possible, and as yet unproven hazards of the transmission of acquired immune deficiency syndrome".

80.4. My view will have then been based on the fact that, whilst the introduction of cryoprecipitate in the 1960s had been highly beneficial for severe haemophiliacs and significantly improved their life expectancy, they still suffered a life constrained by pain, disability and the need for frequent hospital admissions and, in many cases, premature death. With the advent of Factor VIII concentrates both life expectancy and quality of life were greatly improved. In January 1983, there was no consensus amongst experts – even in America where some 10 haemophiliacs had, by then, developed AIDS - that the potential risks from coagulation factor concentrates outweighed their benefits. This was the view of the UKHCDO and also the view that was reached by experts on the Biologicals Sub-Committee (CSM(B)) of the Committee on Safety of Medicines when the issue was considered on 13 July 1983.

80.5. I have been asked whether my views reflected the DHSS's policy at the time. It is probably artificial to speak of DHSS 'policy', as such, on this issue at the time. It was very early days in the evolution of our understanding of AIDS and the risks posed to recipients of blood or blood products. I was commenting to colleagues in the context of the article in the Observer. My comments had no status as policy. I would suggest that any DHSS policy which emerged followed the decision of the Licensing Authority on the advice of the CSM, not to withdraw supplies of commercial Factor VIII. This was on the grounds, as set out in the minutes of the CSM(B), that the benefits to haemophiliacs of coagulation factor concentrates outweighed the risks and that "the perceived level of risk [did] not at present justify serious consideration of such a solution".

Hepatitis Working Party, 19 January 1983

80.6. Turning back to the meeting of the UKHCDO's Hepatitis Working Party on 19 January, from the minutes of that meeting (paragraph (b), p.96 [HCDO0000558]) - which I will not have seen at the time - I note there was an extensive up-date about AIDS from Dr Craske, who had been in touch with Dr Dale Lawrence of CDC Atlanta. So far, 10 cases of AIDS had occurred in

haemophilia A patients, none of whom had any of the "predisposing causes". The cases had occurred in parts of the USA where cases had not been found before. All but one had severe haemophilia and were on regular Factor VIII therapy. The youngest was 7 years old. Five had died. Dr Craske was reported as saying: "It seemed possible that FVIII or other blood products administered to these patients might be implicated".

80.7. Dr Craske said that the CDC AIDS Task Force was working on the hypothesis that an infective agent was involved, possibly a virus specific for human T-cells. Further support for this hypothesis had come from three cases associated with either whole blood or platelet transfusions. The third case he described is recognisable as the 'San Francisco baby'. The incubation periods for the cases were between 6 months to 2 years.

80.8. Dr Craske went on to discuss the cell-mediated immune defect that was found in laboratory testing, with lymphopenia (reduced numbers of lymphocytes) and a T4:T8 ratio of less than 1.0. This was the reverse of the normal T4:T8 ratio, with a significant fall in the T4 (helper) lymphocytes and indicated a profound immunological disturbance. Two recent papers in the New England Journal of Medicine (NEJM) had suggested that transfusions of freeze-dried Factor VIII might be a factor. Discussion of the two NEJM papers drew attention to the fact that the T4:T8 ratio was lower in those who had received freeze-dried concentrate than those who had received cryoprecipitate or in normal controls. Dr Craske went on to describe the reporting system for cases in the US possibly associated with US commercial Factor VIII. He suggested a similar retrospective survey might be conducted in the UK, perhaps adapting the American form. He proposed that consideration should be given to a prospective study of the effects of various factors on cell-mediated immunity in haemophilia A patients, especially comparing the effects of NHS Factor VIII treatment with US commercial Factor VIII. He said he would prepare a form for the reporting of AIDS cases and consider what further information might be needed in a retrospective study. For a prospective study, it was essential to standardise tests if different laboratories were performing tests for cell-mediated immunity for the same project.

80.9. The discussion of AIDS concluded with a reference to an outbreak of tuberculosis infection in young severely affected haemophiliacs in Birmingham Children's Hospital. It would be important to determine whether haemophilia A patients on freeze-dried concentrates were more susceptible to tuberculosis than healthy children not regularly treated with blood products.

80.10. How much of this discussion was conveyed to me by Professor Bloom, I do not now know. From what I can now see, steps were being taken by relevant experts in the field to obtain retrospective surveillance information and to look into the possibility of undertaking a prospective study comparing the effects on cell-mediated immunity of NHS Factor VIII with commercial concentrates.

81. Q81: Letter to Professor Bloom

81.1. I have addressed Q81 alongside Q80 above.

82. Q82: Heathrow Airport Meeting 24 January 1983

82.1. I have been referred to the meeting on 24 January 1983, when representatives of the pharmaceutical company, Immuno met with Dr Craske, Dr Boulton, Professor Bloom and other Haemophilia Centre Directors at a Heathrow Airport hotel.

82.2. Before responding on the meeting of 24 January 1983, I should say that the papers include a minute dated 31 December 1982 from Dr Fowler to me [WITN4461119]. This refers to an Immuno meeting at Heathrow as already having taken place prior to 31 December 1982. It raises the question as to whether there was more than one meeting at Heathrow. However, it does not appear that the Department was involved in any such meeting at Heathrow and I certainly was not.

82.3. I do not know whether, or by whom, the outcome of the January 1983 Immuno meeting was conveyed to the DHSS. I note from the papers I have been shown [RFLT0000050] that a summary of the discussion was sent to one of the participants in the meeting, Dr Peter Kernoff, by Mr Norman Berry of Immuno, on 16 March 1983. I do not know if, or when, the DHSS may have seen that summary.

82.4. I have been shown, in Inquiry papers, a more extensive report of the meeting [PRSE0002647] but it is not clear who wrote it, when it was distributed and to whom. It lists the participants at the meeting. The meeting was essentially about the use of two different methods of chemical inactivation of non-A, non-B hepatitis. A discussion about AIDS was reported, which was led by Dr Craske, and was essentially a reprise of his report to the UKHCDO's Hepatitis Working Party on 19 January 1983.

83. Q83: "Line to Take" (3 May 1983)

83.1. I address Q83 at paragraph 86.2, alongside the other events of May 1983.

March 1983

83.2. On 1 March 1983, I note that Dr Craske, who had been charged by the UK UKHCDO to investigate the issue of AIDS because of its apparent similarity of transmission to hepatitis B, wrote a report [HCDO0000517_002] summarising the position on AIDS in the USA. Between June 1981 and 13 January 1982 the CDC in Atlanta had become aware of an increase in the occurrence of Kaposi's sarcoma, Pneumocystis carinii pneumonia and other serious opportunistic infections, principally among promiscuous homosexual men in the USA. Amongst the cases were seven haemophiliacs with no association with drugs or sexual promiscuity.

83.3. Dr Craske set out the details of the reported cases. At least 40% of the patients had died. There was often a long interval between the onset of symptoms and the diagnosis of AIDS (but, I now can see, no information relating to an incubation period between a putative infection and the onset of any symptoms). He noted that several theories had been advanced about the aetiology of AIDS. Of these the following was thought most likely: "The association with sexual promiscuity, intravenous drug abuse and possibly the transfusion of commercial blood concentrates, together with evidence of clustering and a prodromal phase suggest an infectious agent with a similar epidemiology to that of Hepatitis B, possibly specific for human T cell populations." If this was the most likely cause, Dr Craske observed that it is then:

".. possible that such an agent might be present in the plasma pools used to prepare commercial factor VIII and IX concentrate manufactured from donor plasma collected in the U.S.A. [...] *Presumably this would have been obtained from homosexuals who donated plasma for fractionation when in the incubation period of the disease."*

83.4. The report also stated that it was thought likely that batches of Factor VIII concentrate which might contain the AIDS agent had come into use since January 1, 1980 in the USA. The CDC had therefore requested that HCDOs cooperate with them in reporting any cases of AIDS possibly associated with US commercial factor concentrate. Such reports would be in addition to reports to be made to CDSC.

83.5. From the papers, I think that I saw Dr Craske's report of 1 March 1983 when he sent it to me on 11 April 1983 - see paragraph 84.7 below.

Request for CSM(B) Consideration

83.6. On 28 March 1983, Dr Joseph Smith the Director of NIBSC (the National Institute for Biological Standards and Control) wrote to Dr Keith Fowler at the Medicines Division to suggest that the Biologicals Sub-Committee on the Safety of Medicines (CSM(B)) should examine "the problem of AIDS in relation to licenced blood products". [WITN4461120]. It was suggested that Professor Bloom, as the Chairman of the UKHDCO could attend to advise, and also that information from the CDSC (responsible for surveillance) could be sought. The letters recently released by the US Food and Drug Administration (FDA) were attached; the action advised by the FDA can be seen at [DHSC0001203].

83.7. This seems to have been the initial 'prompt' for the CSM(B) meeting which ultimately took place in July 1983. However, I do not believe that I was copied-into or would have been aware of Dr Smith's letter at the time.

83.8. I did come to know of the proposal to seek advice from the CSM-B. Thus, on 21 April 1983, Mr Godfrey (HS1) minuted Miss Spencer (Medicines Division) [WITN4461121, copied to me] to ask:

"Some time ago you mentioned that the Biological Sub-Committee of the Committee on the Safety of Medicines, Chaired by Dr Smith

(MIBSC [sic]) was considering inviting expert evidence on AIDS and its possible transmission through blood products, notably American Factor VIII. Did anything come of this? I would be very interested, if it were permitted, to see the evidence received by the Sub-Committee."

84. Q84: Protocol for Reporting Suspected AIDS cases

April 1983

84.1. I have been asked to comment on the reporting system for suspected AIDS cases (Q84). The Inquiry will wish to note that the DHSS was not involved in the reporting system. Reporting was between clinicians and CDSC. More broadly, the Department was not involved directly in the surveillance and monitoring of any communicable disease. This was carried out (very effectively, as I found out, when I became head of Med IMCD) by the CDSC and reports were made, as appropriate, to MED IMCD. There are examples of the reports referred in the account below.

84.2. The Inquiry has drawn my attention to a letter Dr Craske wrote to me on 11 April 1983 [DHSC0002353_024] enclosing some papers concerning the basis of reporting of cases of AIDS that were possibly related to Factor VIII therapy. He summarised the basis of reporting as being similar to that for Factor VIII-related hepatitis, but any definite cases would be reported both to CDSC and Dr Dale Lawrence, of CDC Atlanta. The papers he enclosed with his letter were: a report on AIDS, dated I March 1983, prepared for the UKHCDO's Working Party on Hepatitis [HCDO0000517_002] and a second paper of the same date [HCDO0000273_078] on the spectrum of disease presentation on AIDS. The latter paper requested that all patients with coagulation factor defects fulfilling any of the specified criteria for AIDS, should be returned to Miss Spooner at the Oxford Haemophilia Centre on form AIDS/3.

84.3. Further information about the reporting system is contained in the minutes of the meeting of 13 May below.

85. Q85: Meeting at CBLA 27 April 1983

85.1. The Inquiry has noted that on 27 April 1983, my colleagues Mr Godfrey and Mr Winstanley attended a meeting of the Central Blood Laboratories Authority at which there was, at 52/83, a discussion on AIDS [BPLL0003987]. The minutes record discussion of a paper (83/23) from Dr Lane [CBLA0001697] which in turn recorded a discussion amongst the senior management of BPL about AIDS held on 18 April. Dr Lane's paper discussed (amongst other things) the inability of BPL to "manufacture small pool freeze-dried cryoprecipitate in significant amounts, as an alternative to large pool intermediate Factor VIII concentrate."

85.2. Whilst I have not seen the actual note of the BPL meeting of 18 April, there is considerable information about this topic contained in Dr Lane's draft statement for the HIV litigation,[13] paragraphs 628 – 639. He notes that the topic of AIDS was raised by Professor Bloom at the CBLA meeting on 23 March 1983, with a suggestion that it should be discussed at a future meeting. Dr Lane notes that as a result, he wrote a memorandum the following day (24 March), which, amongst other things, discussed the issues raised by a potential demand for a return to cryoprecipitate use and the implications for BPL. However, he noted in his draft statement:

> *"[633] In the event, the anticipated pressure for a switch to the use of cryoprecipitate as a temporary expedient never happened. It was a matter for the haemophilia clinicians (and to an extent the Licensing Authority if it thought US concentrate unsafe) to direct this change. The facilities at BPL/PFL have thus never been used for the production of small pool cryoprecipitate."*

85.3. Dr Lane then sets out an account of the meeting of 18 April, derived from notes written up on 21 April 1983 (I presume that the Inquiry will have access to these and the other documents referenced by Dr Lane). The overall outcome was a decision to make no changes to manufacturing and to continue with research on heat-treatment, pending further information. This was explained in more detail in Dr Lane's note for the CBLA (83/23) on 27 April. Dr Lane's draft

[13] A copy of this document was supplied to me by the Inquiry as part of the process of preparing this Statement. I had not previously seen it.

statement explains the reference to "logistic production considerations" in that note. This "related to the equipment at the laboratory. Our facilities were geared towards production of concentrates from large pools" [paragraph 640].

85.4. In his paper for the CBLA, Dr Lane also set out the difficulties for BPL if there were a decision to move to frozen cryoprecipitate ("wet" cryoprecipitate). He said that "an elaborate programme of pooled capture under sterile conditions of regional cryoprecipitate supernatant would have to be introduced to provide starting material for Factor IX, immunoglobulin and albumin products".

85.5. This point was further elaborated in Dr Lane's draft statement, paragraph 642:

> *"Whilst it was appreciated that special requirements for haemophiliac care/products might require acute attention, BPL was required to preserve a reliable supply of source material for fractionation of Factor IX, immunoglobulin and albumin, all of which are life-saving products. Cryoprecipitate supernatant would necessarily form that source material, should RTCs elect or be required to revert from FFP collection to single unit cryoprecipitate manufacture."*

85.6. I have drawn attention to this evidence as it throws light on the discussion of whether BPL could have pivoted to the production of cryoprecipitate. It also highlights the significant implications for the production of other essential fractions (for example, Factor IX, immunoglobulin and albumin) in the event that the RTCs started to retain significant amounts of the plasma that they would previously have sent to BPL, in order to increase their own cryoprecipitate production.

85.7. I turn then to the questions that the Inquiry has asked about the records of the CBLA meeting of 27 April.

85.8. With regard to the issue of whether the minutes of this meeting had been circulated to others within the DHSS, I did not attend this meeting, although the minutes record that Dr Walford "should be allowed to go to those meetings which Dr Harris was unable to attend" (see for example the meeting of 22 June 1983, when this seems to have happened). I think it follows that the minutes of the CBLA meetings were probably not routinely circulated to those of us in the Department, including myself, who were not expected to attend the meetings.

Dr E.L. Harris was the DCMO and the senior DHSS representative at the meetings of the CBLA.

85.9. The Inquiry has noted that Dr Gunson was reported as stating that no further measures would be recommended at the next meeting of RTDs.[14] Professor Bloom was reported as stating that "his impression was that haemophiliacs were not greatly concerned about AIDS". I have been asked whether the DHSS relied on these statements when formulating its policies on AIDS. However, given my comments on the circulation of these minutes above, I really cannot speculate whether the comments made at the meeting by Dr Gunson and Dr Bloom were relied upon by "the DHSS" (or, presumably, by specific officials or ministers). I have no reason to suppose that my own opinions were influenced by what Professor Bloom is reported to have said, since I very much doubt I will have been aware of his comments. However, at the next CBLA meeting on 22 June (which I did attend, in place of Dr Harris), the minutes record Professor Bloom saying that "since the last Authority meeting apprehension amongst haemophiliacs about AIDS had increased."

85.10. With regard to the reference in the minutes to Mr Winstanley agreeing to contact a television company to try to establish the number of phone calls made to the number provided at the end of a recent television programme on AIDS, I can only speculate about the reason for this. One interpretation would be that the CBLA wished to use this information as a proxy for how concerned the general public was about AIDS, having viewed that particular TV programme. From the minutes of the meeting of 22 June (see below), I can see that Mr Winstanley reported back that he had made inquiries and the TV company "were unable to say exactly how many calls they had received, but it had been 'quite a lot'."

[14] Relevantly, Dr Lane's draft Statement at paragraph 638 references the third Meeting of the UK Working Party on Transfusion Associated Hepatitis on 20 April 1983, as well as a summary report of its work dated 28 April (see paragraph 643). I do not have access to the minutes of the meeting but the decisions which seem to have been taken there foreshadow Dr Gunson's comments on 27 April. The 28th April document states: "The Working Party has followed carefully the information from the USA on AIDS and has considered the recommendations with respect to donor screening and the use of cryoprecipitate. To date, there have been no cases reported following transfusion of blood or blood products. It has been agreed that, until further information is available, the Working Party will not recommend changes to present practices for donor selection or use of product."

86. Q86: Events of May 1983

86.1. I thought it would be convenient to address all the Inquiry's questions concerning the events of May 1983 in chronological order.

"Line to Take" (Q83)

86.2. On 3 May 1983, Mr John Parker (HS1) wrote to Private Office (Mrs Walden) with a briefing for Mr Finsberg. He sent a copy of the "line to take" which had been prepared for Mrs Thatcher, for PMQs, in relation to stories that had emerged in the press over the weekend in relation to AIDS [DHSC0001651]. The "line to take" was accompanied by background note, in Q&A form, for Mr Finsberg.

86.3. I note that the "line to take" was not in fact used by the Prime Minister on 3 May. She was asked about the self-sufficiency by Mr Race MP, but replied:

> *"We first need to find out a good deal more about the incidents and the causes that have been reported before coming to any conclusion."* [WITN4461122].

86.4. The Q&A briefing which I have been shown is said have been circulated by Mr Parker and is at [WITN4461123]. I have no recollection of being involved in the drafting of either document and at this point Med IMCD was in the lead for medical advice to administrative colleagues. The first time I became aware of the Cardiff case was through the minute from Dr Sibellas to Dr Oliver copied to me on 6 May 1983, see paragraph 86.13 below.

86.5. The briefing was copied to me and seventeen others, including officials from SHHD and the Welsh Office. The "line to take" contained the words: "....there is as yet no conclusive proof that AIDS has been transmitted by American blood products. The risk that these products may transmit the disease must be balanced against the obvious risks to haemophiliacs of withdrawing a major source of supplies".

86.6. The Q&A background note explained:

> *IS IT CAUSED BY A VIRUS?*

The cause of AIDS is unknown. Although medical opinion is tending to favour a virus as the agent responsible, there is no proof that this is the cause. There is no means of testing for the presence of AIDS in patients or in blood or blood products such as FVIII."

[.....]

IS IT TRANSMITTED IN BLOOD OR BLOOD PRODUCTS?

As yet there is no conclusive proof that AIDS is transmitted by blood as well as by homosexual contact, but the evidence is suggestive that this is likely to be the case. The evidence relates to some 11 haemophiliacs in the USA and three in Spain, in whom the most likely explanation for the development of AIDS was their exposure to American FVIII concentrates. There is also some evidence that AIDS has been transmitted to babies in blood transfusions."

86.7. The Q&A briefing seems me to be a good and comprehensive account of facts as known at that time, as far as I am aware. The phrase 'there is no conclusive proof' has been much commented upon, but it was an accurate summary of the state of scientific knowledge at the time and it was followed by the qualification 'but the evidence is suggestive that this is likely to be the case'.

86.8. The 'Line to Take' for the Prime Minister was more succinct but acknowledged that there was a risk which needed to be "balanced against the obvious risks to haemophiliacs of withdrawing a major source of supplies."

86.9. To the best of my knowledge the briefing for the Prime Minister was the first time the wording "no conclusive proof" was used within the Department. It remained the 'standard line' used by Ministers and officials for the remainder of 1983, but it was generally qualified by a recognition of the existence of a risk and an account of the steps that were being taken to try to address it (see, for example, the letter of the 26 August 1983 from Lord Glenarthur to ASTMS [WITN4461124]).

86.10. Mr Parker's minute went on to propose that Mr Finsberg should meet representatives of the Haemophilia Society who had requested such a meeting, by the end of the week. Assuming Mr Finsberg were willing to meet the Society,

the intention was to review the 'line to take' after that meeting. Mr Finsberg agreed to meet the Society.

86.11. I understand that the meeting with Mr Finsberg did not happen because of the up-coming election. I do not recall a specific occasion when there was a review of the 'line to take', although the further discussions between officials, mentioned in Mr Parker's note, certainly did take place and, in so far as I was involved in them, are detailed below. It continued to be used because it remained scientifically correct although as I have noted, the wording was generally qualified by reference to steps being taken to minimise risks.

CDSC Alert 6 May 1983 (Q86, 89a)

86.12. I have been asked about actions taken following:

i) the CDSC alert on 6 May 1983 that a haemophiliac patient in Cardiff had AIDS symptoms [DHSC0002227_021]; and

ii) the special meeting of Haemophilia Reference Centre Directors attended by me [HCDO0000003_008] on 13 May 1983.

86.13. About a week before the meeting of the Haemophilia Reference Centre Directors on 13 May 1983, I had become aware (through a minute from Dr Sibellas (Med IMCD) on 6 May 1983 to Dr Oliver, copied to me [DHSC0002227_021]) that there was a report in the CDSC's Communicable Disease Report (CDR) of a case of AIDS in a Cardiff patient with haemophilia. This was the first reported case of AIDS in a UK haemophiliac.

86.14. In terms of response to this report, Med IMCD was in the lead, involving Med SEB, HS1 and Medicines Division as necessary, in relation to the blood and blood products dimension. See for example Dr Sibellas (MED IMCD)'s note to Dr Field dated 26 April 1983, summarising AIDS surveillance [DHSC000384_182], not copied to me and her further minute of 5 May [DHSC0003824_181], which fed in the information about UKHCDs being asked to report cases to CDSC. Dr Field, the head of Med IMCD, decided against setting up an AIDS Working Party as Dr Galbraith, Director of CDSC, had apparently suggested (see Dr Sibellas's minute to Dr Field of 12 May

[WITN4461125]). In relation to the proposed Working Party, please see my response to Q87 below.

86.15. Dr Sibellas's minute also mentioned that she had assured Dr Galbraith that:

> *"... we would liaise with CDSC and also told him that we had already met Dr Gunson (C.A. in blood transfusion) and he was in touch with Regional Transfusion Directors - and that alternative supplies of F VIII are being considered but are not going to be easy to come by - the matter is under active consideration. (Swiss supplies are considered doubtful - is Germany a possibility)?"*

86.16. Dr Gunson picked this issue up with me in his note dated 16 May on the subject of sourcing material from Switzerland, together with his report upon the Council of Europe meeting [WITN4461126]. See paragraph 86.35.

86.17. As far as the blood/blood products issues were concerned, I asked to be invited to attend both a specially convened meeting of the Haemophilia Reference Centre Directors, on 13 May 1983, and also a forthcoming meeting of the RTDs on 18 May. Events at the RTDs' meeting are dealt with in my response to Q92.

Letter from the Director of the CDSC – 9 May 1983

86.18. Before the meeting of the UKHCDOs of 13 May, on 9 May 1983 Dr Spence Galbraith, Director of CDSC, wrote to Dr Ian Field (SPMO of Med IMCD), recommending that all blood products, made from blood donated in the USA after 1978, should be withdrawn from use until the risk of AIDS transmission by these products had been clarified. [PRSE0003286] The letter attached a report setting out his reasoning for his recommendation.

86.19. My comments on Dr Galbraith's recommendations were contained in my minute to Dr Field of 13 May following the meeting of the UKHCDO. I discuss my minute to Dr Field in response to Q89 below.

Letter from Dr Craske

86.20. From the papers, I can see that Dr Craske was aware of both the proposed UKHCDO meeting and Dr Galbraith's views. On 10 May 1983, he wrote to Dr Whitehead, the Director of PHLS. He argued in favour of the creation of a working party to co-ordinate the investigation of cases and the prevalence of

AIDS as it appeared in the UK [WITN4461127]. On the subject of imports, he wrote:

> *"The problem of AIDS and transmission by Factor VIII is being discussed at the meeting of the Haemophilia Centre Directors of the UK to be held at St Thomas' hospital on Friday May 13th. I have been invited to attend this meeting and I understand that Dr. Diana Walford will be attending as an observer. Spence Galbraith and I discussed the problem of Factor VIII on the telephone yesterday, and we have agreed that he should write to the Department suggesting that the DHSS should consider whether American commercial factor VIII should be withdrawn from clinical use in the UK. I am not sure myself that we are at the stage when there is enough evidence to justify this step, but I think both the Department of Health and the Haemophilia Centre Directors will have to face this problem in the near future, and the earlier it is seriously considered the easier it will be to make a rational decision. I think that the outcome of the meeting will be that we will await the appearance of further evidence, but that if any more cases appear than this may well precipitate suspension of the use of this product in the UK."*

86.21. In addition, he noted that he had received the full transfusion records of the "Cardiff case". The patient had only received one batch of American commercial Factor VIII in 1980. But he had also received seven batches of Kryobulin, which was a product manufactured commercially by Immuno Ltd and could be derived from European plasma or from plasma from commercial sources in the USA. Dr Craske noted that it seemed possible that "our case may be related to this product rather than the American concentrate"; he was initiating investigations to see whether any European cases had been reported.

86.22. I was not copied into this correspondence, but I draw it to the Inquiry's attention as it throws light on Dr Craske's opinions at the time, including his view that the evidence was not yet strong enough to justify withdrawing American Factor VIII concentrates from the UK. He was also of the view that there was a need to investigate the potential role of European products.

Meeting of 13 May 1983

86.23. On 13 May 1983, by invitation, I attended a special meeting of the Haemophilia Reference Centre Directors which was specifically convened and attended by the Reference Centre Directors and Dr Craske, to discuss the issue of AIDS in haemophiliacs [HCDO0000394_137].

86.24. Professor Bloom, who was chairing the meeting, mentioned there had been one suspected case in the UK (this was broadly consistent with the alert I have mentioned above). Whilst this was clearly a reference to the Cardiff patient described in the CDR, no further details were given. The minutes show that there was a discussion concerning the definition of AIDS and a concern that many individuals with impaired cell-mediated immunity should not be classified as suffering from AIDS.

86.25. The meeting discussed reporting arrangements for suspected cases of AIDS in haemophiliacs and the steps to be taken should a patient develop the features of full-blown AIDS. For a patient in whom the condition was fully developed, it was agreed that there was no clinical point in changing therapy, because the condition was irreversible, so there would be no benefit. For other patients, the meeting agreed that it would be circumspect to continue the current policy of reserving NHS concentrates for children and mildly affected haemophiliacs. I note there was no mention of cryoprecipitate or DDAVP, but the rather brief minutes may not have reflected the complete discussion.[15] The meeting concluded that "there was as yet insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy". It was noted that there was to be a meeting of the Blood Transfusion Centre Directors to discuss the problem of donor screening in relation to AIDS.

86.26. On reporting, it was agreed that the criteria laid down by CDC Atlanta, and in the form prepared by Dr Craske for use at haemophilia centres, should be followed for diagnostic purposes. It was agreed that any patient who was suspected of suffering from AIDS should be reported immediately (whether to

[15] The fuller letter written subsequently by Professor Bloom dated 24 June 1983, which set out the recommendations of UKHCDO, did deal with both cryoprecipitate and DDAVP.

Dr Craske or Miss Spooner at the Oxford Haemophilia Centre is not clear) on the form provided. Thereafter the clinical course of the patient would be followed and a definitive diagnosis attached "if the patient developed intractable disease".

86.27. Following the meeting, Professor Bloom wrote to me (letter dated 17 May 1983, [WITN4461128]). He sought assurances that American Factor VIII to be used in the UK would be up to the standards required in the USA, following the revised guidelines introduced by the FDA. This is an issue covered further in response to Q89. In fact, I had already written to Professor Bloom, in a letter dated 16 May [DHSC0001206]. I said that:

> *"Following our telephone conversation, I have today both spoken to and minuted Dr Keith Fowler of Medicines Division to draw his attention to the possible need to institute new labelling requirements for FVIII concentrates derived from plasma taken before the new FDA regulations came into force.*
>
> *I have also asked him whether, for products currently available in the UK, it would be possible to find out the period in which the donors were bled and whereabouts in the USA the donor centres supplying each manufacturer are situated.*
>
> *I have asked if he will treat this as a matter of the utmost priority."*

86.28. My minute to Dr Fowler, dated 16 May, is described in full at Q89, below.

86.29. I have been asked what further decisions or actions were taken by the DHSS, as a result of the meeting of 13 May 1983. I reported back from the UKHCDO meeting to the DHSS, to Dr Field, and followed-up on Dr Bloom's concerns, as described above.

Post- UKHCDO meeting report to Dr Field.

86.30. Following this meeting of the Haemophilia Reference Centre Directors, I immediately reported back the views of the HCDs to Dr Field in my minute "Action on AIDS" dated 13 May 1983, [DHSC0002227_047]. In my minute, I expressed the view that Dr Galbraith's recommendation to withdraw American Factor VIII from use was premature in relation to the evidence and unbalanced

in that it did not take account of the risks to haemophiliacs of withdrawing a major source of their Factor VIII supplies. In support of that view, I quoted the views of the HCDs in the draft statement that had been prepared for insertion in the minutes of the UKHCDO meeting of the same date.

86.31. I have been asked (Q89) why I held that view.

86.32. Whilst Dr Galbraith had set out a strong case for an epidemiological association between American Factor VIII concentrate and the development of AIDS, the cause of AIDS and the role of blood products was still heavily contested both in the UK and USA. Furthermore, the potential risks to haemophiliacs in the UK, based on the observed numbers of cases of AIDS per 1000 haemophiliacs in the USA, appeared low. This had to be compared with the known severe and potentially life-threatening risks to haemophiliacs of inadequate treatment, arising from the withdrawal of US Factor VIII concentrates, which included strokes from haemorrhage into the brain and bleeding into organs and joints. In terms of those risks, Dr Galbraith's recommendation appeared premature.

86.33. This was also the view reached by Dr Craske (see his letter) and the UK Haemophilia Centre Directors.

86.34. I have reflected again on this correspondence and on Dr Galbraith's observations that, in effect, the long incubation period between infection and the development of AIDS might mean that more cases would be seen than could be inferred from the low numbers of cases seen to date. Whilst this was an important observation, there were other factors which needed to be considered. For example, how many of those exposed to the infective agent would actually become infected and of those who became infected, how many would go on to develop AIDS. There was simply inadequate information on which to evaluate these possibilities. That lack of information needed to be set against the very well-known and severe harms that would be caused to haemophiliacs if American Factor VIII concentrates were withdrawn or curtailed without any realistic replacements.

Meeting of the Council of Europe, 16 – 19 May 1983

86.35. A meeting of the Expert Committee on Blood Transfusion and Immuno-Haematology of the Council of Europe took place in Lisbon over 16 – 19 May

1983, with a discussion of AIDS apparently taking place on 16 May (at least according to the letter of that date that I received from Dr Gunson, who attended as the expert representative for the UK). Dr Gunson wrote to me summarising the outcome of the meeting and discussions [DHSC0000716] and appending a summary report of the cases of AIDS for most of the European countries (this was not included in my papers). He reported a conversation with the Director of the Swiss Red Cross, who was apparently commenting on press reports that Switzerland might be able to supply Factor VIII to the United Kingdom: "There can be no question of supplying any plasma for the UK and he was not aware of anyone in his Institute speaking to the British press."

86.36. Dr Gunson summarised the draft resolution that was to be placed before the Ministers of the Council of Europe, which I condense further here:

i) expose recipients to minimum numbers of donations of blood components and blood products;

ii) achieve national self-sufficiency in coagulation factor concentrate production;

iii) avoid importation of plasma and coagulation factors from countries with high-risk populations;

iv) provide information to donors so those at risk will abstain from donating and

v) inform all attending physicians and selected patient groups of the potential hazard and possibilities of minimising this risk.

Dr Gunson went on to conclude:

> *"You can see that what they are leading to is the greater use of cryoprecipitate, and we saw two years ago that this tends to be the standard product in many European countries. Although I put forward the UK view of this product the consensus was against us. Like you, I do not think that BPL could change to freeze-dried cryo rapidly and the logistic problems would be considerable. The CBLA is going to have to consider the interim period before the completion of the new plant very carefully and I am not sure yet …. what would be the best solution. Fortunately everyone here was in agreement that it was vital*

to present a balanced view of this problem and to avoid emotive over-reaction..."

86.37. From the papers provided to me, I can see that Dr Gunson's views on the practicalities of BPL rapidly changing to freeze-dried cryoprecipitate were in line with the views of Dr Lane, when he had previously reported back on the BPL's senior management meeting to the CBLA on 27 April (summarised above, Q85).

86.38. I can also see that Dr Gunson reported back on the Council of Europe meeting to the CBLA's next meeting: see his detailed CBLA Report of 13 June 1983 [CBLA0001710]. I have explained that I did not regularly attend CBLA meetings but Dr Harris and, by now, Mr Winstanley did. In addition, Professor Bloom was a member of the CBLA and was at that meeting; there was therefore a channel of communication between the CBLA and the UKHDO.[16]

86.39. Dr Gunson commented on the draft recommendations. With respect to the recommendation for information to be supplied to patients and the public, he wrote:

> *"Physicians and patients, especially haemophiliacs, are being informed of the risks of AIDS. With respect to the informing of donors, the Regional Transfusion Directors have prepared an informative leaflet on AIDS for donors, with assistance from Dr D Walford, and it will be published by the DHSS shortly..."*

86.40. In connection with the recommendation to avoid large pool products he explained that the concept of small pools for coagulation factor products had been one held in many European countries for some time and was concerned with the use of freeze-dried cryoprecipitate as the basic product for the treatment of haemophilia. After describing some disadvantages of yield and standardisation of such products, he said:

[16] I have not seen the Minutes of this meeting, but I also note that Dr Lane refers in his draft statement (see paragraph 638) to the fact that, at the third meeting of the UK Working Party on Transfusion Associated Hepatitis on 20 April 1983, it was noted that Dr Gunson would be attending the Council of Europe meeting on AIDs and blood transfusion in May. I assume that the recommendations were therefore discussed amongst the clinicians who formed this Working Party, at the next meeting.

"the conversion from intermediate concentrate of FVIII to a small pool freeze-dried cryoprecipitate would not seem to be warranted at present".

With regard to the recommendations, respectively, to countries to develop self-sufficiency in blood products and to minimise their importation, he said:

".. the principle of self-sufficiency in blood products has been accepted by the Government with the allocation of money to rebuild BPL. It is important that the allocations of finance to regional centres is adequate for the provision of sufficient plasma to enable the new BPL to function at optimum capacity.

With respect to the importation of plasma products particularly Factor VIII there seems to be little alternative at present. However, since the middle of April 1983, the US commercial companies have tightened the medical examination of donors providing plasma for the preparation of Factor VIII."

86.41. In June 1983, Mr Cumming of the International Relations Branch (DHSS) asked for comments on the draft recommendations, to pass to the FCO [WITN4461129]. I gave my views to Mr Cumming in a minute dated 13 June [DHSC0001659]. I pointed out that however desirable it might be to avoid the use of large-pool products (except, as per the draft Council of Europe recommendation, where such a product is specifically indicated for medical reasons), given that some 80% of the total usage of Factor VIII was with large-pool products (commercial and NHS), the practical reality was "there is no option but to treat the majority of our haemophiliacs with large-pool products". This was consistent with Dr Gunson's views.

Use of Cryoprecipitate

86.42. Underlying a number of these issues, or the questions of the Inquiry, is the issue of a greater use of cryoprecipitate. I have touched on this issue at a number of points, including when I have pointed out that the production of frozen cryoprecipitate remained, at all times, a matter for the Regional Transfusion Centres; in addition, prescribing decisions were for clinicians. I have also

referred to the views of Dr Lane, in particular when discussing the CBLA meeting of 27 April 1983.

86.43. However, it may be useful if I also refer back to the Report of the Working Party to Advise on Plasma Supplies of June 1981 (see Section 2 for an account of this work). In its Appendix 1, the Working Party described the preparation of cryoprecipitate at RTCs, but noted that it would be difficult to have a national programme based on frozen cryoprecipitate because:

i) The potentially high yield was not always attained in large scale production;

ii) lack of confidence in the Factor VIII content led to over-ordering and waste;

iii) there was a significant incidence of adverse reactions due to the presence of residual plasma;

iv) the product was not convenient to store, transport and infuse, particularly for home or self-therapy;

v) there were difficulties in ensuring adequate quality assurance and control.

86.44. Appendix 1 of this Report continues by setting out, in the UK context, the differing problems associated with the manufacture of (i) small-pool freeze-dried cryoprecipitate; and (ii) large-pool freeze-dried cryoprecipitate; (iii) intermediate purity concentrates; and (iv) high purity concentrates. Although this summary dates back to mid-1981, I do not believe that the technical challenges had materially altered by 1983.

86.45. I later set these matters out in my background note of 31 May 1983 (Paper VI) for the meeting and discussions that took place within the DHSS on 3 June 1983 [WITN4461130], when I noted that:

> *"If there was to be a significantly increased demand for cryoprecipitate, this would pose major operational and financial problems for RTCs and would reduce significantly – or even totally – the amount of plasma sent to BPL. The alternative to single donor cryoprecipitate produced in RTCs would be for BPL to change to small-pool freeze-dried*

cryoprecipitate production. The operational problems caused by such a switch in technology would be immense and it is doubtful whether it could be undertaken in the existing facilities. Moreover, the design brief for the redeveloped BPL would have to be totally re-worked to plan for the changed requirements."

86.46. From the point of view of risks (whether of non-A, non-B hepatitis or, in due course, of AIDS), I believe that the observations of Dr Lane in his draft statement at paragraph 512 and 602 - 603, on the size of donor pools, are accurate and to the point:

512. From a fractionator's point of view, it is, in any event, necessary to pool plasma to manufacture concentrate and there are several reasons why large pools are preferable to small ones from a manufacturing standpoint. The most obvious is the economy of scale which this brings to the production process. Second, very small pools do not provide enough product for severe haemophiliacs who would very quickly exhaust Factor VIII or Factor IX concentrate produced in such a way, requiring product from another pool thereby defeating the object of a small pool approach. Thirdly, the administrative aspects of establishing and running small pools on any scale would be quite disproportionate to the amount of product such methods could produce. Fourthly, large pools have the effect of producing a more standardised (and more predictable) product in terms of quality. By way of explanation of this point, we found enormous variations in the Factor VIII content of plasma provided to us by different Regional Transfusion Centres and the pooling process itself eliminated these peaks and troughs which would otherwise have complicated the manufacturing process.

[…]

602. […] I mentioned the small pool experiments undertaken at Oxford. These demonstrated that small pool concentrates offered only limited assurance of safety from transmission of NANB hepatitis. In that it is now known that for hepatitis C, donors have a carrier rate of 0.5 to 1% then on average 1 to 2 donations of infected plasma would be present in each pool greater than 100 litres. Similarly, although the

incidence of HIV in the donor community is much lower, one infected donation in a small pool, by reason of its limited dilution, might carry an increased risk of infecting finished product. To achieve self-sufficiency, the logistics of small-pool fractionation, the reduction in efficacy of process and of consistency in quality, argued against the small pool approach. The answer is to have a successful heat inactivation procedure applicable to product from any size of plasma pool.

603. In short, small pools offered no guarantee of protection, would be quickly exhausted by the severe haemophiliacs most of whom are the Plaintiffs in the present proceedings and, given what was known about hepatitis Non-A Non-B in the early 1980's would not have justified the re-organisation necessary to change production to exclusively small pool. By the time the realities of AIDS were apparent to all, most severe haemophiliacs had, I would submit, already become infected with HIV in any event and the solution in the form of heat treated Factor VIII and IX was just around the corner.

RTD Meeting 18 May 1983 (Q92)

86.47. I have been asked about the meeting of the Regional Transfusion Directors held on 18 May 1983. The minutes record, under the heading AIDS, that I "reported from the DHSS meeting and stated the position of the Department on this matter" [CBLA0001707].

86.48. I asked to be invited to the meeting of Regional Transfusion Directors which took place on 18 May 1983. Unlike many other meetings at which I attended as DHSS observer, many of which I cannot now recall at all unless prompted by papers I have been shown, this meeting stands out, unprompted, in my memory for the somewhat churlish reception I was given. I recall that the Chair, Dr Wagstaff, introduced me with words to the effect: since Dr Walford has wished herself on us, I suppose we had better hear what she has to say!

86.49. The minutes [DHSC0002227_060] are fairly condensed at this point and simply state that I reported from a DHSS meeting. Nothing further is said about that meeting, but I believe it will have related to discussions which had taken place in the Department as a result of which I was urging Directors to produce a leaflet

for donors informing them about AIDS and discouraging donors from high-risk groups from donating.

86.50. Once it became apparent that recipients of blood or blood products appeared to be at risk for developing AIDS, the view in the DHSS was that blood donors who were in the groups which had been identified as being at risk for developing AIDS (e.g. men who had sex with men and injecting drug abusers) should, as far as possible, be excluded from donating blood. At the meeting, I requested that a leaflet be prepared for donors to give them information about AIDS and who should refrain from donating blood. I envisaged that this information leaflet could be used in conjunction with questioning by the transfusion doctor to elicit possible risk factors which would suggest a donation should not be accepted.

86.51. The proposal was not well received. Fortunately, Dr Gunson had also written to RTDs in relation to the preparation of such a leaflet and offered them four options to consider:

i) questioning of donors at sessions;

ii) sessions to be discontinued in areas where there were higher-risk donor groups;

iii) a pamphlet explaining AIDS to donors;

iv) publications in newspapers.

86.52. The RTDs rejected options (i) and (ii) and were adamant that there should be no questioning of donors about their sexual habits or their injecting drug use. Although there was reluctance to proceed with a leaflet, the Directors agreed that one should be prepared.

86.53. To be fair, the resistance from the Directors arose from concerns about deterring donors from donating or causing them offence (homosexuality was still very stigmatising and had only been decriminalised just over a decade before and injecting drug misuse remained a criminal offence). Some donors could also be deterred as a result of a misunderstanding that AIDS could actually be contracted from giving blood. The Directors' concerns would have been that if the effect of such warnings were to deter significant numbers of donors from donating, this would be detrimental to the supply of blood. I note,

from Dr Lane's draft statement, that there was indeed a fall in the number of donors during this period (although the NBTS would be better placed to supply numbers).

86.54. Having seen a tabled copy of the leaflet produced by Dr McClelland of Edinburgh SNBTS, the Directors agreed that a pamphlet should be drafted and be ready for printing in weeks. I undertook to ensure it was printed rapidly, saying that the DHSS would pay for external printers if required and I subsequently wrote to confirm that.

86.55. In the event, it took some time for the first draft to be sent to me. When I received it, I was concerned that the drafting did not make sufficiently clear who should not donate blood and it would be unlikely, in my view, to deter any donor who had already turned up to donate his blood. Overall, it seemed to me not sufficiently informative to do the job of deterring donors from high-risk groups from donating. But I was aware that any drafting suggestions from me would not be well-received, so I asked Dr Gunson if he would redraft it, which he agreed to do. This is one of the occasions where the good relationship which I had with Dr Gunson, for whom I had great respect, was a significant benefit.

Steps taken to discourage donors from higher-risk groups: the AIDS Blood Donor Leaflet (Q76)

86.56. I have been asked (Q76) to describe any efforts made by the DHSS and/or NBTS to discourage donors in higher-risk groups from giving blood, including a description of the preparation of the leaflet mentioned above. I have set out an account of the work on the leaflet below, since it follows on from the RTD meeting of 18 May (although my direct involvement extended through to the middle of June only). The account sets out my own knowledge of the leaflet's preparation. However, as it was considered extensively by others, whether in the DHSS or by the Regional Transfusion Directors and, subsequently, by Ministers, my personal account will not be comprehensive.

86.57. Turning back to the issue of the leaflet's preparation to the point where I had sought help from Dr Gunson in improving the initial draft prepared by the RTDs, he duly prepared a new draft, in conjunction with, I believe, Dr Davies, of Edgware RTC. The leaflet took the form of a question and answer document.

86.58. Once a revised leaflet had been prepared, I submitted it, with a covering minute (17 June 1983) to Mr Winstanley, for onwards transmission to the Information Division. [WITN4461131, WITN4461132].

86.59. There was a time lag between the submission of the leaflet to Ministers and its availability for use by the NBTS and also the Scottish National Blood Transfusion Service, it having been agreed for UK-wide use. What is clear from the papers that I have seen, is that there had been some redrafting of the leaflet by the Information Division (ID). Mr Winstanley's minute of 8 June 1983 to Mr Windsor of ID expressed unhappiness with the revisions introduced by ID, saying that there were some things that were incorrect or misleading [WITN4461133].

86.60. On 1 July 1983, Mr Parker (HS1) sent a copy of the revised leaflet to Mr Joyce, P/S to Lord Glenarthur, also copied to Mr Patten and Mr Clarke's office [WITN4461134]. A paper said to be written by me [Flag A] asked Ministers to agree to the funding of an information leaflet on AIDS [Flag B], for distribution by the NBTS. This was the revised version that had been redrafted and differed from the version originally prepared by Dr Gunson and me.

Comparison of Dr Gunson's Draft and the Revised Version

86.61. Comparing the text of Dr Gunson's original leaflet draft with that submitted to Ministers on 1 July, there are two key changes to be noted, as set out in the table below:

GUNSON Version		REVISED Version	
CAN AIDS BE TRANSMITTED BY BLOOD TRANSFUSION?	Yes, it can. The chances of this happening with the usual blood transfusion…..	CAN AIDS BE TRANSMITTED BY TRANSFUSION OF BLOOD AND BLOOD PRODUCTS?	Almost certainly yes, but there is only the most remote chance….

WHOSE BLOOD IS AT RISK OF TRANSMITTING AIDS?	Until more is known about the disease, people who are in any of the risk groups with a greater risk of developing AIDS should not give blood even if they are in normal health at the present time.	HOW CAN THE RISKS BE REDUCED?	At present, there is no screening test the Transfusion Service can use to detect people with AIDS. So, until there is and until more is known about this disease, donors are requested not to give blood if they think they may either have the disease or be at risk from it.

86.62. In a minute, dated 6 July 1983, from Dr Bell of the Scottish Home and Health Department (SHHD) to their DCMO, Dr Scott, Dr Bell, who had obviously seen the version prepared by Dr Gunson, draws attention to the difference in the strength of the advice to donors in the Gunson version compared with the proposed revised version. He then refers to what he has been informed Mr Fowler's, reaction to the leaflet was (Mr Fowler, the Secretary of State, would have seen the version sent on 1 July 1983). Dr Bell states: "However, we are informed that Mr Fowler's first reaction is that the terms of this leaflet are too strong, and that the DHSS may therefore be making further amendments."

86.63. It may be thought that either "Yes it can", or "Almost certainly yes", in relation to transmission of AIDS by transfusion, imputed a greater degree of certainty to transmission than was being conveyed by the Government's line about "no conclusive evidence". Whilst that latter statement was, indeed, more scientifically accurate than the wording in either version of the leaflet, the leaflet

for blood donors had to serve a different purpose from statements intended for more general use. If blood donors who were, say, homosexuals with multiple partners, were given a leaflet which was not sufficiently clear and unambiguous about the potential for their blood to cause a patient to develop AIDS, there would be less incentive for them to self-exclude from donation or to risk the embarrassment of being declined at the donor centre.

86.64. Mr Patten replied to the submission on 1 July, noting that public concern was "mounting, and rapidly" and asking for the earliest possible publication [DHSC0002309_027], not copied to me. Lord Glenarthur replied on 4 July, also expressing support for the policy [DHSC0002309_025]. However, it is apparent that there were still concerns expressed by Ministers about the wording of the leaflet. I do not remember having any involvement in the discussions that followed.

86.65. Further discussion of the concerns expressed and the way to handle distribution is set out in a letter from Dr Gunson to Dr Oliver dated 14 July [WITN4461135] which was passed to me and to colleagues by Dr Oliver [DHSC0002484_030]

86.66. The papers next show the leaflet, with some further revisions, [DHSC0002309_023] being submitted by Mr John Parker to Mr Alcock of Mr Clarke's Private Office in a minute dated 29 July 1983 (copied widely, including to me). The minute now focussed on printing, distribution and publicity arrangements. However, my substantive involvement with the drafting and handling of the draft leaflet had really ceased in June 1983, when I sent the draft leaflet to Mr Winstanley, for onward transmission to Information Division [WITN4461134].

86.67. The leaflet was eventually published on 1 September 1983.

87. Q87: Minute to Dr Field 23 May 1983

87.1. Returning back to events in May and to the IBI's questions, I have been asked about a minute written on 23 May 1983 and my views on the need for a formal Working Party at that point.

87.2. Piecing together various bits of internal correspondence, I see that on 12 May, Dr Sibellas wrote to Dr Field (SPMO of Med IMCD) in relation to the proposal

that she understood had been made to him by Dr Galbraith, that there should be a Working Party on AIDS. From Dr Galbraith's letter to Dr Field, I see that he had said: "Perhaps the subject could be discussed at an early meeting with haematologists, virologists and others concerned" and it could be that Dr Sibellas inferred from that that he was requesting a Working Party on AIDS to be set up. She made suggestions as to the possible chairmanship of such a Working Party and suggested some names of possible external members. She expected that I, and probably Mr J Parker, would be involved on the blood products side.

87.3. I had no problem at all with Dr Galbraith's proposal for a Working Party on AIDS. In my minute to Dr Field of 13 May, I concluded "with regard to the Working Party on AIDS which Dr Galbraith has proposed I suggest that Dr Bloom be invited to represent haemophilia centre directors".

87.4. In manuscript, at the top of Dr Sibellas's minute are the words: "Mr Green – this idea has been abandoned. Drs will now have ad hoc discussions". I believe this manuscript note to have been written either by Dr Ian Field or by Dr Sibellas.

87.5. On 23 May, I wrote to Dr Field agreeing with his suggestions, in his minute to me of 19 May headed 'Action on AIDS', about the handling of the issue of AIDS. Whilst I do not now have a copy of Dr Field's minute to which I was responding, I surmise it was explaining that Med IMCD had abandoned the idea of having a formal Working Party in favour of holding ad-hoc discussions or possibly describing some other course of action. From my response of 23 May [DHSC0002229_004], I think it possible that Dr Field was asking me if I wished to press for a formal Working Party. Whilst it seems I was perfectly happy that there should be a Working Party, it was a matter for Dr Field's Division to determine, which would presumably explain why I replied that "I certainly didn't wish to press for one at this stage".

88. Q88: Special Meeting of Haemophilia Reference Centre Directors 13 May 1983

88.1. Please see my response under Q86 at paragraph 86.23.

89. Q89: The FDA Regulations 23 March 1983

89.1. The Inquiry has asked about the response to the FDA regulations (Q89) and the decision not to restrict US imports of concentrates (Q90). For my response to Q89, which refers to my minute to Mr Field of 13 May 1983, please see paragraph 86.31 above. I believe my response to Q89 below also covers Q90. Given the breadth of this request, I have broken my response into a number of sections.

Introductory Comments

89.2. I have been asked to describe, as fully as I can, the impact on the DHSS's policies, decisions and actions of the introduction of FDA regulations in March 1983. As this was an issue that generated activity throughout a large part of 1983, I have divided this response into two sections: (i) before the meeting of the CSM(B) in July 1983 (paragraphs 89.3 – 89.15) and (ii) after that meeting (paragraph 99.4 onwards).

89.3. It is not clear to me, from the papers, when the DHSS first became aware of the 23 March 1983 FDA regulations. I presume that Medicines Division would have been the first to be aware of them. I note, however, that Dr J Smith (Chairman of CSM(B)) referred to the FDA regulations in his letter to Dr Keith Fowler of 28 March, which I have referred to above.

89.4. The earliest reference I can find to my own knowledge of the directive is in the minute, dated 9 May 1983 from the Managing Director of Travenol Laboratories, which mentions the 24 [sic] March 1983 directive on screening procedures issued by the National Centre for Drugs and Biologics in the United States [WITN4461116]. I have also referred to the letter from Professor Bloom of 17 May 1983 on the topic.

Investigations Undertaken

89.5. On 16 May I sent a minute to Dr Fowler of Medicines Division, headed Factor VIII and AIDS [DHSC0001394]. In my minute, copied to Dr Field and Dr Oliver, I referred to the fact that we had spoken on the phone. I explained that, following the introduction in March 1983 by the FDA of requirements in respect of the selection of donors, which aimed to reduce the possibility of transmission of

AIDS, UK Haemophilia Centre Directors had expressed concern that contaminated US Factor VIII would be 'dumped' in the UK (the letter to me from Professor Bloom of 17 May refers [DHSC0001205]).

89.6. I have been asked by the Inquiry if the DHSS shared this concern. I cannot speak for the DHSS, but I regarded the issue as a real possibility that required proper consideration.

89.7. Later, on 20 May, in my update on AIDS for Departmental colleagues, I spoke of my further concern that the FDA regulation stated that plasma taken from a donor in a high-risk group should be labelled as being only for use in the preparation of albumin, Plasma Protein Fraction (PPF) or globulin. I felt that allowing plasma from donors in known high-risk groups to be used in this way – on the basis that they were heat-treated – was extremely dubious since there was no way of knowing that the heat treatment would inactivate any infective agent causing AIDS, should one be present [DHSC0002227_060].

89.8. In the USA, labels were required to identify products manufactured from plasma taken before the new regulations came into place. However, UK product licences did not contain this requirement.

89.9. I asked whether it was possible:

i) to obtain concentrates made from American plasma which did not come from donor centres in New York (particularly) but also from San Francisco and Los Angeles which were cities with the highest number of AIDS cases?

ii) to accept only concentrates made from plasma taken after the 24th (sic) March FDA Regulations were published?

iii) to find out, for each manufacturer, the date of plasma collection in relation to each batch of concentrate in current use in the UK?

iv) whether Immuno - or other European manufacturers – could produce sufficient material derived from European plasma to supply up to 30 million i.u. of Factor VIII concentrate, should it prove necessary to withdraw some or all of the American products?

89.10. My minute was copied more widely to colleagues by Dr Oliver (DCMO) on 17 May [WITN4461136]. He noted the importance of the issues raised and suggested a meeting. He added: "Whatever we do we must not take any precipitate action which might affect the supply of necessary Factor VIII."

89.11. Dr Fowler replied to the questions I had asked in two consecutive minutes, both dated 23 May 1983 [DHSC0002229_006]. His answers, taken in the order of my questions, can be summarised as follows:

i) No. Manufacturers would be unlikely to segregate plasma on geographical grounds.

ii) Yes, probably (subject to legal checking), because Factor VIII concentrates are subject to full 'Stop Orders'. But Dr Fowler doubted there would be adequate supplies of post-24 March concentrate – there were batches of the pre-March material in a queue at NIBSC awaiting batch release.

iii) Yes. Date of plasma donation could be required through the protocol for the NIBSC Stop Orders.

iv) Neither Immuno, nor the other European manufacturers could have any chance at all of producing a fraction of the 30m i.u. referred to from European plasma, for sale in the United Kingdom. The Swiss were said to have a small surplus of "home grown" concentrate but the amounts involved were minuscule.

89.12. I have been asked to explain the reference to Stop Orders. As I recall, every batch of biological product for use in the UK was subject to batch-release checking by NIBSC, who checked the composition of each batch against the manufacturer's specification, or any licensing conditions, before allowing it on to the market. As a result, a product that did not meet specification could be prevented from being released by the decision not to issue a formal batch release certificate. This form of control was known as the system of Stop Orders. My understanding, from Dr Fowler's letter, was that NIBSC could make the inclusion of the date of plasma donation part of the required protocol for the batch to be released and could advise the Licensing Authority to reject concentrates made from plasma donated before the 23 March 1983.

89.13. A further minute from Dr Fowler to me of the same date, 23 May [DHSC0002229_006] added that manufacturers would be able to identify those batches of plasma collected before and after 23 March 1983; whether they would release that information was another matter. He set out the control exercised by Dr Duncan Thomas's Department at NIBSC over the method of production and the potential role of the Licensing Authority.

89.14. I have been asked whether in 1983, the date of plasma collection formed part of the information that Factor VIII protocols had to include when they were submitted by manufacturers to NIBSC. I have been asked whether, if not, this information was required after the 1983 FDA changes and if not, why not.

89.15. I have already noted that this was not a labelling requirement before the new FDA Regulations. It is not clear to me, from the papers, whether or not a requirement to include the date of plasma collection was made a requirement of the NIBSC protocol, or what discussions or investigations led to conclusions on this issue. Whilst it is pure speculation on my part, it may be that because no licensing action was to be taken (see the recommendations of the CSM-B/CSM), no labelling requirement was actually introduced. The MHRA or NIBSC may be able to assist with this question. The lead responsibility for licensing requirements lay with the Medicines Division.

90. Q90: Restriction of American Imports

90.1. I have addressed this both above in Q89 and further in the narrative below.

91. Q91: Impact of election of June 1983

91.1. I believe I have addressed this question at paragraphs 95.2 alongside other events in May and June.

92. Q92: Update 18 May 1983

92.1. I believe I have addressed this question at paragraphs 86.47.

93. Q93: Update on AIDS 20 May 1983

93.1. I have been asked about steps taken following my 20 May 1983 'Up-date on AIDS' [DHSC0002353_031 and DHSC0002227_060].

93.2. My May Up-Date on AIDS on 20 May was simply a factual briefing for officials, including the DCMO, Dr E.L Harris. In addition, in response to a request from his Private Office, I sent briefing for Mr Finsberg, also on 20 May [DHSC0002353_031], relating to AIDS in non-homosexuals. This request appears to have arisen after Mr Finsberg had read an article about AIDS in the Daily Telegraph. I do not know what particular line the Daily Telegraph was pursuing, I simply reported factually on the current state of knowledge of the prevalence of AIDS in the different risk groups.

93.3. In my up-date, I referred to a suspected case in Cardiff that according to the CDSC met the USA criteria for AIDS, but the clinician in charge did not consider that it should be regarded as a confirmed case. (This was Professor Bloom's patient, who subsequently, sadly, died). Likewise, I reported that there was also a possible case at the Bristol Royal Infirmary. We now know that this was the unfortunate man who, tragically, died just a few months later, in August 1983, becoming the first known fatality from AIDS amongst people with haemophilia, in the UK. It was reported that Dr Galbraith, Director of CDSC, had been concerned that he had had no knowledge of the case prior to his death. From a subsequent report, it appears that the clinician concerned had not reported the case to CDSC because he was unsure that the patient met the criteria for a diagnosis of AIDS.

93.4. I also reported, in my up-date for officials, on actions that had already been taken, by the Haemophilia Reference Centre Directors (HRCDs) and by the Regional Transfusion Directors (RTDs). In the case of the former, I reported that, although the HRCDs believed, on the evidence available, that no restrictions should be placed on the use of imported Factor VIII because of the benefits of treatment, they had reiterated their policy of using only NHS material for children under the age of 4 years and for mild haemophiliacs.

93.5. As far as the RTDs were concerned, I reported on the information leaflet for donors they were preparing and that they were proposing to approach the

Medical Gay Society to enlist their help in the dissemination of information about AIDS to homosexual groups. I also reported that RTDs were adamant there would be no direct questioning of donors about their sexual habits, nor about the presence of symptoms such as night sweats, weight loss etc. As reported below at 96.17, I subsequently contacted the Chairman of the RTDs to challenge their approach to questioning about symptoms. (Although I was not present, the record of the meeting of 6 July shows that Ministers were at one with RTDs in not wanting any questions to be posed about donors' sexual habits).

93.6. I then gave a point-by-point account of the requirements for donor education and screening that had been introduced under the FDA March 23 directive and went on to describe the relevance of the FDA regulations for UK imports of USA concentrate. I also spoke of the concern we had that a disproportionately high percentage of plasma from high-risk donor groups was likely to find its way into imported albumin, PPF and gamma globulin preparations, which might be claimed, by the manufacturers, to be safe because they were heat-treated. However, I said there was no proof that the heat treatment would inactivate the AIDS agent and that Medicines Division would be considering the implications of this. There was also the concern that more pre-March 1983 stocks would be sent to export markets like the UK, with the US retaining the 'safer' material for the home market. I explained that Medicines Division had been asked (see my minute to Dr Fowler, 16 May) to consider any ways, perhaps by means of new labelling requirements, to prevent this happening; also whether it would be feasible, in terms of the amount of material currently available, to restrict imports of Factor VIII to those made after 23 March. The Department was also looking into whether Immuno or other European manufacturers would be able to supply up to 30m i.u of Factor VIII, made wholly from European plasma. (To which, it transpired, the answer was 'no'; see 86.35 above).

93.7. Finally, my up-date referred to the proposed introduction by commercial manufacturers of heat-treated product, on the basis that heating would inactivate the agent of AIDS, a process they had been developing in the hope of inactivating hepatitis viruses. I pointed out that there had been no clinical trials which could substantiate the claims of viral inactivation of hepatitis and,

were they to be licensed for use in the UK, there could be significant cost consequences, because heat treatment both increased production costs and substantially reduced the yield of Factor VIII. If BPL were to heat treat its product, there would need to be a significant increase in the amount of plasma supplied. I concluded by referring to the need for controlled clinical trials to establish if the inactivation process worked. However, I was concerned that such trials would pose ethical issues because the material would need to be used in previously untreated patients.

93.8. To explain the ethical issue that concerned me: previously untreated patients would be highly susceptible to becoming infected with non-A, non-B virus(es) as it had already been shown that a first exposure to concentrate, whether NHS or commercial, caused virtually 100% incidence of non-A, non-B infection in previously untreated recipients.

93.9. In the event, I understand that the ethical issues were to be addressed by the protocols used for the clinical trials, which required that the trial material only be given to patients who were in clinical need of concentrate therapy because, for example, they needed to undergo surgery. In such cases, treatment with concentrate would be clinically warranted and the question to be addressed was: did heat-treated commercial concentrate carry less risk of transmitting non-A, non-B hepatitis than un-heated NHS concentrates?

94. Q94: Dr Tedder Meeting Mid-May 1983

94.1. I have been asked what I can recall about a meeting with Dr Richard Tedder in mid-May 1983, and his subsequent letter to me [DHSC0003824_164].

94.2. I do recall a meeting with Dr Tedder, in my office. I do not actually remember anything about the meeting itself, except that it happened. From Dr Tedder's letter, dated 20 May 1983, which he sent to me after the meeting, the purpose of the meeting had been to explain to me the nature of the research into AIDS that he, and Dr Philip Mortimer who had accompanied him, wished to do; and that they and were seeking DHSS funding to be able to conduct it.

94.3. I assume I must have asked him to write to me with the detail, so that I could explore with colleagues whether it would be possible for the Department to

provide research funds. Please see also my account of first meeting of the CBLA's Central Committee for Research and Development in Blood Transfusion on 21 June 1983, below: this too was attended by Dr Tedder and there was discussion of the means of applying for research funding and I confirmed that it was possible to obtain funding from the DHSS.

94.4. On initially looking at these papers, I could not recall what the outcome was and whether it proved possible to for the Department to fund his research. However, Dr Tedder's letter to me mentioned that, following our meeting, Dr Catterall had now contacted Dr Graveney (of the Office of the Chief Scientist, OCS) to whom I had presumably indicated at the meeting that a bid could be made.

94.5. At the meeting of officials on 3 June referred to above, Dr Graveney reported that there had been an exchange of correspondence with Dr Catterall and a formal application for funding was awaited. It was agreed that Dr Graveney should liaise with the MRC group on AIDS that was shortly to be established.

94.6. I have been shown papers relating to the establishment of an MRC Working Party on AIDS [DHSC0003824_080] and its first meeting on 10 October 1983 ([WITN4461137], minutes at [WITN4461138]). I see that I attended this meeting. Notably, the Working Party discussed the current state of knowledge about AIDS and recommended that the Adler/Tedder project should be funded. I have not seen the application for funding but it seems reasonable to suppose that this was the same project.

95. Q95: June 1983

95.1. As a number of questions (Q91, Q95, Q97) concern events in June 1983, I have dealt with them chronologically below.

Q91 (1983 Election)

95.2. I have been asked whether the June 1983 election (9 June 1983) had any impact on the actions and decision-making of the DHSS in relation to AIDS.

95.3. I am not aware of the election in June 1983 having any particular implications on the actions or decision-making of DHSS in relation to AIDS (although there were changes in Ministerial post-holders afterwards). I have been referred to

the minutes of the RTDs on 18 May 1983 [CBLA0001707]. I am quoted as reminding RTDs that because of the impending general election, all press enquiries on AIDS should be directed to the Department. This would have been standard advice to all public bodies dealing with sensitive subjects. From other papers I have now been referred to, it seems that a proposed meeting between the Haemophilia Society and Mr Finsberg was delayed until after the General Election and ultimately took place with Lord Glenarthur on 8 September 1983.

96. Q95 and Q96: Meeting 3 June 1983

96.1. I have been asked about the purpose of the meeting that took place at the DHSS about AIDS on 3 June. This was intended to be a comprehensive review of the steps being taken in this area, examining possible further courses of action. It was chaired by Mr J Parker (HS1). The meeting was attended by colleagues (both medical and administrative) from a number of Divisions – HS, Supply, Medicines, CHD, OCS, Med SEB, Med IMCD, as well as by the Director and another member of NIBSC.

96.2. I believe, but from the papers provided I cannot be sure, that the meeting had, for background information, five papers dated 31 May 1983, apparently prepared by me ([WITN4461133]; the papers available are numbered I – IV and then VI; I believe this was a numbering mistake and does not indicate that a paper is missing). The agenda included the following items:

i) To consider whether there is any further action the NBTS or Haemophilia Reference Centres can take, and whether any further assistance or complementary action by the Department is appropriate.

ii) To consider what action can be taken by Medicines Division and Supply Division to minimise risks in light of the new FDA requirements.

iii) To consider what action is appropriate with regard to the implications of the introduction of heat-treated Factor VIII concentrates.

iv) To consider what should be done further to encourage research into AIDS.

v) To consider the implications for NBTS of the line taken by the Council of Europe. (Paper II paragraph 4).

vi) To consider the implications for CBLA and the plans for the redevelopment of BPL.

vii) To consider what action is needed by DHSS in respect of homosexual rights groups.

viii) To consider what further action should be taken with the Haemophilia Society.

96.3. Discussions at the meeting on 3 June 1983 covered the following topics [WITN4461139].

The draft AIDS leaflet for donors

96.4. It was felt that more positive steps should be taken at donor sessions. I was asked to go back to the Chairman of the RTDs, to see if they would reconsider their decision not to question donors about the presence of symptoms such as night sweats, weight loss etc.

96.5. I reported that the RTDs had already gained the cooperation of the Medical Gay Society to help in the dissemination of information on AIDS. A colleague suggested alerting the Home Office in relation to any action concerning homosexual males. I do not know the reason for that suggestion.

Control of imports

96.6. In relation to the control of imports, the meeting discussed the question of restrictions on imports of Factor VIII manufactured from plasma which had been donated before the introduction of the new FDA requirements on 23 March. Miss Spencer explained that the effective application of legal restrictions would present significant practical difficulties and suggested that informal discussions with the companies concerned were more likely to lead to successful control.

96.7. I have been asked for the basis of this assertion about "practical difficulties", but it was made by Miss Spencer, of Medicines Division. The meeting agreed that the matter should be discussed by Medicines and Supply Divisions with manufacturers. I assume that such discussions took place, but I was not directly involved and do not know what was said.

96.8. I warned about the problems of supply and their potential impact on haemophiliacs if restrictions were placed on the importation of such material such that they were unable to receive all the treatment that they needed, and said that the opportunity should be taken in the proposed discussions to establish the supply situation. It was agreed that I would obtain details from individual HCDs of their levels of importation (sic) / usage of individual brands of Factor VIII (which I subsequently did, see my minute of 6 June with the attached figures).

96.9. I have been asked about the basis for my statement about the severe consequences of excessive restrictions. The usage of imported Factor VIII concentrates was of the order of 50% of all the Factor VIII concentrates used in the UK at the time. I was aware at the time of the meeting, that there were significant stocks. For example, in July 1983 the stock take confirmed that there were 15.15m i.u of stocks held in the UK, of blood products manufactured from US plasma collected prior to March 1983 for sale in the UK. Of this, just under 8m i.u had been subject to the manufacturers' special precautions [MACK0002661_089]). Since this amount constituted a significant proportion of the UK's annual usage of commercial Factor VIII (and bearing in mind that any products additionally held by haemophilia centres, RTDs and hospitals would also have had be withdrawn) to ban the use of such material or restrict its importation would have led to a crisis in supply, with foreseeable harms to haemophiliacs.

96.10. With regard to looking for alternatives, my paper [CBLA0001719] for the CBLA meeting on 22 June 1983 sought the views of the Authority on whether there were any plans to develop small pool Factor VIII products or heat-treated concentrate. The development of heat-treatment concentrates, and the challenges faced, was also one of the topics discussed on 3 June.

Heat-treated Factor VIII

96.11. I explained that the reduction of yield of Factor VIII per litre of plasma from heat-treatment could almost double production costs, with significant cost implications for BPL. I also reported that HCDs were adamant that heat-treated

products should not be introduced without proper examination and meaningful clinical trials. It was agreed that HS1A would keep a close watch on this area.

Plasma supply and Factor VIII production in the UK

96.12. Self-sufficiency hinged on an adequate supply of plasma; RHAs should be reminded that there was an immediate need for an increase in plasma collection. It was agreed that Mr Parker would write to Regional Administrators stressing the urgency for action. Utilisation of all available UK fractionation facilities should be considered and the feasibility of speeding-up the redevelopment of BPL should be examined.

Research

96.13. It is not entirely clear from the note of the meeting what research was being discussed under this heading, but it seems likely, in view of the reference to a bid for funding from Dr Catterall, that it refers to Dr Tedder's proposed project. The possibility of establishing an "expert group" to consider, specifically, research on AIDS was mooted and that there should be liaison with the proposed Group on AIDS being set up by the MRC.

Council of Europe

96.14. The meeting noted Dr Gunson's report, and agreed to draw to the Council's attention, when the opportunity arose, "the problems for the UK created by small-pool production and the ban of imports".

Implications for the CBLA and the Re-Development of BPL

96.15. It was agreed that Dr Harris should be asked to seek the comments of the CBLA on the greater use of singe donor or small pool products and the introduction of heat-treated Factor VIII. As a result, I wrote a paper for Dr Harris for the CBLA meeting [DHSC0002231_051].

Follow-up from 3 June meeting

96.16. On 6 June 1983, I reported back to Mr Winstanley, HS1A upon the actions I had taken following the 3 June meeting [DHSC0002231_051].

96.17. In summary, I had: (i) asked the Chairman of the RTDs if Directors would reconsider their refusal to question donors about symptoms such as night

sweats and unexpected weight loss and to review Directors' intentions with regard to the distribution of the leaflets; (ii) ascertained, from the statistics held by the Oxford Haemophilia Centre, the latest figures for usage of each manufacturer's Factor VIII; (iii) written a paper for the next meeting of the CBLA on 'Possible implications of AIDS for plasma supply and manufacture at BPL' [DHSC0002231_051].

96.18. With regard to the AIDS donor leaflet, I referred to my discussions with the Chairman of the RTDs, Dr Wagstaff, about the need to question donors about symptoms such as night sweats etc. He said he would write to all Directors to ascertain their views. I explained that, if they were not in favour, the Department would need to have a note of their reasoning. Dr Wagstaff offered, as a possible compromise, that such questions could be added to the list of questions that a donor reads prior to donation and then signs, although he was doubtful of the effectiveness of this approach.

96.19. I also discussed the best way of distributing the leaflets, and whether to hand them to donors or just have them available at the session. I think Dr Wagstaff preferred the latter approach, as being more low-key (but, unfortunately, my minute incorrectly refers to 'former', when it seems from the context, I should have used "latter"). Ultimately the issue of distribution was put to Ministers and it was their decision, together with the views of the RTDs, which determined what was done.

96.20. In the course of the same discussion, Dr Wagstaff had urged the importance of considering the ability of PFC Liberton to fractionate some English plasma, if US imports were to be restricted. He had heard from Dr Watt, of PFC, that if shift-working could be introduced there, considerably more English plasma could be processed there than previously thought. I suggested Mr Winstanley pursue this with SHHD, reminding them that DHSS had previously invested some £400,000 in PFC's capital development, in anticipation of getting a return on that investment in terms of English plasma fractionated. I have addressed the topic of co-ordination with Scotland elsewhere in this statement (Section 2)

96.21. I attached to my report a table (from the statistics held at the Oxford Haemophilia Centre) [DHSC0002231_051] showing the quantities of each

manufacturer's Factor VIII used in UK haemophiliacs in 1980 and 1981 (later figures were not yet available).

96.22. I had also prepared a paper for Dr Harris, for the forthcoming meeting of the CBLA (22 June) on 'the Possible Implications of AIDS for Plasma Supply and Manufacture at BPL' [DHSC0002231_051]. The paper sought the CBLA's opinion on the possible impact of AIDS on the activities of BPL and whether there were any plans to develop small-pool Factor VIII product or heat-treated concentrate. I asked for comments on the paper.

Advice from Dr Gunson

96.23. On 9 June 1983, Dr Gunson made his views known to Sir Henry Yellowlees (CMO) in a letter that was copied to me [NHBT001067]. This is an example of the process that happened more generally, of the Consultant Adviser briefing the CMO. He noted the reports of AIDS in the press. The aetiology of the disease was unknown but there was a "strong possibility" of an infectious agent, which had been implicated in transfusion of blood and blood products. The significance was two-fold:

i) There was a need to ensure that persons in high-risk groups are not enrolled as blood donors. A pamphlet had been prepared by RTC Directors.

ii) Approximately one-half of the Factor VIII concentrate used in England and Wales was derived from US plasma. Dr Gunson argued that there was "no alternative to the continuation of this policy in the short term."

96.24. Dr Gunson asked to address the meeting of the DHSS Consultant Advisers on 17 June 1983 to update them. [NHBT0001067].

97. Q97: Minute 14 June 1983

97.1. I have been asked to explain the actions that followed my minute of 14 June 1983 to Mr Egerton. I wrote to Mr Egerton on 14 June 1983 with a list of 11 detailed questions to be put to manufacturers of imported Factor VIII concentrates [WITN4461140] about the provenance of the plasma used to prepare their concentrates and, if from the USA and whether the concentrates

were prepared from plasma collected after the 23 March regulations. They were also to be asked if their company had instituted, in advance of the FDA requirements, any special precautions to be taken by plasma collection centres in respect of AIDS. They were also to be asked if they would confirm that all future supplies to be sold in the UK would be manufactured from plasma collected in accordance with the FDA directive (or in accordance with the special precautions, if any, instituted by the company before the FDA directive came into force).

97.2. The latter question was important because the DHSS was being informed, either directly or through Dr Gunson, that certain American manufacturers had actually instituted more stringent donor restrictions than required by the FDA regulations and, in the case of Travenol, for instance, had shut down their plasma collection centres in locations such as New York, Los Angeles and Miami, where cases of AIDS were more prevalent. In addition, manufacturers were working on heat-treating their concentrates.

97.3. The questions I formulated were to be put to manufacturers by Supply Division. Mr Wrigglesworth's minute in reply dated 28 June [WITN4461141] reported that the questions posed in my minute of 14 June had been put to 10 manufacturers, of whom five had replied. He attached a table with a summary of their responses. He drew attention to the following points:

97.4. For the five firms who supplied blood products to the UK (Alpha, Armour, Travenol, Immuno and Miles Laboratories), their annual imports to the UK totalled 42-50 m units. With the exception of Immuno, the firms stated they had all ceased, or did not, collect from 'Epidemic' areas. All their collection centres were FDA licensed. The plasma collected from their centres was pooled prior to processing (although Immuno did not pool its plasma from its European and US centres). The origin of all plasma was identifiable. Future sales would comply with FDA guidelines although Miles' Laboratories' products made from post-March 23 would not be available until August and those from Immuno would not be available until September.

97.5. This issue was further considered by the Biologicals Sub-Committee of the CSM, in its report of 13 July 1983. I have picked up the account of events in respect of this issue under that heading, below at paragraph 99.4.

First Meeting of the CBLA's Central Committee for Research and Development in Blood Transfusion, 21 June 1983

97.6. On 21 June, I attended the first meeting of the CBLA's Central Committee for Research and Development in Blood Transfusion, chaired by Dr Gunson and attended by a number of clinicians and experts including Professor Bloom, Dr Lane, Dr Rizza and Dr Tedder, as well as representatives of the SHHD and MRC. I explained that it was possible to obtain research funding from the DHSS. There was a discussion of AIDS, without any new ways of dealing with the problem of the disease being agreed, and of research efforts; a Working Party was to consider these.

Briefing to Lord Glenarthur, 22 June 1983

97.7. On 22 June 1983, Dr Oliver sent to Lord Glenarthur (Joint Parliamentary Under-Secretary of State) a copy of a paper written by me, giving the background to AIDS and the up-to-date position on steps being taken [DHSC0002309_123].

Meeting of the CBLA, 22 June 1983

97.8. On 22 June, I continued to follow up the actions agreed at the DHSS meeting on 3 June, when I attended the Sixth Meeting of the CBLA (I note that this was a meeting which Dr Harris was not able to attend; it may be that I attended as his replacement, together with Mr Winstanley). I have referred to the paper which I had prepared for the meeting of the CBLA ('the Possible Implications of AIDS for Plasma Supply and Manufacture at BPL' [DHSC0002231_051]). The paper sought the CBLA's opinion on the possible impact of AIDS on the activities of BPL and whether there were any plans to develop small-pool Factor VIII product or heat-treated concentrate.

97.9. The minutes record that Dr Gunson's report upon the Council of Europe's recommendations (CBLA 89/29) was received and noted, before continuing "Dr Walford circulated a report from the DHSS on the possible implication of AIDS for plasma supply and manufacture at BPL. She drew the attention of Members

to the paragraph referring to heat-treated Factor VIII, and asked for the views of the Authority on it. It was agreed that a short report should be prepared by the Secretary and Dr Lane." [WITN4461142].

97.10. Given the contents of the underlying paper, this was a request for information on all the issues raised by the paper, including the development of a small-pool product, and not merely a request for information on the progress of heat-treated Factor VIII concentrate. I can see that Dr Lane's response was tabled at the subsequent CBLA meeting of 27 July 1983 (paper 83/40), although I was not in attendance.

The Council of Europe's Recommendations, 23 June 1983

97.11. I note that on 23 June 1983, the Council of Europe's Committee of Ministers, adopted Recommendation R(83)8. I can see that a minute was sent by Mr Cumming (IR1B AFH) to Mr Patten's office (Mrs Walden), and copied to other Ministers' Private Offices (Mr Clarke and Lord Glenarthur), on 2 July 1983, enclosing the Recommendation in question. [DHSC0002309_086]. The copy list suggests this was led by IMCD and I was not copied in to this or the reply [DHSC0002309_029].

98. Q98: Preparations for the Meeting of the Sub-Committee on Biologicals 13 July 1983

98.1. On 13 July 1983, the Biologicals Sub-Committee of the Committee on the Safety of Medicines (CSM(B)) held a special meeting on AIDS.

98.2. The CSM(B) was a standing Committee of the CSM that advised the CSM specifically on licensing issues relating to biological products, such as vaccines, antibodies, blood products etc. Although I was involved with the CSM(B) as a medical assessor when I was in Medicines Division, I had no role in relation to the Committee after I joined Med SEB.

98.3. Before the meeting, a working paper was circulated by Mr Morgan of MB1c on behalf of the Chairman (Dr J Smith, at the time the Director of NIBSC) [DHSC0001209], together with a paper written by Dr Fowler [DHSC0002229_059]. I, together with colleagues, was sent a copy on 6 July 1983 [WITN4461143]. The working paper stated:-

"Recipients of clotting factor concentrates are at risk. The degree of risk cannot yet be quantified. The risk is likely to be greatest from products derived from the blood of homosexuals and i.v. drug abusers resident in areas of high incidence, and in those who repeatedly receive concentrates in high dosage …

Conclusion? Recipients of clotting factor concentrates are at risk, the degree of risk cannot yet be quantified. The risk is likely to be greatest from products derived from the blood of homosexuals and i.v. drug abusers resident in areas of high incidence, and in those who repeatedly receive concentrates in high dosage."

98.4. In his paper the Chairman of the Biologicals Sub-Committee suggested a possible conclusion concerning the value of the donor screening procedures required by the 23 March FDA Directive, in mitigating the risks:

"Conclusion? The new US procedures are noted and approved. They could have some effect in reducing risk, but this effect may be relatively small, since the procedures are unlikely to exclude all high risk donors, and the causative agent(s) may also be present, although less frequently, in apparently healthy donors from non-high risk groups."

Also notable was the Chairman's view in relation to a postulated option of withdrawing all Factor VIII and Factor IX and using only cryoprecipitate:

"Conclusion? This step cannot at present be recommended: (a) it is probably impossible to satisfy UK needs in this way: (b) even if needs could be satisfied it would involve a major rethink of UK policy for preparing blood products; (c) the perceived level of risk at present does not justify serious consideration of this solution."

98.5. I have been asked how the paper's assessment of risk informed the DHSS's assessment of risks and actions taken. The risk factors were already known to the DHSS; had been publicly acknowledged by Ministers; and actions were underway on a broad front to investigate what could be done to mitigate the risks, for example, the preparation of the information leaflet for blood donors.

98.6. I have further been asked what steps the DHSS took to ensure that those who received, or might receive, factor concentrates were made aware of the risk.

As I have previously pointed out, the DHSS did not have a direct role in informing patients of any potential adverse reactions to licensed medicinal products – other than by making sure, through Product Licences, that appropriate warnings were made clear on package labelling and information leaflets. The Department would have looked to the medical profession – and, in particular, the specialists in the relevant field - to disseminate information to patients. In relation to patients with haemophilia, the DHSS would look to Haemophilia Centre Directors to ensure that potential recipients of coagulation factor concentrates were made aware of the risks.

99. Q99: Meeting of the Sub-Committee on Biologicals 13 July 1983

99.1. The Sub-Committee met on 13 July. It was attended by Dr Smith (Chairman, Director of NIBSC) and Prof J A Dudgeon; Prof G C Jenkins; Prof H Lambert; Dr R S Lane; Prof J Melling; Dr T M Pollock; Dr D A J Tyrrell; Mr J G Watt; Mr H M Morgan (Dr Fowler was also named as a speaker). The expert advisers asked to assist the Sub-Committee were Professor Bloom, Dr Craske, Dr Galbraith, Dr Gunson and Dr Mortimer. I did, however, attend (morning only) as an observer at the 13 July meeting, having been invited because of my role in Med SEB in relation to blood products policy.

99.2. I, with colleagues including Dr Oliver (DCMO), was sent a copy of the Summary of Main Points on 27 July by Mr Morgan [of MB1c]. It is apparent that the Summary had been tabled for discussion at a meeting of the Committee on the Safety of Medicines (CSM). Mr Morgan recorded that the CSM had endorsed CSM(B)'s views [DHSC0002353_051].

99.3. I have been asked about the conclusions of the meeting, by reference to the "Summary of Main Points" [DHSC0001208]. Responding to each sub-question in turn:

i) I do not know the factual/evidential basis for the Committee's conclusion that replacing factor concentrates with cryoprecipitate was "not feasible in the UK on grounds of supply" (Summary, paragraph (3)). They will presumably have known that imported Factor VIII concentrate constituted about 50% of the total UK usage of Factor VIII and, given the

attendance at the Committee, of experts such as Dr Lane and Dr Gunson, it is not surprising that they would have formed this view. The conclusion expressed by the Committee on the scope for use of cryoprecipitate is consistent with the reports from Dr Lane, who was present at the meeting: see the discussion of the CBLA meeting on 27 April 1983, above and [WITN4461144].

ii) In relation to the "efforts" that were "being made to secure UK independence of foreign suppliers of clotting factor concentrates" (Summary, paragraph (4)), I assume this paragraph relates to the UK's efforts to reach self-sufficiency, by the redevelopment of BPL and by increasing the supply of plasma from UK donors. I have covered this elsewhere in this statement.

iii) As I understand it, the policy adopted by the UK Haemophilia Centre Directors for use of US Factor VIII (Summary, paragraph (4)) was to minimise risks as far as possible by treating children and mild haemophiliacs with cryoprecipitate whenever possible or with DDAVP when appropriate. See my account of the meeting of 13 May 1983, or the subsequent letter from Drs Bloom and Rizza dated 24 June to HCDs [WITN4461145].

iv) The actions taken by the DHSS in the light of the advice of the Biologicals Sub-Committee of the CSM that, it was advisable that "all clotting factor concentrates derived from US plasma sources and intended for use in the UK be prepared only from material manufactured from plasma collected after new regulations were introduced by the FDA on March 23rd 1983", (Summary, paragraph (5)) relate back to the steps I have described that were put in hand after the FDA Regulations became known to the DHSS. However, the recommendation went on to say it [that is, the implementation of this advice] cannot "be taken until supplies of post-March 23 material can be assured".

Consideration of US Concentrates, July 1983 onwards

99.4. In paragraph 5 of their recommendations, endorsed by the full meeting of the CSM on 21 July 1983, the Biologicals Sub-Committee recommended that it was:

> *"Advisable that all clotting factor concentrates derived from US plasma sources ----be prepared only from material manufactured after the new regulations were introduced by the FDA on March 23 1983…….This step is recommended notwithstanding the possibility that its practical value may be relatively small.* ***It cannot, however, be taken until supplies of post-March 23 material can be assured*** *(my emphasis)*

99.5. The recommendation went on to suggest that close contact be maintained between the Licensing Authority and Supply Division with the aim of introducing this step immediately it becomes feasible.

99.6. I have already described steps taken as a result of FDA Regulations before the meeting, above at 97.1.

99.7. In the light of the CSM(B)'s recommendations, Supply Division sought to explore the size of the stocks already in the UK and whether there was any scope for US material made after the March 23 regulations to make up for the deficit in supplies from not using up the existing stocks. See below.

99.8. Any wider actions, including consideration of whether and if so how Ministers should be updated, would have been a matter for Medicines Division, given that it led on the work of the Committee on the Safety of Medicines.

Events following the CSM meeting: contact with the US Embassy

99.9. On 19 July 1983, Dr Field sent me a copy of a telex received that day from Dr M G Norton, the First Secretary (Science) with the British Embassy in Washington. The telex read: "FDA says they have reports of UK restricting (or about to restrict) imports of US blood products as a result of AIDS. Can you please advise us if this is so." Dr Field asked me to reply to Dr Norton.

99.10. I have been asked what caused the FDA to become concerned that the UK would restrict the import of US blood products as a result of AIDS. However, I

am afraid I do not know what caused this concern. I would surmise that he may have been concerned that the CSM would recommend banning the importation of Factor VIII made with plasma taken before 23 March 1983.

99.11. After receiving the minute from Dr Field, I sent a minute to Mr Wrigglesworth of the Supply Division dated 20 July 1983. I advised that there was a need to put Dr Norton in the picture about possible restrictions on importation of Factor VIII because of AIDS, and asked the Supply Division to provide an answer. [DHSC0002229_097]. I was copied into the answer sent on 28 July by Mr Wrigglesworth: "At present no restriction of imports of US Blood Products to UK. We have contacted manufacturers to ascertain application of new food and drug administration regulations and stocks of pre-March 1983 material. Will advise you if there is any change in the situation." [DHSC0002231_007].

July 1983 Investigations

99.12. I took the opportunity, in my minute to Mr Wrigglesworth, of 20 July 1983 [DHSC0002229_097] to ask whether he was happy with the reassurances "so glibly given" by manufacturers that future supplies of Factor VIII would be derived from plasma taken in accordance with the 23 March regulations. I was concerned that only two manufacturers had given the dates from which such supplies would be available and I asked if there were a need to obtain such information from the other companies involved.

99.13. Minutes in reply from Mr Wriggleworth dated:

i) 22 July 1983

ii) 2 August 1983 .[DHSC0002231_014] and [MACK0002661_089];

show the results of the enquiries made by Supply Division of five companies, about stocks of plasma collected before March 1983. I noted in my minute of 3 August that we now knew the extent of the pre-March stocks in the UK. See paragraph 99.22.

The UK approach to FDA decision-making

99.14. I minuted Mr Wrigglesworth on 25 July, recording a conversation between us: "We spoke. I suggested that we should ascertain the outcome of a recent FDA meeting which was, I believe, to discuss the problem of plasma/finished product

which pre-dated the 23 March regulations. If there is to be no restriction on the use of this material in the USA, I suggest that we should follow the same line. If, however, use of this material is restricted in some way (eg by the imposition of a quarantine period), then, provided supplies are not prejudiced, the UK should presumably refuse to accept material that is not considered acceptable for use in the States. You agreed to take this forward with Dr Fowler."

99.15. I have been asked why I felt the UK should follow the same approach as the USA in relation to the use of stocks of Factor VIII made from plasma taken before the 23 March 1983 regulations.

99.16. I suggested that the UK should follow the US line because if the US decided to ban the pre-March 1983 material, it would not be tenable for DHSS to continue to use any stocks of such material it had left and, if the UK continued to allow their use, there would be an even greater risk of the dumping of such products on the UK market. On the other hand, if there was no ban imposed, this would be in line with the CSM's observation to the Licensing Authority that it was not practical to restrict the use of such concentrate until adequate supplies of post-23 March 1983 could be assured.

99.17. In his minute to Mr Wrigglesworth of 28 July 1983 copied to me, Dr Fowler set out the outcome of the FDA meeting. He stated the meeting of the FDA was held on 19 July 1983 to discuss the implications of AIDS for blood products. The meeting was attended by senior members of the administration together with representatives of the US and Canadian Red Cross, haemophilia organisations and the manufacturers. He stated "Although the subject got a very thorough hearing nothing new came to light. The possibility of banning all products made before the implementation of the March '83 regulations was discussed but was rejected on a majority vote. The hiatus in supplies which such action would cause was the deciding factor." [DHSC0002231_063]

99.18. Dr Fowler also reported that there was likely to be a Congressional hearing on the same subject the following week and that he would report back as soon as possible. In the event, Congress endorsed the FDA's decision.

99.19. Dr Fowler later made it clear (see his minute of 3 August 1983 to Mr Wrigglesworth [WITN4461146]) that the FDA decision of 19 July and the CSM(B) recommendation of 13 July were consistent with each other:

> *"Although the first sentence of the CSM(B) recommendation (5) states the ideal situation, that only those products made from "post-March '83" plasma should be used in the UK, it goes on to explain why such a step is impractical because of the effect it will have on essential supplies. Although it is not specifically stated that "pre-March '83" material should be used until adequate supplies of "post-March '83" material are available, this is clearly implied in the full text as being the only practical approach to this difficult problem. The CSM(B) and FDA would thus seem to be in accord on this matter."*

99.20. Equally, I did not consider there was a conflict between the FDA and the CSM(B) decision, for the reasons expressed by Dr Fowler in his minute to Mr Wrigglesworth.

August 1983:

99.21. Mr Wrigglesworth wrote a minute to me on 2 August 1983 [DHSC0002231_014]. He reported that three of the manufacturers (Miles, Armour and Alpha Therapeutic) had introduced a special screening programme for donors, prior to the introduction of the 23 March 1983 directive. Miles Laboratories had submitted a document describing "the Cutter system of plasmapheresis", which presumably described the screening programme referred to. I did not see that document; the likelihood is that efforts were being made by the manufacturers to cease collecting plasma from donors in the known risk groups for AIDS and from plasmapheresis centres in locations with greater numbers of AIDS cases, such as New York, Los Angeles and Miami and to try to screen-out donors from high-risk groups.

99.22. I responded to Mr Wrigglesworth on 3 August 1983 [DHSC0002351_017] I explained that we now knew the extent of the manufacturers' stocks [of pre-March 1983] product in the UK. We also knew that in the case of three manufacturers (Miles, Armour and Alpha) all, or a substantial proportion, of those stocks had been manufactured from plasma collected in accordance with the special precautions instituted by the manufacturers themselves.

99.23. I went on to say that if we could make comparison between the special precautions for the collection of plasma undertaken by these manufacturers with those required under the FDA's regulations, this should allow us to judge if products made from such plasma could be considered 'as safe as' material collected in accordance with the FDA requirements. "If that was so, we need have no qualms over the continued use of such material until all the stocks are exhausted". In other words, *provided* that these precautions had been taken, the safety of those products should be no less than the safety of products made in compliance with the 23 March 1983 regulations.

99.24. At the time of writing that minute, it seems I did not yet know the outcome of the US Congressional hearing. I speculated that if Congress were to overturn the FDA's decision not to ban all products made before the implementation of the March 1983 directive, we would be "on the horns of a very nasty dilemma". What I think I meant by this was, on 21 July, the CSM had just decided that no such ban should be imposed (until there were adequate stocks of post –1983 material available), whereas here was Congress, in early August, potentially taking a decision that there should be such a ban. Either the risk to haemophiliacs of withdrawing such material outweighed the benefit of doing so, or it did not. Which was it to be? That would have been the essence of the nasty dilemma, had it arisen.

Stock-Take, September 1983

99.25. I have described the stock-take in July; there was another in September. On 7 September 1983, [DHSC0002231_052] Mr Egerton (S/HSIB1) wrote to me with the stock position of Factor VIII concentrate for UK use manufactured prior to 23 March 1983. The total from Miles Laboratories, Armour Pharmaceuticals, Alpha Therapeutic, Immuno and Travenol amounted to 12.45 m i.us, with clearance times for the stock varying by manufacturer, from between 2-9 months. A proportion of the material had, it was claimed, been manufactured in accordance with plasma taken under the special precautions introduced by three of the manufacturers (see above). Mr Egerton was not happy with the claim made by Miles Laboratories that 100% of its product had been manufactured using these special precautions.

99.26. In my minute in reply to Mr Egerton of 20 September 1983 [DHSC0000207_0001], I expressed surprise at the discrepancy shown in the stocks of Immuno product, which, in the July stock take, was shown as 5.44m i.u with a 10-24 month clearance date, and which, one month later, was said to be 2.60 m i.u with a 6 month clearance.

99.27. It subsequently transpired that Immuno had transferred a large quantity of the stock designated for the UK market to Vienna, leaving the 2.6 m i.u. in the UK which represented 2 batches cleared by NIBSC (see the minute of 27 September from KA Egerton [DHSC0002233_009]).

99.28. Whilst there was some doubt as to the reliance that could be placed on the information being supplied by the manufacturers, nevertheless it is worth noting that the total stocks reported in September (12.5 m i.u) constituted in the order of 35% of the total annual usage of US Factor VIII in the UK. Even if those stocks made under the manufacturers' special precautions were deemed satisfactory for use, there remained a need to replace some 7m i.u. There was no realistic way that this gap in supplies could be made up, at least in the short-term, either from importation of material manufactured from plasma drawn from voluntary donors or from increasing supplies of NHS or PFC Factor VIII, or from increased production of cryoprecipitate. In the case of the latter, any plasma used to increase the manufacture of cryoprecipitate, would be at the expense of plasma sent to BPL for fractionation, so reducing supplies of NHS concentrate as well as affecting the manufacture of other factor concentrates such as Factor IX and the production of albumin, immunoglobulins etc, which would require RTCs to start a complex new process of providing large volumes of cryoprecipitate supernatant to BPL to enable fractionation of these products.

99.29. I have been asked what steps (recall, warning or other actions) were taken regarding pre-March 1983 stocks. I am not aware that any steps were taken since the material remained licensed for use in the UK. The reasons for this, together with the decision not to restrict American imports (Q90) have been explained in the correspondence set out above.

Briefing paper, 20 July 1983

99.30. Returning to events in late July, I was asked to provide a briefing about cryoprecipitate in order for Lord Glenarthur to give further information to Baroness Masham, following an oral question in the House of Lords. I prepared a note, dated 20 July 1983 [DHSC0001109], which I sent to Mr Parker for a contribution to Lord Glenarthur's reply.

99.31. After explaining what cryoprecipitate was, my note concluded by saying:

> *"There is no conclusive proof that AIDS can be transmitted by blood, cryoprecipitate or FVIII concentrates but the assumption is that such transmission may be possible."*

99.32. However, the draft of the reply for Lord Glenarthur that was submitted by Mr Parker to Private Office on 26 July, attaching what was said to be my background note, omitted that final sentence, including the wording: "but the assumption is that such transmission may be possible" [DHSC0002309_032]. Only the factual information about cryoprecipitate was included. Lord Glenarthur's reply to Baroness Masham simply used the "no conclusive proof" wording, and explained the position on supplies and the information available to practitioners (see [DHSC0001405_001], a draft) and the letter of 30 August 1983 [WITN4461147].

99.33. The line to take remained in its "no conclusive proof" form until some time in early 1984, presumably for the reason that, although the epidemiological evidence was building for transmission of an infectious agent in blood, it remained impossible to demonstrate conclusively that such transmission occurred. Whilst the statement was scientifically correct, its use was frequently followed by a qualifying sentence such as: "Nevertheless we are taking all practicable measures to reduce any possible risks to recipients of blood and blood products" or similar statements which indicated that the Government was by no means dismissive of the growing epidemiological evidence and was taking such steps as it could, in the absence of a test for HIV, to minimise possible risks, including surveillance of AIDS by CDSC and providing information for blood donors. (See for example the letter to Mr Jenkins of the

Association of Scientific, Technical and Managerial Staff or ASTMS dated 26 August 1983 [DHSC0002231_036]).

100. Q100: Ad-hoc working group on AIDS around 27 July 1983

100.1. I have been asked to set out what I can recall about the establishment of an Ad-hoc Working Group on AIDS under the chairmanship of Dr Gunson, as recorded in the minutes of the CBLA meeting on 27 July 1983.

100.2. I do not recall anything about the setting up of the Ad-Hoc Working Group on AIDS. From the paper provided [CBLA0001732], it seems Dr Gunson needed to seek approval from the CBLA to set up this group. I did not attend meetings of the CBLA. However, I have seen the minutes of a meeting of the CBLA Central Committee on Research and Development in Blood Transfusion, which included a report of the first meeting of the Working Group on AIDS (held on 14 October), which was attached as an appendix [CBLA0001754]. This report was obviously a preliminary discussion of the issues concerning the aetiology of AIDS, reaching no specific conclusion as to next steps. The Chairman of the CBLA Central Committee on Research and Development informed the committee that the MRC had also established a Working Party on AIDS and that Professor Bloom had agreed to provide a link between the two groups. The minutes of the CBLA's meeting of 28 September 1983 [BPLL0003980] record further discussions about ensuring joint membership of both groups (I was not present however).

101. Q101: DHSS's policy on collecting blood from Borstals and Prisons.

101.1. I have been asked about the DHSS's policy in 1983 on the practice of collecting and using blood from borstals and prisons, by reference to the papers discussed below.

101.2. The minute from Mr Winstanley dated 23 August 1983 [PRSE0004729] dealing with the query from Mr Brown of Medicines Division about the Department's policy on the collection of blood from prisons and borstals, suggests there was no settled Departmental policy on this matter. It was a matter for RTD's

discretion. Some regions had a greater need to source plasma from these places than others. He acknowledged that the advent of AIDS called the wisdom of continuing to use prisons as a source of blood even further into question and said that the RTDs were to discuss the matter at their meeting in September.

101.3. I subsequently attended the RTD meeting held on 19 September 1983. But the minute I wrote about the meeting [WITN4461148] does not mention the issue and neither do the draft meeting minutes that I have been shown [WITN4461149]. I do not know what the outcome of that discussion was.

102. Q102: Minute 16 August 1983

102.1. On 16 August 1983, I wrote a minute to Dr Oliver and Mr Parker, attaching a paper for the September meeting of the Advisory Committee on Dangerous Pathogens (the ACDP). I noted that, with the agreement of the Health and Safety Executive (the HSE), the DHSS was asking the ACDP to consider providing guidance on the safe handling of clinical and other material which might be capable of transmitting AIDS [DHSC0001403].

102.2. I have been asked, first, why I considered that the Department had reached the stage of being "obliged to seek expert advice" in August 1983; that is, the advice sought from the ACDP.

102.3. My comment regarding the need for expert advice was specifically in relation to the occupational risks to healthcare workers. There was increasing disquiet about the possibility that healthcare workers were at risk of contracting AIDS through needlestick or laboratory accidents, although no such incidents were yet known to have occurred, nor had any yet been reported in the USA by CDC, Atlanta.

102.4. In relation to why such advice had not been sought earlier, the modes of transmission of AIDS appeared to be very similar to those of Hepatitis B. There was a great deal of advice already available to healthcare workers about precautions to be taken in relation to the possibility of acquiring hepatitis B infection in the course of their work, whether clinical or in the laboratory. Whilst this guidance would have been equally relevant in relation to occupational risks

associated with the transmission of AIDS, it was important to seek the advice of a suitably constituted advisory committee on the safe handling of clinical or other materials which might be capable of transmitting AIDS.

102.5. The reservations I had about the role or ability of the Advisory Committee on Dangerous Pathogens to provide the advice that was required were as follows.

102.6. The ACDP, which was a joint Committee between the Health and Safety Executive (HSE) and the DHSS had become something of a forum for disagreements between the employer members and the employee members. The latter included representatives of the relevant Trades Unions. That had made it a less valuable forum for providing expert advice for the Department and there had seemed, until the advent of AIDS, an insufficient work agenda to keep the Committee in being. A submission had been prepared for Ministers suggesting that it should be disbanded. However, I recommended to my line manager, Dr Oliver, that the ACDP remained the most appropriate committee on which to seek the advice we needed and he agreed [DHSC0001404].

September 1983

102.7. I was invited to attend a meeting of the Haemophilia Reference Centre Directors on 19 September 1983 [PRSE0003196]. The minutes of the meeting state that I had been invited to attend "in view of the Department's interest in AIDS". By this time a haemophiliac in Bristol had sadly died of AIDS, although the CDSC had not been made aware of the case until after the patient's death. At the meeting, I indicated that the DHSS was considering the possibility of centralising and controlling the supplies of commercial Factor VIII. The DHSS felt that there was a strong case for all orders of Factor VIII, commercial and NHS to be made via the Blood Transfusion Service.

102.8. The problem was that any hospital, not just haemophilia centres, could order and receive commercial Factor VIII, provided their health authority would fund it. This was both bad for patient care and also for data collection on usage, including batch numbers. The suggestion was not well received. There seemed to be a concern – which was actually without foundation - that HCDs would be deprived of their ability to secure the products of their choice.

102.9. The topic was picked up at a meeting of the CBLA on 28 September 1983 (I was not in attendance) and then in a letter from Mr Armour, the Secretary of the CBLA, to Mr Winstanley on 13 October 1983 [DHSC0002235_012]. Mr Armour acknowledged the freedom of DHAs to make their own purchases but wished to secure agreement that BPL products would be used; he asked that this be put on the agenda of the Advisory Committee for the NBTS.

103. Q103: Special Precautions by Manufacturers

103.1. I have addressed this at paragraph 99.29 onwards.

104. Q104: Potential conflict between Sub-Committee on Biologicals and FDA's July decision

104.1. I have addressed this at paragraph 99.19 to 99.20

105. Q105: Response by the DHSS to first reported death of a haemophiliac from AIDS in September 1983

105.1. I learned about the death of the patient in Bristol from a minute circulated by Dr Sibellas on 13 September 1983 [WITN4461150]. As the Inquiry states in its question, this was the first reported death of a haemophiliac from AIDS in the UK. His death was subsequently reported in the CDR of the week ending 30 September, as having taken place in August 1983 [DHSC0002235_116]. He had received American Factor VIII concentrate in December 1981 but otherwise had been treated with a variety of NHS material.

105.2. At the 13 September meeting of the RCDs, it was reported that the Director of CDSC, Dr Galbraith was concerned that he had not been notified about the Bristol case, until after his death. This was apparently because the case had not seemed to fulfil all the criteria for an AIDS diagnosis, so it had not been reported to CDSC. Henceforth Dr Craske would take it upon himself to report all cases of AIDS or suspect AIDS, unless the reporting doctor withheld permission for him to do so ([DHSC0002231_059] is my 19 September note of the meeting).

105.3. I have been asked what, if any, decisions or actions were taken by the DHSS following or in light of this death. The report from Dr Craske on AIDS dated 6 October 1983, to the DHSS Advisory Committee on Hepatitis, sets out an overview of knowledge current at the time, including about this patient's death, his exposure to concentrates (December 1981) and the steps planned: "Intensive follow-up of this case is planned to see if evidence of an association with a batch of Factor VIII can be demonstrated." [DHSC0002235_007]

106. Q106: Minute 19 September 1983

106.1. The Inquiry has noted that in a minute from me dated 19 September 1983, I highlighted to Mr Winstanley that Dr Craske required more resources to track haemophiliacs who had received infected products (see [DHSC0002231_059]). I recommended to Mr Winstanley that the Department should "come up with some money" to fund this request. Whilst I do not know for sure what happened in this instance, I believe it is the case that Dr Craske continued to be able to undertake the necessary surveillance.

106.2. In the same minute, I mentioned the view expressed at the meeting by Directors that RHAs would not be prepared to increase plasma production to meet the mid-1980s target for Factor VIII unless they were provided with additional funding. Although I knew (from seeing the fate of other bids) that there was little hope that a bid for additional funding in the next Public Expenditure Survey Committee (PESC) round would be successful, I nevertheless proposed there would be no harm in trying.

107. Q107: Consideration of alternative countries for blood product supplies, October 1983

107.1. The Inquiry has noted that in October 1983, further attempts were made to ask other European countries whether they could supply blood products.

107.2. I have been shown a copy of the Mail on Sunday newspaper article which sparked these letters [DHSC0002233_025]. This stated that although the newspaper "highlighted the problem five months ago, Health Minister Kenneth Clarke was still saying yesterday that there was little that could be done." The

article quoted Mr Clarke as saying: "We will make every effort to find a risk-free source of blood. If we find such a country we will certainly stop imports from America, where AIDS is prevalent." The article continued: "But many experts believe that a risk-free source of blood already exists – in Switzerland. This has already been offered to Britain by the Swiss Red Cross in Berne but officialdom in Britain has so far turned them down."

107.3. In a minute to Dr Oliver and others, dated 5 October 1983 [DHSC0002233_025] I explained that, in the light of these allegations in the Mail on Sunday and the quoted statement by Mr Clarke, it was felt "necessary to seek an official statement from the Swiss Red Cross."

107.4. It is apparent that given the assertions in the article, we needed a statement upon whether the Swiss Red Cross was in a position to supply the UK with either Factor VIII concentrate or plasma from unremunerated Swiss donors. I was also concerned that the comment made by Mr Clarke could mean that we had to go further and seek a similar statement from other European countries or even from further afield, such as Australia (which had a voluntary donor system). I attached to this minute a draft of my letter to Dr Hassig, Director of the Swiss Red Cross, although I also explained that we knew, unofficially, through the CMO's consultant adviser, Dr Gunson, that the Swiss would be unable to supply us with such material. Thus, the allegation in the Sunday Mail – that an offer of assistance had been made by the Swiss Red Cross but turned down – was untrue.

107.5. Mr Lupton responded to me on 6 October [DHSC0003618_166] with some queries; from the minute I wrote the following day, it seems likely that we then spoke on the telephone.

107.6. On 7 October 1983, I wrote to Mr Lupton (International Relations Division) [DHSC0002233_031] confirming what we had agreed in a phone call the previous day, to the effect that, although such an enquiry should normally be addressed to the Swiss Government, in the interests of speed, I should go ahead with my letter to the Director of the Swiss Red Cross. My minute also confirmed that Mr Lupton would be considering, with his medical colleague, Dr

Hyzler, how best to request the same information from countries word-wide which had a system of non-remunerated blood donation.

107.7. I commented that I thought we were all aware that this global approach was purely cosmetic, since all the expert advice we had received was that the type of material we were seeking was not available. I acknowledged that the same applied to our approach to the Swiss Red Cross, but that it was a special case (presumably because it might have been specifically referred to in the Mail on Sunday article). I recognised that we might need to pursue this global approach if it were felt that Mr Clarke's statement in the Mail on Sunday warranted it.

107.8. I note that Dr Oliver (DCMO) commented on 10 October. The copy available to me is very faint, but it appears that he questioned the advisability of tackling the problem through the WHO and suggested that it would be enough to approach two or three of the "respectable" large countries to see what they said (i.e., if they could offer anything); if, as suspected, their answer was negative, there would be no need to go anything further [WITN4461151].

107.9. I have been asked why my letter to the Swiss Red Cross of 7 October 1983 stated that "much ill-informed criticism has been levelled at the UK Government for the continued acceptance of imported US blood products" (see [DHSC0002235_093]).

107.10. I sent my letter to Dr Hassig on 7 October. I assume what I said about ill-informed criticism must have related particularly to whatever had been alleged in the Mail on Sunday. In particular, I went on to say that it had been claimed that AIDS-free plasma or blood products could be obtained from non-US sources and that, in particular, the Swiss Red Cross had offered Britain such material. I explained that whilst we understood that Switzerland could not provide the UK with such material, I was seeking confirmation of the position. Our requirement for Factor VIII was of the order of 40m i.u. I also took the opportunity to ask if Switzerland had identified any AIDS cases.

107.11. Dr Hassig responded to my letter on 17 October [DHSC0002235_092] as follows:

> *"Dear Dr Walford, Reference is made to your letter dated October 7th, 1983. We very much regret to inform you that the Swiss Red Cross*

Blood Transfusions Service is not able to supply the United Kingdom with plasma or factor VIII concentrates. We have just enough plasma to cover the needs of our Swiss haemophiliacs. Concerning AIDS we may inform you as follows: until July 13 1983, 13 cases were registered by our Federal Office of Health. Four of them were in Zaire or Kingo [sic], three in Haiti, the remaining six persons were homosexuals. Until today, no case of AIDS is known which may have been transmitted by blood or blood products."

108. Q108: Meeting of the Advisory Committee on the National Blood Transfusion Service 17 October 1983

108.1. On 17 October 1983, I attended a meeting of the Advisory Committee on the National Blood Transfusion Service on 17 October 1983. I have been asked about the record in the minutes [CBLA0001763], where it is recorded that I stated that "the UK could anticipate between 2-4 deaths amongst haemophiliacs from the disease".

108.2. What is recorded in the minutes is that I said: "comparison with reported incidences in the UK population suggested that the UK could anticipate between 2-4 deaths amongst haemophiliacs with the disease." As it stands, that sentence does not make sense. Presumably, I had been making comparison with reported numbers of cases in haemophiliacs in the US, not with haemophiliacs in the UK. That would have made more sense (but I did not see the draft minutes of this meeting in order to correct them). I think it is much more likely that I was making a comparison between observed numbers of cases of AIDS per 1000 haemophiliacs in the USA (which was generally quoted at the time as being 1.0 per 1000 haemophiliacs) and the numbers of cases which might be expected in the UK which would, in the context of 2000-4000 UK haemophiliacs, equate to 2-4 cases.

108.3. Of course, what sadly became much clearer subsequently, was that the long incubation period between infection and the development of symptoms of AIDS and subsequent death, compounded by the existence of a variable period of asymptomatic infectivity, meant that the estimate of numbers of both cases and deaths was gravely mistaken. I have given a more detailed explanation of the

general understanding of the risks of infection, and of the uncertainties regarding how many of those infected might go on to develop AIDS, at paragraph 86.34 above.

108.4. The paragraph in the minutes appears in a brief summary update on the topic. It is apparent that there was no detailed discussion of either AIDS or the policy response to it, at this meeting.

109. Q109: The Guardian Article, "US Blood Caused AIDS"

109.1. The Inquiry has referred to a Guardian article headed "US blood caused AIDS" [DHSC0002235_048], and the handwritten question and answer on the document. The date for the article is given as 1 November, and the handwritten question to me is dated 23 November.

109.2. I have been asked to confirm that the writing "Thanks, Yes it is OK" is mine, and I confirm that, yes, that is my handwriting.

109.3. With regard to the question of why I gave that response, I was asked the same question by the Penrose Inquiry [WITN4461152]. I reproduce my answer to Lord Penrose below, only using the IBI reference numbers, as it remains my answer to this question:

> *"9. When on 23 November 1983 and with reference to an article in the Guardian [DHSC0002235_048] I was asked by a colleague from HS Division whether it was 'OK' for him to continue to say that 'there is no conclusive proof that the disease has been transmitted by American blood products' I responded that it was 'OK' to do so. As I explained in my letter to the [Penrose] Inquiry dated 26 February 2011, given the state of knowledge about AIDS and its causative agent at that time, this was the appropriate answer to the question as posed. The Bristol man referred to in the Guardian article was one of two cases already known to the Department of Health (the other being the case in Cardiff). There was discussion of the Bristol case at the 19 September 1983 meeting of the Haemophilia Reference Centre Directors which I attended [PRSE0003196_0001]; the Guardian had first reported this death on 28 September 1983 [DHSC0002233_011_0002] and I had myself reported the existence of the two cases of AIDS in UK*

haemophiliacs to the meeting of the Advisory Committee on the National Blood Transfusion Service on 17 October 1983 [CBLA0001763_0004]. The report in the Guardian in November 1983, to which my colleague drew my attention, therefore did not constitute new evidence which would have justified a change in the form of wording being used, nor did it add anything further to the scientific debate that was ongoing between experts at that time."

109.4. Lord Penrose had asked me whether this 'line to take' gave a false sense of security. I answered that part of the question as follows:-

> *"……. the Haemophilia Society was by this time already aware of the Bristol death and the suspected Cardiff case. From the papers before the Inquiry I see that in September 1983 (prior to the publication of the first Guardian article) the Haemophilia Society had produced a factsheet on AIDS [WITN4461153] which referred to one recorded death from AIDS in a person with haemophilia and one other suspected case in Cardiff. The factsheet shows that the Haemophilia Society, whilst aware of a possible AIDS risk, was also clearly concerned that patients might refuse treatment, a course of action which itself carried significant risks. The factsheet stated:*
>
> *'Assuming blood to be a transmission agent, it is not yet possible to state that imported blood products are AIDS-free (nor indeed that the UK product is so), the chances are that the risk involved in imported concentrates has been reduced considerably… Our message remains unchanged: THE ADVANTAGES OF TREATMENT FAR OUTWEIGH ANY POSSIBLE RISK. BALANCE THE RISKS for yourself, but we would state again that the risk of AIDS is tiny compared to the risks of untreated bleeding episodes. By refusing treatment or not following your Centre Director's advice you are probably exposing yourself to even greater risks.'" (Emphases in original).*

109.5. I have been asked when, and how the 'line' changed. The standard line did not alter during my time in post in Med SEB, which I left on 3 December 1983. I do not know precisely when it altered, nor on whose advice. It continued to be used and discussed after I had left: see for example the letter from Lord Glenarthur dated 5 January 1984 [PRSE0001727].

109.6. In addition, the NIBSC Annual Report for 1983-84 reveals that at a meeting held at NIBSC in February 1984, involving NIBSC scientists, plasma fractionators (both commercial and NHS), virologists, Blood Transfusion Directors and a representative from the US FDA, there was no suggestion that all large-pool coagulation factor concentrates should be withdrawn. Instead, what was proposed was that:

> *"...if the diagnosis of AIDS in a donor is definite, then products prepared from pools to which the donor had contributed should be withdrawn".*

109.7. Thus, it is clear that, despite the growing numbers of haemophiliacs with AIDS, particularly in the USA (although not yet in the UK), and the strong association with large pool coagulation factor concentrates, the dilemma of what to do to halt the spread of AIDS by this route remained.

109.8. A potential solution was to destroy any viruses in such products by the use of heat-treatment. But the heat-treatments so far in use had not proved capable of reliably preventing the transmission of non-A, non-B viruses, and there was no way of establishing whether the putative agent of AIDS would be susceptible to heat. The report of the NIBSC meeting went on to say:

> *"There was also discussion about the value of heat-treating Factor VIII concentrates, which is being widely carried out in the United States. Even though there was no conclusive evidence that heat treatment reduced the infectivity of blood products in relation to non-A, non-B hepatitis, or AIDS, there was considerable pressure on plasma fractionators, particularly in the US, to carry out various forms of heat treatment."*

109.9. Thus, it seems that all the public health and ethical dilemmas that existed during my final year in Med SEB, persisted into at least the start of the following year; and the continuation of the narrative of how they came to be resolved must be left to those dealing with events after 1983.

Section 7 Other Issues

110. Q110: Anonymous HIV Testing in 1989

110.1. The Inquiry has asked for a description of the DHSS's, and my own, involvement in discussions and decisions regarding anonymous HIV testing in 1989.

110.2. I recall there were numerous discussions about the ethical, legal and practical considerations surrounding the proposal to introduce unlinked anonymous screening for HIV. These discussions took place in around 1989-1990 towards the end of my time as head of Med IMCD and, subsequently, after I had been promoted to Deputy Chief Medical Officer (DCMO). Whilst I clearly recall these discussions took place, they involved numerous external bodies, including the MRC, GMC, Nuffield Council of Bioethics, BMA, UK Central Council for Nursing, Royal College of Midwives, Medical Defence Organisations and others. I have only the sketchiest recollections of the substance of these meetings, many of which I did not attend. The Chief Medical Officer (CMO), Sir Donald Acheson was closely involved in all the discussions and decisions about the principle of introducing such programmes. My circular letter to the NHS, EL(90)175, provided to me by the Inquiry, [DHSC0033431], provides a good description of the practicalities of what the surveys were about – through the information in the publicity material for the public which was enclosed with the letter. The letter also flagged up what further surveys were intended in the future.

110.3. I feel it may be of assistance to the Inquiry if I refer to a very useful publication, which is a contemporaneous review of the scientific, legal and ethical basis for the programme, written just prior to its launch (Gill, O.N, Adler, M.W, Day, N.E, *Monitoring for the prevalence of HIV.*, BMJ, 1989, 299. 1295-1298 [WITN4461154]). This review, whose authors were involved closely with the Department in the development of the programme, seems to me to give a good account of the principles that underpinned the programme and the various bodies that were consulted and consented to its introduction.

110.4. For the purpose of this statement, I reproduce here the principles of the unlinked anonymous method:

i) The blood specimens used must have been taken with the patient's consent for clinically necessary laboratory tests unconnected with HIV.

ii) Only the usual amount of blood should have been collected and the satisfactory conduct of the original laboratory test should not have been compromised in any way.

iii) Personal identifiers must be irreversibly removed before the specimens are tested for HIV.

iv) A restricted data set, such as sex or exposure category, if known, could accompany the sample but no information that could possibly identify the patient.

v) Those in the target population being tested must have ready access to named HIV testing service, including proper counselling before and after testing.

110.5. As the Circular letter, EL(90)175 made clear, there must be information provided in clinics which explained to the public that the surveys were being undertaken and make it clear that they were fully entitled to opt-out, should they wish to do so.

111. Q111: AIDS Litigation 1989

111.1. I have been referred to a submission [MHRA0017681] dated 26 June 1989 concerning AIDS Litigation, into which I was copied. I have been asked to set out my views at the time regarding the issues identified in the submission.

111.2. I was one of a long list of copy recipients of this submission. I had not been party to the discussions in the Department, as far as I can recall, and I cannot, I am afraid, say what my views may have been regarding the issues identified in the submission.

112. Q112: HCV Testing

112.1. I have been asked to describe my knowledge of, and involvement with regard to, the decisions, actions or policies of the DHSS regarding HCV testing and/or screening donors for HCV.

112.2. The Advisory Committee on the Virological Safety of Blood (ACVSB) advised the Department, towards the end of 1990, (I do not have the precise date) that screening tests for HCV antibodies in blood donations should be introduced as soon as practicable. The Committee was chaired by my DCMO colleague, Dr Jeremy Metters and he was in the lead for this policy, together with administrative colleagues in the EHF1A Division. The operational lead for the NHS Management Executive, responsible for considering the implications for the NHS of the proposed policy and for holding discussions with relevant parties and issuing the guidance to the National Blood Transfusion Service (NBTS) to undertake this screening, was Mr Mike Malone-Lee. For some reason, I note that I was the signatory to the letter of instruction to General Managers (draft provided by the Inquiry [NHBT0000061_202]), which is slightly surprising because the letter mainly dealt with issues relating to the handling charges for blood and blood products, with very little content that required a medical signatory.

112.3. I had previously been asked my view, as Medical Director of the NHS Management Executive, on whether HVC testing should be introduced. My response (in manuscript on a draft of the submission to Ministers, [NHSBT0000061_207_0001] was that I agreed that "there is no option but to advise Ministers that we <u>should</u> screen for HCV" (emphasis in the original).

113. Q113: Financial Assistance

113.1. I have been asked to describe my knowledge of, and involvement with regard to, decisions, actions or policies of the DHSS regarding the provision of financial assistance for those infected with HIV through blood transfusion or donated organs.

113.2. Various documents relating to this issue were sent to me by the Inquiry. However, I was simply a copy recipient of these documents and was not

involved in the decisions, actions or policies of the DHSS regarding the provision of financial assistance for those infected with HIV through blood transfusion or donated organs. My one fleeting involvement with the issue, which is shown in my handwritten note on paper [DHSC0002658_002], was to say that I believed that the CMO letter about the payments scheme, which was to be sent out to all hospital consultants, should also be sent to all general practitioners.

113.3. I have set out my personal views on this topic in the opening remarks to this Statement.

114. Q114: Role of Public Health Laboratory Service

114.1. The Inquiry has asked for a description of the role of the Public Health Laboratory Service (PHLS) in relation to infection (whether with HIV, HCV, HBV, new variant CJD (vCJD) or other infections) through blood and/or blood products.

114.2. My predecessor, as Director of the PHLS, provided a useful description of the role of PHLS in the inquiry into BSE/vCJD. Sir Joseph Smith stated in his witness statement that:

> *The Role of the PHLS, 1985-1992*
>
> *4. The PHLS Board's responsibility, as described in The Public Health Laboratory Service Act 1960, is to "provide a bacteriological service for the control of infectious diseases", for which it is accountable to the Health Ministers of England and Wales. The National Health Service Act 1997 (Schedule 3) incorporated the PHLS Board. The PHLS was funded from the central funds of the Department of Health and Social Security/Department of Health.*
>
> *5. The Public Health Laboratory Service Act 1979 gave the Secretary of State the power to include in the role of the PHLS additional activities which could be carried out in conjunction with a microbiological service. The PHLS Board's responsibilities were extended under the Act to include management of the Centre for Applied Microbiology and Research (CAMR) at Porton Down. CAMR*

was formerly the Microbiological Research Establishment of the Ministry of Defence.

The PHLS Organisation and Work:

6. In the time I served as its director, the PHLS organisation included the following:-

6.1 52 Area and Regional (peripheral) diagnostic PHLS laboratories spaced over England and Wales, each providing diagnostic services and support for outbreak investigation to local hospitals, public health authorities and environmental health departments. Each laboratory also provided surveillance data and microbiological samples to the central PHLS units at Colindale, and also took part in national investigations into infectious diseases.

6.2 The Central Public Health Laboratory (CPHL) at Colindale, London, which provided national reference laboratory services to both PHLS and NHS laboratories.

6.3 The Communicable Disease Surveillance Centre (CDSC), also at Colindale but with a Welsh Unit located in Cardiff. CDSC served as the epidemiological arm of the PHLS. It kept human infectious diseases under surveillance and, working with other PHLS units, provided expert epidemiological support for the study of infectious diseases including the investigation of outbreaks. Its surveillance function was based upon regular returns of diagnostic data from the peripheral and central PHLS laboratories, supported by other information, including when necessary reports from clinicians and others.

6.4 CAMR, Porton Down. As well as providing a few services supporting the PHLS' public health work, such as diagnostic tests for dangerous pathogen infections, CAMR was expected by the Secretary of State for Social Services to generate income from its research. To this end the Board in 1985 made an agreement with Porton Products Limited for marketing the products and processes resulting from CAMR research.

114.3. I agree with Sir Joseph's description. The only material changes during my time as Director of PHLS between 1 January 1993 and summer 2002 were:

i) that the responsibility for running CAMR moved from the PHLS to the Department of Health;

ii) the area and regional laboratories were managed in nine regional groupings;

iii) four PHLS Collaborating Centres were set up in teaching hospitals in London, to compensate for the relative lack of public health laboratories in London;

iv) and a country-wide Regional epidemiology service was set up under contract with the NHS Executive.

115. Q115: The HCV Lookback Exercise

115.1. The Inquiry wishes to be supplied with a description of my knowledge of the HCV lookback, and of my involvement and that of the PHLS in this exercise.

115.2. The PHLS supported the National Blood Authority (the NBA) in the testing element of the Look Back Exercise (the LBE). It was involved in two ways.

115.3. First, the PHLS carried out tests for those members of the public who expressed concerns to their medical advisers (e.g., GPs/consultants/RTC doctors) as a result of any publicity about the LBE, or about transfusion risks more broadly, and who were referred for a test as a result. This was not a formal part of the LBE itself, but sat alongside it.

115.4. The EPINET communication from Mr TJ Dingley (at PHLS headquarters) dated 13 January 1995 noted the announcement of the LBE on 11 January 1995. Mr Dingley informed PHLS Directors of the potential demand for tests from anxious patients who thought that they have may have had a blood transfusion and who were worried about the risks. He advised that, in advance of the LBE, anti-HCV testing might be the appropriate response to those who had had transfusions and had abnormal liver function tests. GPs were encouraged to perform liver function tests. However, he stated that patients who were anxious but did not

have abnormal liver function tests should not be denied testing [NHBT0002757].

115.5. The subject was picked up in the LBE Working Party's first meeting on 20 January 1995 [NHBT0009715], chaired by the DCMO, Dr Metters. The notes of that meeting record that the LBE was to be regarded as a sub-group of the Committee on the Microbiological Safety of Blood and Tissue for Transplantation (MSBT). Dr Metters explained that "Ministers had undertaken to do all that was reasonable to trace, counsel and where appropriate treat those who might have been exposed to HCV through transfusion. It would not be possible to track all such patients and it would be for consideration what was reasonable in the circumstances". The meeting noted the need for the PHLS to inform the transfusion centres of the details of any patients - not part of the LBE - who were found to be HCV antibody positive, particularly any patients who had received or donated blood.

115.6. The letter dated 23 January 1995 from Dr Metters to me [NHBT0036689] followed the meeting. He noted that such 'early' (my word) patients, who consulted their GPs because they were anxious to learn their hepatitis status, might in due course be picked up by the LBE and proposed arrangements to enable the results of such tests to be passed back to the transfusion service, provided that patient consent was obtained.

115.7. As is apparent from Dr Metters' letter, the Working Party had also noted that abnormal liver function tests should not be a requirement for a referral for testing. The memorandum from Dr Hewitt at the North London Blood Transfusion Centre, Colindale dated 26 January 1995 (below) confirms that "PHLS have corrected their original statement" that anti-HCV testing was warranted in those who had abnormal liver function tests; "It has been made clear that normal liver function test is no assurance of lack of HCV infection."

115.8. The memorandum from Dr Hewitt at the North London Blood Transfusion Centre, Colindale dated 26 January 1995 also shows arrangements being made to ensure that the information from such tests was duly fed back to the RTCs. As Dr Hewitt noted "We hope that, by the use of this form, RTCs should get information about any anti-HCV positive recipients of blood, not located by

Look-Back" [NHBT0019915]. Dr Robinson subsequently wrote to me to reinforce the desirability of ensuring that transfusion history was collected and that suitable arrangements could be made to notify the local transfusion centre should the hepatitis C test prove positive, in the presence of a past history of transfusion. See her letter of 20 March 1995 [NHBT0009676].

115.9. As noted in the minutes of the LBE Working Party held on 14 March 1995, PHLS agreed to absorb the costs of these 'additional' tests up to the end of February 1995 [WITN4461155].

115.10. Second, and in relation to the processes of the central LBE itself, the process of testing was set out in a diagram (referred to as an algorithm) in the CMO's letter of 3 April 1995 to all NHS hospital consultants and general practitioners in England [WITN4461156]. PHLS's role was to take receipt of samples from individuals who had been identified as being at risk from past transfusions and counselled. Samples from the patient were sent for testing using initial (duplicate) screening with ELISA anti-HCV antibody tests with positives being confirmed by RIBA (recombinant immunoblot assay) testing and then PCR testing for viral RNA. In addition, Dr Philip Mortimer's letter to PHLS virologists (28 July 1995) specified that an EIA (Enzyme Immunoassay) test for anti-HBc should also be carried out on all samples~~]~~. PHLS was reimbursed by the NBA for carrying out these tests.

115.11. The letter of 28 July 1995 [NHBT0036669] from Dr Mortimer to PHLS shows that attention was given to the practical arrangements needed to make these procedures work.

116. Q116: HIV Transmission by Transfusion in April 1997

116.1. I have been asked to describe my knowledge of an investigation in 1997 into HIV infection transmitted through transfusion, and the involvement that I and the PHLS had in this matter.

116.2. My recollection of these events is limited. However, my recollection has been partly aided by reviewing the following contemporaneous documents:

i) A letter from Kate Solden of the PHLS Communicable Disease Surveillance Centre to Dr Robinson (who was then Medical Director of

the National Blood Service (NBS)) enclosing a copy of the Communicable Disease Report (CDR) (Volume 7, Number 16, 18 April 1997) which included an article entitled 'HIV infection transmitted through transfusion.' [NHBT0008791_005].

ii) A chronology of the investigation in March/April 1997 [NHBT0081211].

116.3. As the chronology demonstrates, the Central Public Health Laboratory in Colindale (CPHL - sometimes referred to as Colindale in the contemporaneous documents) played a central role in confirming the transmission and the donation that contained HIV. For example, the CPHL performed the PCR test (polymerase chain reaction) which confirmed the existence of HIV RNA (ribonucleic acid) [page 4 of NHBT0081211]. A PCR test may be positive prior to the development of HIV antibodies. In addition, the CPHL identified the donation which contained the HIV RNA [page 5] and performed tests on previous donations by the same donor [page 6]. There are multiple references made to incident meetings. I very much doubt that I would have attended these. The managerial oversight of the Colindale testing operation would have been by the Director of the CPHL, Professor Peter Borriello. However, I certainly would have been aware of the transmission incident and would have been kept informed of developments.

116.4. I can see from Ms Solden's letter to Dr Robinson that it was stated that Dr Bartlett, the Director of CDSC, the CMO (Sir Kenneth Calman) and I changed the wording of the draft report to be published in April 1997 CDR so that it merely said that those at risk of introducing HIV into the donation pool are 'advised' not to donate, as opposed to there being, effectively, a 'prohibition' on donation, which her letter implies was a more accurate description of the approach to donors from high-risk groups. In addition, she suggested that I (alongside Dr Bartlett and Sir Kenneth) sought to remove references to the estimated risk of HIV transmission from blood donations taken in the "window period" before HIV antibodies had developed.

116.5. I cannot recall if those are accurate representations of the conversations that occurred. However, we may have been concerned that the data on which the estimate of risk of an infectious donation entering the blood supply, could be

open to challenge. Such an estimate could beg the question of how many cases of transmission in the window period may, over time, have gone undetected, despite donors from high-risk groups being strongly advised not to donate and despite the screening of donor blood for HIV antibodies.

116.6. Concern about the potential for a challenge to the validity of any estimate of risk for what appeared to be this extremely rare event, seems to be supported by what is stated in the publication which is referenced at the end of the CDR report. This publication is a letter from Crawford R J et al. (1987) in the BMJ [WITN4461157] referring to the controversy surrounding the selection and testing of blood donors. It includes the sentence: "There seem to be only two published reports of HIV transmission by blood definitely negative for antibody to HIV to recipients with no other risk factors, *although other cases are apparently under investigation*." (My emphasis).

116.7. The non-inclusion of a risk estimate would not have compromised the public health information being provided in the CDR. Conversely, an under-estimate of risk could have generated complacency in the public's mind, and an over-estimate of risk could have caused fear, in potential recipients, of having to receive a blood transfusion.

117. Q117: vJCD

117.1. The Inquiry has noted that in October 2001 Dr Mortimer (Director of Sexually Transmitted and Blood Borne Virus Laboratory) wrote to the DCMO (with the letter being copied to me) regarding "Haemovigilance and the vCJD risk" [NHBT0000700]. I have been asked to describe my knowledge of the risk of vCJD through blood and blood products and the assessment of, and response to, that risk; as well as the part played by me and the PHLS.

117.2. My recollection of these events is limited; however, I have had the opportunity to review a number of contemporaneous and near contemporaneous documents:

i) first, my first and second witness statements to the BSE inquiry drafted prior to 16 October 1998 [WITN4461006, WITN4461007];

ii) second, a letter dated 1 October 2001 from Dr Mortimer to DCMO Pat Troop at the Department of Health;

iii) third, a letter dated 11 April 2002 from Dr Mortimer to Dr Angela Robinson and Mr Martin Gorham at the NBS [NHBT0001130_001].

These documents have aided my recollection, but it remains incomplete.

117.3. For obvious reasons, the document that provides the greatest insight into my knowledge and involvement at the time as well as the involvement of PHLS was my second witness statement to the BSE inquiry. In addition, that statement was supported by a number of contemporary documents and I have provided copies of these to the Inquiry.

117.4. Prior to taking up my role as Director of the PHLS and whilst at the DoH, I was aware, in general terms, that the PHLS was not involved in the work on BSE/CJD. The DoH first heard about BSE in February 1988, during a regular meeting of the Central Zoonoses Group, which I chaired. These meetings with the Department involved veterinary officers, from the Ministry of Agriculture, Fisheries and Food (MAFF) together with scientists from the PHLS.

117.5. Once he had been notified of the occurrence of this new disease in cattle, the CMO, Sir Donald Acheson, wished to investigate the matter further, in case there were implications for the public health. Initially, it fell to my Division to support the CMO in this, but, because of the major load of communicable disease outbreak-related work being carried by my Division, the CMO decided, in about April 1988, that the work associated with the BSE should move, with Dr Hilary Pickles, to Med SEB and that my Division, Med IMCD, would have no further responsibility for it.

117.6. I was not, therefore, involved in the setting-up of the National CJD Surveillance Unit in May 1990. I left the DoH at the end of 1992, to take up my post as Director of the PHLS.

117.7. In my second statement to the BSE Inquiry, I explain, in detail, how and when I came to learn about the prohibition placed on the PHLS by the DoH, against engaging in any work whatsoever in relation to BSE. I reproduce below paragraphs 4 and 5 of my second statement, as these convey the position precisely.

"4. As far as I am aware, there were no specific discussions, in the early days following my appointment, about the PHLS's involvement, or otherwise, in relation to BSE/CJD. At some point, during 1993, I was informed of the existence of a letter, dated 25 January 1991, to Sir Joseph Smith from Stephen Dorrell (attachment 1) (YB 91/01.25/4.1-4.2). Mr Dorrell was then the junior Health Minister with responsibility for the PHLS. This letter indicated that the Minister did not expect the PHLS to become involved in work on Transmissible Spongiform Encephalopathies (TSEs)."

5. It was made clear to me, in various conversations with colleagues in the PHLS and with the Chairman, Dr Godfrey, that the understanding within the Service was that the PHLS was under instruction not to become involved in the surveillance of TSEs. Furthermore, there was an understanding that we should not ***"be seen to work or to comment on the subject...."*** *The quotation is taken from Sir Joseph Smith's evidence to the Inquiry and very aptly describes the position as it was represented to me at the time."*

117.8. My view was that PHLS could make a considerable contribution to the understanding of TSEs and I expressed that in my witness statement to the BSE inquiry in the following terms:

'I believe PHLS's unique expertise in communicable disease epidemiology, coupled with its experience in the investigation and handling of major national incidents, should have been fully utilised by the Government in a matter of such vital public health importance.'

117.9. By April 1994, the then CMO (Sir Kenneth Calman) appeared to be more open to possible involvement of PHLS to assisting in the surveillance of CJD. I wrote to Sir Kenneth on 11 April 1994 proposing a discussion group to review whether there were any gaps in surveillance that the PHLS could help address. The CMO politely but firmly rebuffed our approach on 24 April 1994. I persevered in seeking to change his mind and wrote again 20 July 1994 and met with the then CMO on 1 September 1994. The CMO showed some sympathy with the suggestion that PHLS might have a greater role and stated he would consider observer status for the PHLS on the Spongiform Encephalopathy Advisory

Committee ('SEAC'). PHLS was not granted observer status and played no role on SEAC.

117.10. I approached Dr Robert Will, Director of the National CJD Surveillance Unit, directly in November 1995 as I was deeply concerned by the small number of cases of CJD which were occurring in unusually young people. I was open about this approach with the CMO. As well as telephoning the CMO to keep him informed, I wrote to him informing him that I had arranged a meeting between Dr Will of the National CJD Surveillance Unit, colleagues from PHLS and me, together with Professor Peter Smith of London School of Hygiene and Tropical Medicine, who had been providing statistical input to Dr Will's unit. The CMO wrote back stating that the meeting should not go ahead as it might compromise SEAC as the single source of scientific expertise on prion disease. I, therefore, felt I had no alternative but to cancel the meeting.

117.11. This was a source of deep frustration for me. As I stated in my second witness statement to the BSE inquiry:

> *20. I was deeply concerned that my repeated offers of assistance by the PHLS were rebuffed on each occasion. This exclusion of the PHLS from a role that appeared to fall squarely within its corporate purpose of protecting the population from infection caused dismay and frustration amongst our staff. It also elicited adverse criticism from those outside the Service of the perceived inaction by the PHLS in an area in which it might reasonably have been expected to play a significant, if not a leading, role.*

117.12. On 21 March 1996 (the day after the announcement of the discovery of vCJD), I wrote to the CMO putting PHLS's expertise in communicable diseases at his and SEAC's disposal. In addition, I wrote to the head of the Health Aspects of the Environment and Food Division at the Department of Health, Dr Eileen Rubery offering our assistance. Subsequently, PHLS became involved in a number of aspects of work on vCJD and these are detailed in my witness statement to the BSE inquiry (at paragraph 23). In summary, PHLS was involved in a number of DoH funded projects such as a project to set up a panel of clinical samples from patients with neurological disorders, to be obtained through the PHLS network of laboratories to aid and evaluate candidate tests

for CJD. In addition, I was appointed a member of the CMO's Committee on the Human Aspects of Spongiform Encephalopathies.

117.13. My recollection of events concerning the risk of transmitting vCJD following its discovery in 1996 through blood products is extremely limited. I have had the opportunity of reviewing the two letters of Dr Mortimer (in 2001 to the DCMO, Dr Pat Troop, and 2002, to Dr Robinson, Director of the NBS), which were copied to me and these broadly reflect my and PHLS's understanding at the time. In summary, my understanding was:

i) There was no evidence at the time that vCJD had been transmitted through a blood transfusion.

ii) There was no test available at the time to screen for vCJD.

iii) The risk of vCJD being transmitted was not quantifiable given the extremely long incubation period of vCJD and similar diseases such as kuru.

iv) Therefore, the risk of vCJD from blood transfusion was at that stage theoretical but was a real possibility that should be considered and minimised wherever possible.

v) There was no realistic prospect of eliminating the risk of vCJD by donor screening. No lifestyle factors (including a vegetarian diet) removed the possibility of a donor carrying vCJD. An exception was to prevent those who had already received a blood or tissue donation from becoming donors themselves.

vi) The prospect of replacing homologous transfusion (person to person transfusion) with autologous transfusion (pre-surgery deposit by the patient for later transfusion) was not practical in a considerable number of cases and the infrastructure for autologous transfusion did not exist at the time and would have required a significant investment by Government.

117.14. The continued use of blood transfusions, without a significant alteration in clinical practice and without major logistical changes to the collection and banking blood, as suggested by Dr Mortimer, posed the same sort of risk /

benefit considerations that have characterised the blood transfusion field for the entirety of my career.

117.15. By the time I had left the PHLS, in July 2002, to the best of my knowledge, no case of transfusion-transmitted vCJD had been reported, but, as Dr Mortimer said, the risk, whilst theoretical, was there and subsequently, transfusion-transmitted vCJD has been shown to occur, albeit very rarely.

118. Q118: Any other matters

118.1. I have been asked to explain, in as much detail as I am able, any other matters that I believe may be of relevance to the Infected Blood Inquiry, having regard to its Terms of Reference and to the current List of Issues.

118.2. Between 2005 - 2009, I was a Non-Executive Director on the Board of the NHS Blood and Transplant Authority (NHSBT). By this time, there existed a highly professional system of haemovigilance, known as the Serious Hazards of Blood Transfusion (SHOT) scheme. During my time on the Board of NHSBT, key issues of potential interest to the Inquiry that I recall being discussed (but not in any detail because I have had no access to relevant papers) were: (i) the possible use of Nucleic Acid Testing (NAT) of donor blood for certain more unusual types of hepatitis viruses and (ii) the possibility of introducing an extra filtration step into whole blood donations aimed at eliminating prions. At the time I left the NHSBT Board, the effectiveness of such filtration procedures had not been demonstrated and I do not recall whether any decision had been made with regard to NAT screening.

Statement of Truth

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

Signed GRO-C

Dated 5 July 2021