Witness Name: Lord Glenarthur
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INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF LORD GLENARTHUR

Contents

Introduction

I, The Rt Hon Simon Mark Arthur, Baron Glenarthur, will say as follows: -

0.1. My professional address is The House of Lords, London, SW1A 0PW and my date of birth is GRO-C 1944. I am providing this statement in response to a request for information from the Inquiry dated 7 May 2021.

0.2. For the Inquiry's convenience I have endeavoured to use the Rule 9 paragraph requests to structure my witness statement. The "Sections" in my witness statement correspond to those in the Rule 9 request and, where possible, so too does the paragraph numbering.

Opening Comments

0.3. I would like to begin my witness statement by making a few brief opening comments.

0.4. I would like to start by acknowledging that the fact that infected blood and blood products caused the infection, death or serious illness of so many, is and remains a tragedy. I appreciate that it has been the cause of much suffering and distress not only to those who were infected, but also to the families and friends of those infected. I deeply regret that treatment with infected blood or blood products has caused such infection, with all its terrible consequences.

0.5. I have tried to explain in my statement how the decisions taken at the time were based on the best clinical and scientific advice available at the time and were recommended by highly qualified experts in this field. As a Minister, I would have expected to follow clinical advice on matters of medical care and treatment, although it distresses me that there were no realistic alternatives advanced to the policy adopted.

My Involvement in the Matters Relevant to the Inquiry

1.1. I was appointed as Joint Parliamentary Under Secretary of State at the Department of Health and Social Security ("the DHSS") on 13 June 1983. Although I had been a Government Whip (Lord-in-Waiting) in the House of Lords for the previous year, I had not had to handle any matters involving DHSS responsibilities in that role. I had no previous background in the health or social security fields and arrived at the department with no prior knowledge of or involvement in general policy in these fields, other than from general interest gleaned from the press, but not in any detail.

1.2. I became aware that, once my portfolio of responsibilities was decided, I would need considerable background briefing on all the subjects in my portfolio and was assured that this would be provided, which it was; either at the beginning or when issues arose for decision.

1.3. I brought with me no preconceived ideas about how I should tackle any of my policy areas, but was very much aware that I was the most junior and least experienced Minister in the department and that advice was available from many officials in each of my areas, and also recourse as necessary to my ministerial colleagues. The department was hierarchical. At the political level, the chain of command was: the Secretary of State, the Ministers of State (one for Health and one for Social Security) and the Parliamentary Under-Secretaries of State. I have given the names of office-holders at paragraph 2.2 below. There was also, of course, a civil service hierarchy headed by the Department's Permanent Under Secretary of State. The official hierarchy was supplemented by a parallel medical hierarchy, headed by the Chief Medical Officer ("CMO"), who was supported by a number of Deputy Chief Medical Officers and other medical advisers. All would have been accessible to me if required.

1.4. I had read press reports about AIDS, but only in a general way and without any deep knowledge of its prevalence or likely spread. I was not then aware about the possibility of AIDS being transmitted by blood or blood products.

The Role of Ministers

1.5. After appointment, I rapidly became aware that there was a very large amount of knowledge to assimilate in each of my areas of responsibility (see paragraph

2.3 below), both from a general background perspective and, where necessary, in detail. I was also very much aware that there was a huge body of DHSS staff who would deal with the day-to-day aspects of either on-going policy or agreed new policy and that Ministers would be invited to agree, or otherwise to request submissions on these policies as required.

1.6. The reality was that it would be utterly impractical for Ministers to be involved in the detail on any topic to the extent that officials would be; but that when it was necessary for a Minister to fully understand an issue and make a decision, the briefing would be very thorough and the detail debated.

1.7. In the case of policy with regard to blood and blood products, there was quite a long history, some of it involving Governments of a different political persuasion. But then, as now, it was not the convention to share with other Governments the details of decisions taken by Ministers in previous administrations or the official advice on which those decisions were based, nor to grant access to the papers of previous administrations, at least unless there was felt to be a real need to do so. The point is more fully set out in the Directory of Civil Service Guidance: at Vol 2, pp.8-9: [WITN5282002]. Consistently with this convention, and as far as I can recall, I was not briefed in depth on any earlier history or how policy had been derived.

1.8. I held a substantial portfolio of responsibilities, described more fully below. Blood and blood products, assumed early on considerable significance and I am as certain as I can be that I dealt thoroughly, speedily, thoughtfully and inquisitively with all submissions on AIDS and on blood or blood products that came my way. My other responsibilities required much attention and briefing, as did my responsibilities in the House of Lords. I am equally aware that there will have been a vast amount of background information, decision making and management taking place at official level which would not always have been brought to the attention of Ministers. It would have been physically impossible for Ministers to deal with every detail, and, in any case, to do so would have required very detailed technical, scientific and clinical knowledge to be able to contribute usefully.

1.9. For those of us whose responsibilities it was to try and ameliorate risk of infection while protecting those whose clinical need was great, the fact that infections occurred as a result of treatment by blood or blood products has genuinely been a source of sadness and distress. However, I, and other Ministers, only knew what we knew at the time. The science of the surrounding issues was not fully understood (although a new Blood Products Laboratory was regarded as essential, its redevelopment was ongoing whilst I was in office). Resources were stretched. The misuse of drugs in the UK and abroad, the sharing of needles and other human factors which were likely to exacerbate matters in relation to the risks of contaminating blood, were rife. There was no test for infections such non-A, non-B hepatitis or AIDS, and the aetiology of AIDS was still under research.

1.10. Looking back at the period, what I remember is that reliance on some imported blood products to boost supply was deemed essential to protect haemophiliacs against the risk of insufficient supply and that a balanced judgement of the competing risks had to be made. That judgement, as I have explained in more detail below, was essentially a matter for the clinical experts, on whose advice Ministers relied.

Documents and Papers

1.11. I now have a very limited recollection about the events about which the Inquiry has asked questions - it is now about 38 years since I took up my post in the DHSS. What remains in my memory is how concerned I was about the risk that AIDS might be spread by blood or blood products, and a real concern both to ensure their safety and that communication on this front was effective. However, it is impossible for me to remember the detail of events or of my thinking. I have been shown papers dating back from 1983 – 1985 in order to prepare this Statement and they have helped. But there are a number of significant gaps. For example:

(i) Any briefings that were provided to me on taking office are not available;

(ii) The written briefing, Q & As and 'lines to take' that would have been supplied to me in advance of my appearance in the House of Lords on

14 July 1983 are not available. There does not seem to be anything relating to the debate held in March 1985 either;

(iii) The main briefing provided before my meeting with the Haemophilia Society on 8 September 1983 is not available and nor is any minute of the meeting, although I would have expected one to have been made. The same applies to the meeting with the Society held in late 1984.

1.12. These are just examples; they are not comprehensive. But they are significant as they make it much more difficult to 'reconstruct' my thinking at the time, as the Inquiry is asking me to do. I am reliant on the documents that I have been shown. If any more are made available to me, I will have to reflect on them and consider whether any alteration is needed to what I have set out.

1.13. I do not know why documents are not available now. Generally, my observation, based on the other government posts which I went on to hold, was that the Department of Health's record keeping (for the Ministerial Private Offices at least, which is what I am familiar with), was poor. In particular, when I served as Minister of State in the Foreign and Commonwealth Office (in June 1987 – July 1989) I noticed that staff in my Private Office devoted much time and effort to storage and record-keeping; one was an archivist. Of course, this did reflect the fact that there was a great deal more classified information circulating in the FCO office.

Section 1: Knowledge of and response of risk of infection associated with blood products – AIDS

1.14. My only professional qualification has been as the holder of an Airline Transport Pilots Licence (Helicopters) with Instrument Rating. I have also been a Fellow of the Chartered Institute of Logistics and Transport; and of the Royal Aeronautical Society.

Career History

1.15. The following table outlines my employment history:

Employment History

1963 -1975	Initially a Short Service, latterly a regular Commission in The Army [The Tenth Royal Hussars (PWO), subsequently The Royal Hussars (PWO)]
1976 – 1982	Captain with British Airways Helicopters Ltd
1982 – 1989	Government Minister (details below)
1989-1996	Senior Executive, Hanson plc, and Deputy Chairman of Hanson Pacific
1989 – 1999	Consultant, British Aerospace
1991 – 1998	Chairman, St Mary's Hospital Paddington NHS Trust
1992 – 2004	Chairman, The British Helicopter Advisory Board (now Association). President since 2004-
1996 – 2003	Chairman, European Helicopter Association
1996 – 2004	Non-executive Director, Millennium Chemicals Inc
2002 – 2006	Non-executive Director, The Medical Defence Union
2001- 2007	a Commissioner, The Royal Hospital, Chelsea
2000 – 2009	a Governor, Nuffield Health

2002 – 2010	Chairman, National Employer Advisory Board for Britain's Reserve Forces
2010 – 2013	a Governor (later Chairman) King Edward VII's Hospital
2001 – to date	Consultant, then non-executive Director, Audax Global S.a.r.l.
2011 – 2019	a Governor, Sutton's Hospital in Charterhouse
1 July 2021 – 30 June 2022	Trustee, The Royal College of Organists (Chairman until 1 July 2021)
2015 – 2020	Chairman, British European Aviation Group Ltd
I remain an elected Hereditary Peer in the House of Lords	

Positions in Government

2.1. I have held the following Government posts:

(i) 27 May 1982 – 10 June 1983 Government Whip (Lord-in-Waiting) House of Lords. Spokesman variously on Treasury, Employment, Industry, Home Office and Defence.

(ii) 14 June 1983 – 26 March 1985, Joint Parliamentary Under Secretary of State, Department of Health and Social Security.

(iii) 27 March 1985 - 10 September 1986, Parliamentary Under Secretary of State, Home Office. My principal policy responsibilities were the Prison Service, The Fire Service, and the Channel Islands and the Isle of Man. I was principal spokesman on all Home Office matters in the House of Lords. I do not recall any health issues relevant to this Inquiry.

(iv) 10 September 1986 – 13 June 1987, Minister of State for Scotland. My responsibilities were Health, Social Work, Tourism and the Highlands and Islands Development Board. I was a member of the Cabinet Home Affairs and Social Affairs Sub-committee on AIDS and attended certain meetings. I handled all Scottish matters in the House of Lords.

(v) 13 June 1987 – 24 July 1989, Minister of State for Foreign and Commonwealth Affairs. My responsibilities were: the UK's relationship with countries in South Asia, South East Asia, the Far East, and the South Pacific. I had particular responsibility as Minister for Hong Kong. I was also responsible for overseeing several functional departments in the FCO. None of my responsibilities were relevant to the Inquiry.

2.2. In relation to the time that I spent as a Minister in the Department of Health and Social Security, the ministerial structure was as follows:-

HEALTH

(i) Secretary of State: Norman Fowler MP

(ii) Minister of State for Health: Kenneth Clarke QC MP

(iii) Parliamentary Under Secretary of State: John Patten MP

(iv) Joint (i.e. with Social Security responsibilities) Parliamentary Under Secretary of State: myself, Lord Glenarthur

SOCIAL SECURITY

(i) Secretary of State: Norman Fowler MP

(ii) Minister of State: Dr Rhodes Boyson MP, until 11 September 1984 when Tony Newton MP took over

(iii) Parliamentary Under Secretary of State: Tony Newton MP, until he was succeeded by Mr Raymond Whitney on Tony Newton's promotion

(iv) Joint (i.e. with Health responsibilities) Parliamentary Secretary of State: myself, Lord Glenarthur.

My roles as Parliamentary Secretary of State

2.3. My main policy areas of responsibility, allocated by the Secretary of State, were:

(i) <u>Mental Health (including the 4 Special Hospitals)</u>

This substantial topic required intensive briefing in order to understand: what constituted the term 'mental health', compared with 'mental handicap'; its treatment, and the move away from institutional treatment; the planned closure of the 'Epsom Cluster' of several very large mental

health hospitals and a gradual move towards 'care in the community'. During the time I was in office, it included work to finalise the structure and operation of the Mental Health Act Commission created by the Mental Health Act 1983.

The Special Hospitals had their own sensitive elements. Whatever the nature of the treatment and the patients' previous history, those sent there were 'patients undergoing treatment' and their release when deemed safe could sometimes lead to re-offending with serious results.

(ii) Mental handicap

As far as I can recall, my main role in this subject was the oversight of existing policies to ensure that facilities were available, staffed and funded under the Regional Health Authorities and Social Services, to give a decent quality of life to patients so afflicted, often very severely.

(iii) Hospital Scientific Services

From what I can recall, this involved understanding the needs for up-to-date scientific equipment required by hospitals for analysis of everything from blood parameters, medical devices, technological advance and speed of producing results.

(iv) Alternative Therapies

There was much interest shown in osteopathy, chiropractic, homeopathy and a range of other treatments which were deemed beneficial to patients but were not then adequately regulated so as to be approved by the Committee on the Professions Supplementary to Medicine. I believe we instigated independent assessment of their viability.

(v) The NHS Estate

My responsibilities included oversight of the entire NHS estate, including an understanding of the complexities of pre-NHS private interest in some NHS properties and how change of use, or sale of these properties by the NHS, could be achieved.

(vi) The Public Health Laboratory Service (PHLS)

The PHLS comprised a number of reference laboratories nationwide which protected the public against diseases and other health hazards. I had broad, general oversight. I believe it is now the Health Protection Agency.

(vii) The Centre for Applied Microbiological Research (CAMR)

This facility was at Porton Down where the DHSS had a research laboratory. A particular feature was the Fermentation Pilot Plant which had been running for several years, but was rapidly moving to the end of its useful and safe life. The team of scientists involved had teamed up with a private individual with a view to commercialising it. Discussion of the pros and cons of such a sale was one of my responsibilities and required many visits, meetings and papers.

(viii) Healthcare Exports

The British Healthcare Exports Council was the industry-wide group which sought to encourage the sale or provision abroad of the UK's healthcare industrial output, for the benefit of international healthcare facilities and UK industry.

(ix) Blood, Blood Products, the Blood Products Laboratory (BPL) and the Central Blood Laboratories Authority (CBLA)

I had delegated responsibility for these areas because they fell under the general umbrella of the PHLS. In practice, as I was the most junior

Minister in the Department, any matters of concern were also copied to the Minister of State for Health whose experience and seniority were considerably greater and who generally determined most of the financial matters. I was briefed as necessary by both policy officials and by clinical/ scientifically trained officials within the Department.

(x) The Warnock Report into Human Fertilisation and Embryology

I was asked to take on oversight of this in light of the report, not least because of debates in the House of Lords and the recommendations the report contained about potential legislation.

(xi) The Office of Population, Censuses and Surveys (OPCS)

I had a general oversight role, not least in preparation to represent the UK ministerially at the World Conference on Population in Mexico in August 1984.

(xii) War Pensions

General supervision of policy towards the War Pensions Committees which assessed need for disability payments etc. There was sensitivity as the number of Committees reduced as the number of, in particular, World War One pensioners died.

(xiii) National Insurance Contributions

My responsibilities included giving a degree of supervision to this subject as it affected Social Security policy, including introduction of the National Insurance Number card.

2.4. In the House of Lords, I was the lead spokesman on both Health and Social Security matters, and a spokesman also on Defence and Treasury, and I

assisted on the passage of several Bills from other departments. At times The Earl of Caithness (a Government Whip (Lord-in-Waiting) in the Lords) might respond on some of these issues, depending on my availability. As I recall, 1983 – 1985 was a busy legislative period for the DHSS as a whole. As a general indication, in the Health and Social Security arena, a significant number of Acts of Parliament were passed, a number of which I worked on personally: for further details please see [WITN5282003]. There was also work on the aftermath of the passage of the Mental Health Act 1983, centred on the formation of the Mental Health Act Commission.

2.5. I have set out the breadth of my responsibilities above. They were many and varied and they inevitably generated a good deal of work.

Committee Memberships

3.1. I have been asked to set out my membership (past or present) of, or my involvement (past or present) with, any committees, associations, parties, societies, groups or organisations relevant to the Inquiry's Terms of Reference, including the dates of membership and the nature of my involvement.

3.2. I have not been a member of or involved with any committees, associations, parties, societies, groups or organisations relevant to the Inquiry's Terms of Reference, other than as a Minister.

Business Interests

4.1. I have been asked to provide details of any business or private interests that I have or have had which are relevant to the Inquiry's Terms of Reference.

4.2. I have had no business or private interests relevant to the Inquiry's Terms of Reference.

Evidence to Previous Inquiries

5.1. I have been asked to confirm whether I have provided written or oral evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products.

5.2. I was not asked to give evidence to the Penrose Inquiry, but received a Warning Letter from that Inquiry indicating that I was likely to be criticised for the expression 'no conclusive proof' which I and other Ministers had used. The matter was handled by the Treasury Solicitor's Department, Litigation Group who wrote to the Penrose Inquiry on 23rd April 2014. My letter to the Penrose Inquiry is attached at [WITN5282004] and discussed at paragraph 25.10 below.

5.3. I have not provided, nor been asked to provide, any written or oral evidence to any inquiry, investigation, criminal or civil litigation in connection with HIV, HCV or vCJD other than in relation to that described above.

5.4. I was Chairman of St Mary's Hospital NHS Trust when vCJD arose; and was briefed in confidence about the prion by the Professor in the Medical School who discovered it.

Ministerial Responsibilities: Blood and Blood Products

6.1. I have been asked whether I had ministerial responsibility for blood products and the National Blood Transfusion service during my time as Parliamentary Under Secretary of State for Health and Social Security.

6.2. I have set out at paragraph 2.3 (ix) details of my delegated responsibilities and the context in which these operated. I was given the responsibility for blood and blood products, among many others, soon after joining the Department. My immediate predecessor in the House of Lords was Lord Trefgarne. I do not know whether he held the same portfolio of responsibilities as was given to me; I understand that responsibility for blood products lay with Mr Finsberg. I cannot now be sure, but I believe that the responsibility for blood and blood products

came under the more general heading of the Public Health Laboratory Service for which I had been given a ministerial oversight role.

6.3. The ultimate responsibility for decisions within the DHSS lay with the Secretary of State. The Minister of State for Health was the senior Minister dealing with all health issues and he delegated day-to-day involvement to junior Ministers. Routine matters, acting on clinical and scientific advice, were generally left to me. Some submissions, particularly in areas of complexity or controversy, were also copied to Minister of State for Health and to Mr Patten, the Parliamentary Under Secretary of State who handled business relating to my areas in the House of Commons. In addition, some were referred to the Secretary of State.

6.4. When matters arose in either House of Parliament, such as questions or debates, the Minister handling such matters would receive written and verbal briefing from officials, including a 'line to take' on topical matters. I would deal with debates and questions in the House of Lords, while either Mr Clarke or Mr Patten would be briefed to deal with debates and parliamentary questions in the House of Commons. When dealing with matters related to my portfolio, I believe I would have had sight of the briefings they received.

6.5. At no time did I feel that I had absolute 'autonomy', nor did I exercise it. If I had done so, against advice, other Ministers and officials would have been alerted. Examples of the interaction between Ministers can be seen in the body of this statement; see for example the role of the Minister of State for Health and Mr Patten in relation to the AIDS leaflet, or the Minister of State for Health's role in relation to financial matters.

6.6. Other Ministers were very alert to the public perception and political mood generated by decisions taken, and to any likely press comment.

6.7. Thus, in exercising these responsibilities I did not operate alone and collaborated, in particular, with the Minister of State for Health. There was considerable liaison between the Minister of State for Health and the two Parliamentary Under- Secretaries (although I was rather more isolated in the Lords, as the rules and conventions of the Palace of Westminster meant that MPs, including Ministers in the Commons, and peers including Ministers from the Lords, did not easily mix socially or informally, in the Palace). Despite this,

we had meetings to seek reassurance and to check that there was general consensus on policy.

6.8. As an example of this, I would refer to the meeting that took place between, I believe, myself, Mr Patten and Mr Clarke on 15 September 1983, on the subject of the response to AIDS. The date of the meeting appears from my personal diary, a copy of which I still have; the relevant extract is attached at [WITN5282005]. I cannot remember whether any officials also attended and there does not seem to be any record of the meeting. It was a meeting that I asked for, to seek reassurance from my ministerial colleagues that we were on the right track and were doing all that was possible to guard against the risks of AIDS in blood products, because of growing concerns. It took place a few days after my meeting with the Haemophilia Society on 8 September 1983 and this was fresh in my mind. The Society was adamant it wanted the imports of US Factor VIII to continue. As far as I can recall now, I wanted to discuss the policy options with my colleagues. Whilst I cannot recall the detail of the discussion, I emerged from the meeting with a degree of comfort from the experience of my colleagues and the sense that there were no viable alternatives to the policies being pursued. . This may not have been the only example of a meeting but it is one that I recall and is in my diary.

6.9. My work as a Parliamentary Under Secretary of State was carried out on the basis of information and briefings from officials. These were often in verbal form, following circulation of relevant papers for study.

6.10. I can recall that the first official who briefed me on blood issues was Dr Diana Walford, a haematologist by background, who provided clear, instructive advice on several occasions, both in print and in person. I believe that I asked for a briefing on this topic very shortly after taking up my post on 14 June 1983, initially because of the developing interest in AIDS and also because of a prospective Parliamentary Question I would answer in July 1983 (such questions could be laid by members of the House of Lords up to four weeks in advance). I believe Dr Walford was a senior principal medical officer in the Department.

6.11. As a non-scientist and non-clinician, I was entirely reliant on advice from officials, which was of the highest quality. I was always able to call for any additional advice in written form or at a meeting, if necessary. The names of other advisers will be apparent from the papers exhibited to this statement.

Decision-Making within the DHSS

7.1. I have been asked to describe my experience of how the decision-making process within the Department worked, including how, typically, decisions were requested of and taken by the Secretary of State and Ministers; the procedures within the Department for providing advice to the Secretary of State and Ministers; and the flow of information within the Departments between civil servants and the Secretary of State or Ministers.

7.2. Submissions were generated by officials for approval and any necessary decisions by Ministers. Equally, Ministers would request advice from officials. My recollection is that official submissions on routine matters of policy came to me first but were probably copied to the Minister of State for Health. Responsibility for blood matters also might also involve the Minister of State for Health as my more senior colleague depending on the circumstances. More complicated submissions were often copied to him or the Parliamentary Under Secretary of State so that they would be aware of, or could query, any view or decision I had taken; and would help provide background to any relevant matter arising in Parliament. Matters involving substantial cost (e.g. construction of the new Blood Products Laboratory), would have certainly been seen by the Secretary of State who would have to argue the case with Cabinet colleagues.

7.3. As a Minister, I also dealt with a substantial amount of ministerial correspondence. The Inquiry has referred to a few examples in its request for a witness statement, but there would usually be many tens of letters per week to be answered, dealing with the full range of topics for which I had ministerial responsibility. This correspondence was handled by the ministerial Correspondence Unit. Letters received would first be directed there and sent out by the Unit to relevant policy experts, in order to produce a draft reply. These suggested replies would be provided to me for signature. The letters

would be prepared and agreed at official level and passed to me in 'final' form for signature. I would read each draft reply carefully, conscious that my signature was being requested. If letters appeared coherent and logical, I would generally sign them. In certain cases, I would take a more hands-on approach to drafting the letter, for example where letters were being sent to tenacious colleagues.

Ministerial Responsibilities

8.1. I have been asked to describe the extent of my responsibilities and powers as Parliamentary Under Secretary of State for health policy and delivery in Scotland, Wales and Northern Ireland.

8.2. I do not recall detail in relation to my powers and responsibilities within DHSS, as regards Scotland, Wales and Northern Ireland. Nor do I recall any direct contact whilst a DHSS Minister with any of these. I believe I must have been aware of the AIDS leaflet produced in Scotland, before DHSS produced their own, but I cannot recall details.

The Administrations of Wales, Scotland and Northern Ireland

9.1. I have been asked to describe, from my experience as Parliamentary Under Secretary of State at the DHSS, the way in which I and the Department generally interacted with the Scottish Office, the Scottish Home and Health Department, the Welsh Office, and the Northern Ireland Office, and any other relevant government agencies and departments, on health policy in relation to the issues of concern to the Inquiry. In particular, I have been asked how much oversight, if any, the DHSS retained over health policy decisions made in respect of Scotland, Wales and Northern Ireland upon such matters.

9.2. So far as interaction between the Scottish Office, Scottish Home and Health, the Welsh Office and the Northern Ireland office were concerned, my understanding was that they broadly kept in parallel with DHSS thinking through expert committees. But I do not now recall attending any joint meetings of Ministers on any relevant issue and do not think that I can assist further.

10.1. I have been asked to identify by name any Secretaries of State, Ministers and civil servants from the Welsh Office, Scottish Office, the Scottish Home and Health Department, and Northern Ireland Office with whom I regularly liaised

on health policies, and the matters of interest to the Inquiry. I have been asked to identify any individuals from within this group upon whose advice I particularly relied or with whom I particularly liaised.

10.2. I do not believe that that on any occasion I liaised with any Secretaries of State, Ministers or civil servants from Scotland, Wales or Northern Ireland on matters related to blood. I cannot recall whether any submissions were copied to Ministers or officials in either direction.

11.1. I have been asked to describe any interactions I had, in my capacity as Parliamentary Under Secretary of State, with other health-related public bodies in Scotland, Wales and Northern Ireland, on blood-related matters.

11.2. I do not recall any other interactions I had, in my capacity as Parliamentary Under Secretary of State, with other health-related public bodies in Scotland, Wales or Northern Ireland.

Section 2: Knowledge of and response of risk of infection associated with blood products – AIDS

Knowledge of Risks in Spring/Summer 1983

12.1. I have been asked when it was first suggested to me, in my role as Parliamentary Under Secretary of State for Health and Social Security, that blood products in the UK might risk the transmission of AIDS.

12.2. As to this, a minute dated 22 June 1983 records that I had asked the CMO, at that time Sir Henry Yellowlees, for information on AIDS. As I have explained above, I asked for this briefing very shortly after taking up my post, on 14 June. I believe that it was probably prompted not only by the general concerns about AIDS at the time, but also knowledge that a Parliamentary Question (PQ) on the topic had been laid. This was the question that I answered on 14 July 1983, but PQs were generally laid about 3 weeks in advance (and the earliest a PQ could be laid was 4 weeks in advance).

12.3. In response, I was sent a paper prepared by Dr Walford which gave the background and up to date position. A copy is attached at [DHSC0002309_124]. The information that I was supplied with can be seen from that paper. I should add that the norm for oral questions and debates was also that I would be briefed orally by officials, usually the day before, and I believe that this too happened on this occasion, although I cannot remember any details of the briefing now. The briefing would normally take the form of a folder containing the PQ, the suggested reply, background to the subject, and likely supplementary questions which might be asked, with suitable replies.

12.4. I did not have much informal discussion with fellow Peers on this topic, although I may occasionally have been approached by them in the House of Lords.

12.5. At this stage, I was made aware that action to reduce the risks posed by US imports was being taken by work to ensure that imported products would conform to the standards laid down by the FDA in March 1983, as explained in Dr Walford's briefing paper. Plans were also afoot for securing our own self-sufficiency once the new facilities at BPL had been built and commissioned. Officials and all others concerned continued to work on the issues outlined in

Dr Walford's paper but at this point I was not asked to approve further specific steps.

13.1. The Inquiry has asked how my knowledge of the risk of transmission by blood products evolved over time.

13.2. The Inquiry will be able to trace the sequence of briefings to me throughout the course of 1983 and following, and the information on risks or hazards set out in these.

13.3. In very general terms, the early explanations to me suggested that the risk of transmission by blood products that might prove to contain the AIDS agent (which was not fully understood at this point) had to be set against the risk to haemophiliacs of not providing Factor VIII. Given this issue, there was no doubt in the papers provided to me that we had to continue to import Factor VIII from the US, and I was advised that reassurance was being obtained from US manufacturers that their products were of the post-March type and safer than earlier products. As far as I recall, the risk of blood products being contaminated were described to me as small.

13.4. On the matter of 'risk', I later became sufficiently concerned about the 'balance of risk' and our public statements, in Parliament and elsewhere, that I asked for a meeting with the Minister of State for Health, and the Parliamentary Under Secretary of Health, to be assured, or otherwise, that our actions were sound and defensible. That meeting was held on 15 September 1983 and I have already described it at paragraph 6.8 above. I accepted the view, as the other Ministers did, that the official advice represented the only reasonable course of action, even if it had difficult aspects in relation to risk. Given the invidious nature of the choices, we could be criticised whichever choice we took. Neither option was risk-free, and the Haemophilia Society (with whom I had met on 8 September 1983) was pressing for continued use of US imported products.

14.1. The Inquiry has asked further questions about the brief from Dr Walford sent to me on 22 June. I can confirm that I read it. I believe it was sent to me because I had asked for it, in light of the fact that: AIDS was a completely new condition to me; I had responsibility for blood; and it would be helpful background for the

subject being raised in the House of Lords. I had no earlier briefings on AIDS (having only been appointed a week earlier) to the best of my knowledge, and that brief can fairly be said to represent my state of knowledge at the time. I did not have any other official sources of knowledge at the time, although no doubt I would have kept abreast of newspaper articles and therefore public concerns on this issue.

14.2. As to the comments on the spread of AIDS in the briefing to the haemophiliac community, I understood that there was a risk of AIDS being transmitted through infected Factor VIII, but on the current state of knowledge the number of haemophiliacs in the USA being infected was not rising markedly (see the observations at the top of p2 of the briefing), and so the risk of using imported blood products was deemed acceptable. The briefing outlined the steps that were being taken to minimise the risk from these products.

14.3. My only other comment on the briefing is that Dr Walford always provided briefings in written and oral form of the highest quality and clarity.

15.1. The Inquiry has noted that this briefing from Dr Walford was subsequently provided to Mr Patten and has asked for details of his responsibilities. Mr Patten was responsible, as was the Minister of State for Health, for answering questions and debates on topics including blood and blood products in the House of Commons. It would be natural for Private Offices of other Ministers to be copied in on background material.

15.2. The involvement of Mr Patten did not imply any blurring of the lines of ministerial responsibility; there was none. But there was a general need for relevant Ministers to be kept informed, and as a new Minister I was always quite clear that, if I had doubts about any aspect of policy, I could seek advice from my ministerial colleagues, as I did on 15 September 1983.

The September 1983 donor leaflet

16.1. I have been asked to set out an account of my involvement in the production of a leaflet for blood donors on AIDS, to discourage high-risk groups from giving blood.

16.2. It is apparent that the topic was first raised with me on 1 July 1983 and I responded positively on 4 July 1983, agreeing with the proposal and the

contents of the proposed leaflet [DHSC0002309_025]. A similar response came from Mr Patten [DHSC0002309_027].

16.3. On 6 July 1983, I attended a meeting with Mr Clarke and officials including Dr Oliver (Senior Principal Medical Officer), to discuss the necessity of a leaflet and to agree how publicity surrounding it should be handled [DHSC0001511].

16.4. I myself was quite clear that such a leaflet was necessary. I was perhaps not as sensitive as were some of my ministerial colleagues to any concerns about upsetting the homosexual community, and the adverse press coverage that could ensue. My greatest concern was to minimise the risk of donors passing on infection. That there were sensitivities about potential 'discrimination' against homosexuals can be seen from the minute from the Home Office dated 8 July 1983, to Mr Parker [DHSC0002229_072]. I have no reason to think that I saw this particular letter at the time – it is at official level – but it illustrates the concerns that were 'live' at the time.

16.5. The IBI has noted that the minutes of the meeting of 6 July 1983 record that "the main objective was to minimise any damage to the transfusion service". The leaflet and the press release that would accompany its distribution in due course had slightly different, but complementary, objectives. The purpose of the leaflet was to discourage high-risk donors from giving blood. The purpose of the press release was to avoid alarmist publicity about the leaflet, which in turn could provoke an over-reaction and lead to a sudden drop in donations generally. That is how I understand the phrase "damage to the transfusion service". That this was a real risk can be seen from the minute of 26 August 1983 [DHSC0002309_034], referring to a shortage of blood in New York caused by alarmist publicity.

16.6. I do not think that I can comment further on the language of the minute, which was neither drafted nor approved by me.

16.7. The proposition that the damage to the transfusion service must be minimised was put forward by the Minister of State for Health, as far as I recall having seen the minute; and I was content to accept his anxieties. I was not concerned at the time that a press release emphasising that there had been only a small number of AIDS cases reported might undermine the wider purpose of the

leaflet. It was a fact that the number of AIDS cases was small. I further note that the press release that was ultimately used did not, in fact, refer to the numbers of those infected, see [DHSC0006401_006].

16.8. I have been asked whether a leaflet would have been published had it not been for a transfusion director "letting slip" that one was to be published. This did not make a difference. There was every intention to produce a leaflet, work on it had been done, and any 'letting slip' about the leaflet would not have changed the need.

16.9. I have further been asked about the discussion, at the meeting on 6 July, about the terms of my oral answer to a potential Parliamentary question on 14 July and whether the risks to haemophiliacs was "very small".

16.10. At the moment, the only trace of a written briefing before that Parliamentary answer was supplied by me is the earlier and general briefing on AIDS from Dr Walford dated 22 June 1983. But I am certain that I would in addition have received a thorough paper briefing in the usual format ("Question/ Suggested Answer/ Background/ Answers to likely supplementary questions"), although I understand that this document has not been found and has not been made available to me. I can see that I did receive an oral briefing the day before Baroness Dudley's PQ. This is indicated both in my personal diary, which records a briefing on AIDS with officials at 10:00 on 13 July [WITN5282006] and also in Dr Walford's follow-up note to Mr Joyce, in which she references "this morning's meeting" [DHSC0002229_114]. I cannot, however, remember any details now.

16.11. On 6 July 1983, I would surmise that the statement that the risk to haemophiliacs was very small would not have seemed to me to be inconsistent with the 22 June briefing. It represented the advice of experts in the subject (the meeting was attended by Dr Oliver), and I understood it to be factually correct. In the event, I did not actually use this language in Parliament on 14 July; see the Hansard record, [DHSC0002229_085].

16.12. I have been asked if I perceived, at the time, any tension between three propositions, namely:

(i) The statement that "*the risk to haemophiliacs was very small*" (taken by the Inquiry from the minutes of the 6 July 1983 meeting [DHSC0001511];

(ii) The observation that "*haemophiliacs are at particular risk of contracting the disease because Factor VIII concentrates are made from the pooled plasma of up to 5,000 donors*" (taken from the 1 July submission on the AIDS leaflet [DHSC0002309_121]);

(iii) The statement in the draft leaflet that AIDS could "almost certainly" be transmitted by blood products. In proper context, that section of the draft leaflet read: "*Can AIDS be transmitted via transfusion of blood and blood products? Almost certainly yes, but there is only the most remote chance of this happening with ordinary blood transfusions given in hospital*" [DHSC0002309_122].

16.13. I do not think I perceived a tension at the time. The risk was being expressly acknowledged but was deemed by medical experts to be very small. I was being briefed by experts to that effect and had no reason to query it. At the time, everyone was rapidly trying to understand what AIDS was; what caused it; and what to say about it without alarming the public unreasonably.

16.14. In the light of what we now know, I can see that there is a tension, yes. But contemporary views and knowledge are not the same as the knowledge we had at the time. At the time, I expect officials took some degree of comfort from the fact that there was only one reported case of a haemophiliac with AIDS in the UK and 10 or so cases out of an estimated 12,000 requiring treatment, in the USA.

17.1. I have been asked if I was aware of the views of the Secretary of State for Health, Mr Fowler, on the leaflet (as reported in a letter dated 6 July 1983 from Dr Bell of the Scottish Home and Health Department, PRSE0000049). I do not believe that I was aware of Mr Fowler's views. I believed the matter was being handled by the Minister of State for Health. It is not clear whether earlier minutes were copied to the Secretary of State (the submission of 1 July appears to have been copied to Mr Clarke and Mr Patten only). I have explained that I did not agree that the leaflet was too strong, but I would have accepted the Secretary of State's wisdom and that of the Minister of State for Health.

17.2. Any changes subsequently would have been in response to the concerns expressed by the Minister of State for Health, whose experience of publicity matters and press releases on sensitive subjects was far greater than mine. If I compare the draft version of the leaflet sent to Ministers on 1 July 1983 [DHSC0002309_122], the revised draft of 29 July 1983 [DHSC0002327_117] and the published version [BPLL0007247], as far as I can see the changes made were minor:

(i) Under the heading "Who is at risk from AIDS?" the figure for the number of patients diagnosed in the USA has been updated from 1,450 in the draft to 1,500 in the final version. The qualifier "up to the middle of 1983" has also been added;

(ii) Under the heading Under "Has AIDS occurred in the UK?": the draft stated "a few cases"; the final version stated "about a dozen cases" and again added the qualifier "by the middle of 1983";

(iii) Under the heading: "Can AIDS be transmitted by transfusion of blood and blood products?" the draft stated "about twelve" haemophiliac patients in the USA had developed AIDS; the final version stated "a very small number" of patients.

Distribution Arrangements

18.1. At the meeting of 6 July, I put forward the view that there should be consistency of approach in the distribution of the leaflet. I have now seen a series of correspondence on the topic of distribution, consisting of:

(i) A minute from Mr Parker to Dr Oliver dated 19 July 1983 [DHSC0002321_026]. Dr Parker stated that "If my memory serves me correctly, I understood MS(H) to say at the meeting with Lord Glenarthur that he would prefer some consistency with regards to the distribution of the leaflet but did not want it to be distributed with call-up cards. This was said against the background of need for a low-key approach…"

(ii) A reply from Dr Oliver to Mr Parker dated 20 July [DHSC0002321_027], which further addressed the merits of sending the leaflet out with call-up

cards, as opposed to making it available at donor sessions. He noted my preference for a consistent approach. He argued in favour of sending the leaflet with call-up cards. But he added that Ministers would have to be told that "our ability to influence the Regional Transfusion Directors is limited and many will do what they themselves think is in the best interests of their donors. At present a majority seems persuaded by the above arguments for notification with the call-up cards." (emphasis in original);

(iii) A further minute from Mr Bolitho to Dr Oliver dated 21 July (which again I would not have seen at the time) suggested that Dr Oliver's proposal was contrary to the view of Mr Clarke, at the meeting of 6 July [DHSC0002321_028];

(iv) Dr Oliver's reply to Mr Bolitho on 25 July 1983 [DHSC00002321_029]. He commented that "*I cannot accept that the leaflet should not be seen as a "as leaflet which you read and then change your mind about giving blood." To my mind that is precisely what is intended…*" He argued in favour of the points set out in his earlier minute and pointed out that they must be brought out in the ministerial submission. "On purely medical grounds I am convinced that sending out the leaflet with the call-up cards is the only sensible thing to do and indeed this is the independent advice we have received from our consultant advisor…"

18.2. As I have stated, I did not see this correspondence at the time.

18.3. In response to the specific questions asked by the Inquiry: I may have been aware in a general sense of the Minster of State for Health's wish to keep the leaflet 'low key', but I note that the minutes were not copied to my office and it is difficult to recall details. I believe I can recall a strong sense of concern about adverse publicity, as well as concern about donor embarrassment and a drop in blood donations. I have already referred to the subsequent minute about events in New York from Mr Clarke's office, dated 26 August (and copied to my office) which shows that these concerns were not fanciful [DHSC0002309_034].

18.4. Regarding my own views on distribution, I believe that I would have been keen for as wide a dissemination of the leaflets as possible in order to minimise risk of infected blood being donated.

18.5. I have further been asked whether I wished to keep distribution as "a very low-key operation". I think I would have argued against it, but I would have been sensitive to the Minister of State's views and experience in matters of publicity.

18.6. I have been asked whether I agreed with the view that the leaflet "*should not be seen as 'a leaflet which you read and then change your mind about giving blood'*". As I was not copied on in the minute, I was unaware of that sentiment or expression, nor can I realistically comment on whether it accurately reflected what the Minister of State for Health had actually said at the meeting. For my part, I would have disagreed with such a broad statement. The purpose of the leaflet was to encourage people from specific high-risk groups to change their mind, but without deterring donors generally as a whole.

Submission of 29 July 1983

19.1. After the meeting on 6 July, the following papers were sent to me:

(i) Submission about the Council of Europe's Recommendations; I replied on 22 July by noting that we should accept them and refer to the 'European' advice when Mr Clarke announced the publication of the leaflet (as Mr Clarke did in due course). See further paragraph 31 below;

(ii) A submission dated 29 July, which asked for ministerial approval of the arrangements for the printing, distribution and publication arrangements for the AIDS leaflet.

19.2. This submission stated that the leaflet had been revised to take account of the points made at the meeting of 6 July. I have covered this topic above.

19.3. With regards to distribution methods, the submission noted that a survey of Regional Transfusion Directors had been undertaken to determine their view. Opinion amongst Directors was divided and no one method seemed to fulfil the all the necessary criteria. There was a detailed discussion of the two main alternatives. The submission stated:

"... it is not immediately obvious which method is to be preferred. Indeed there is evidence that Directors' opinion were influenced by what they saw as being most appropriate in their Regions ... As Directors are responsible, under the Medicines Act, for the safety of the blood which they issue, due weight must, of course, be given to their clinical decisions in this matter."

19.4. The recommendation from officials was that:

"RTDs should be given a discretion to decide, for a trial 6 month period, the most effective means of distribution on their own Regions. Officials will be able to obtain regular feed-back information from Directors during this trial period."

19.5. I have been asked to comment on this submission of 29 July [PRSE0004171]. I understood that the concern that there would be "misinformed press publicity" was a concern that that there would be widespread, uninformed and sensationalist press coverage, and that blood donations would possibly be reduced. Specifically, the concern was that potential donors would be deterred by a fear of facing intrusive questioning about their sexual practices.

19.6. I have been asked for my opinion on the recommendation for a 6-month trial. I believe I felt that 6 months was too long and that RTC Directors, despite their clinical autonomy in this field, should speed things up. See my reaction to the submission, below.

19.7. The proposals set out in the submission were, broadly, accepted by Mr Clarke, Mr Patten and myself. I commented on 3 August, approving the draft of the leaflet and statement; asking if there was a publication date in mind, and who should deal with distribution. I noted that I favoured both means of distribution and the risk of embarrassment to donors was outweighed by the need to achieve wide distribution.

19.8. I refer the Inquiry to:

(i) my views, as recorded in Mr Joyce's minute of 29 July 1983 [DHSC0002327_120];

(ii) Mr Patten's views, as recorded in Ms Walden's minute [DHSC0002327_118];

(iii) Mr Clarke's views, as recorded in Mr Alcock's minutes [DHSC0002327_119] and [DHSC0002309_033].

20.1. I have been asked several questions about my response to the submission, given on 3 August 1983 [DHSC0002327_120]. In particular:

20.2. First, I have been asked why I favoured using both methods of distribution and why I considered that the risk of embarrassment to potential donors was outweighed by the need to achieve wide distribution. I believe that I would have felt that there was a developing urgency about the need to control the incipient spread of AIDS and that minimising the risk outweighed some of the concerns about sensitivity.

20.3. Second, I have also been asked for comment on how others responded to my proposal. I cannot recall the views of officials (and had not seen the correspondence summarised at paragraph 18 above), but I note that the Parliamentary Under-Secretary of State for Health broadly shared my view in his minute [DHSC0002327_118].

20.4. I have been asked about particular phrases in my response:

(i) As part of my response I noted: *"We may be at the tip of an iceberg with AIDS and find ourselves in trouble in 18 months' time unless we are really positive in our approach – even if it does embarrass a few "gay" people.* I have been asked why I said this. At this time, we did not know the cause of AIDS although certain clinical and scientific ideas were being postulated. There was growing public interest, if not a degree of alarm; and the overall uncertainty indicated to me that it would be wise to plan for the worst and not be too concerned about any embarrassment caused as a result. My comment about being at the "tip of an iceberg" was, I think, about AIDS generally, not specifically about blood products.

(ii) I have been asked whether at the time I thought that there was strong circumstantial evidence that AIDS could be transmitted by blood products. My recollection is that there was clear evidence that AIDS

could be transmitted by blood products, but that the risk appeared to be small.

(iii) By saying that we should be "really positive" in our approach, I meant that we should not be too diffident in alerting people to risks posed by a disease which was not fully understood. There was increasing concern in the press about AIDS; its causes and aetiology were uncertain, and I believed that we should consider being more assertive about what we knew of the disease, its likely causes and how to minimise it.

(iv) Finally, I have been asked to provide any further comment based on Mr Patten's position (recorded in DHSC0002327_118) and Mr Clarke's position (recorded in DHSC0002327_119 and DHSC0002309_033). I believe that the Minister of State for Health's concerns were beginning to be overcome in relation to distribution and earlier sensitivities. Mr Patten was keen to press on with the printing and distribution "as soon as possible" and he suggested that regional directors should trial both methods of distribution (DHSC0002327_118). Mr Clarke also approved and suggested we keep the issue of distribution under review. He asked for press queries to be dealt with by the Department, not by regional directors (DHSC0002327_119). He also expressed his preference for handling any press interviews personally (DHSC0002309_033). All of this is apparent from the correspondence and I do not think I can add to that.

21.1. A note dated 26 August from Mr Naysmith of Mr Clarke's Private Office (copied to my office) refers to Mr Clarke's concerns that advance press coverage had been alarmist, with headlines such as "Docs Ban Gays' Blood" etc. There was a report that similar alarmist action (i.e., presumably, alarmist publicity) caused a shortage of blood in New York. Mr Clarke also raised the issue of distribution again, due to the range of views from Directors and the possibility for "a fuss and a scare" if different methods were used in different parts of the country. The Minister asked for advice on whether he could insist on one national method.

21.2. I can see from a minute from Mr Naysmith (PS/Mr Clarke) that a meeting between myself and Mr Clarke apparently took place on 30 August. I find this reference to a meeting puzzling. I have been asked about what I can recall about it, but I cannot specifically recall a meeting. Having checked my personal diary for 1983, it shows that I was at a social event in Scotland on Monday 29 August (a bank holiday) and booked on a 15.20 flight to London on the following day, Tuesday 30 August: [WITN5282007]. It is difficult to see where a meeting would have fitted in.

21.3. In any event, the minute confirmed that the leaflets were ready for distribution. Mr Naysmith referred back to Mr Clarke's views in early August when he had been content to allow the RTCs discretion for a six-month trial period. Mr Clarke had confirmed that he was content to maintain that approach, "subject to any last-minute views which Lord Glenarthur may have". Mr Naysmith asked for my views to be secured.

21.4. There is a further note from Mr Naysmith also dated 31 August which went to my office, covering much the same ground [DHSC0002309_035]. I responded to this on 1 September, suggesting a trial period of three rather than six months. Mr Ghagan (in my Private Office) recorded that Mr Clarke had agreed to this.[DHSC0002309_036]

21.5. In response to the specific questions asked of me, I proposed shortening the trial period from 6 to 3 months because I could see no reason why a 6-month trial would be necessary, and the apparent degree of urgency over-rode the need for an extended trial.

21.6. As stated above, the proposal to shorten the trial period to 3 months was agreed by others and was implemented at official level. I exhibit to this witness statement [WITN5282008] a note prepared by my legal advisors which summarises contemporaneous documents and sets out actions taken, at an official level. I do not remember knowing about this, at the time, because I was not involved at this level of detail. But, assuming the note is accurate, then it appears the 3-month proposal was implemented.

21.7. I agreed that leaving Regional Transfusion Directors to decide on the methods of distribution was the preferred solution.

22.1. I have been asked if I played any further part in the arrangements for the publication, etc. of the leaflet. I do not recall any further action being taken by me.

23.1. The Inquiry has noted that work on a draft leaflet begun in May 1983. A draft leaflet was submitted to Ministers on 1 July 1983 and it was published on 1 September 1983.

23.2. I have been asked if I find the length of time that it took for the pamphlet to be published surprising. As to this, this was the first leaflet publication in my time as a Minister with which I was involved. Yes, I do find it surprising that it was to take so long, but perhaps I was naïve about the sensitivities of such publications, which other Ministers had more experience of than me.

23.3. As to why it took that long:

(i) I was not aware at the time of the process that was followed before the draft leaflet was sent to me for the first time on 1 July. The brief from Dr Walford (22 June) referred to a leaflet having been prepared by the Regional Blood Transfusion Directors (the RTDs); it seems to have taken some time to move from a leaflet being circulated amongst the RTDs to one being presented to Ministers.

(ii) There were concerns about detailed drafting, costs and methods of distribution when the leaflets were distributed. The views of the RTDs were sought. The draft leaflet was resubmitted to Ministers on 29 July, approved by them by 3 August and printed within the month, by 1 September. There is a reference in the note of 5 August 1983 that printing would take 3 weeks: [DHSC0002309_033]. Whilst I would have preferred things to progress even faster, we had been able to complete the process relatively swiftly.

23.4. I have been asked whether I had any concerns at the time, in 1983, about the length of time that it was taking for the pamphlet to be published. The answer is that yes, I did, and I think my minutes at the time reflected this. See for example my minute of 3 August, where I was asking about publication arrangements and voicing the need for positive action.

23.5. Looking at the matter now and with hindsight, I do have concerns about the length of time it took to publish the leaflet. But I was not autonomous in this field.

The contents of the AIDS leaflet

24.1. I have been asked to comment on the leaflet that was issued [BPLL0007247].

24.2. The first issue raised is whether the leaflet "could have made it clearer that blood products made from blood donated in the USA were commonly given to patients in the UK and carried a risk of transmitting AIDS". Respectfully, that was not the purpose of the leaflet – it was a leaflet addressed to UK blood *donors*, not the *recipients* of blood products.

24.3. I have also been asked whether the leaflet would have been more effective had it been phrased or distributed in a different way. Regarding the wording, it was drawn up and agreed between medical experts, the Information Division (which advised on publicity materials). Ministers would suggest amendments, perhaps even insist on them; and the draft would go back to officials for further comment. This is what we did in the case of the leaflet, and the leaflet was the product of all these many forms of input. Regarding the distribution and whether other methods might have been more effective, this was within the remit of the RTCs (and we were reminded of their clinical responsibility for the blood service). But we decided to exercise a supervisory role, hence the decision to keep it under a review on a 3-month trial basis.

'No conclusive Proof'

25.1. I have been asked about the phrase "no conclusive proof", as used by me or other Ministers in statements such as:-

(i) Hansard, July 14 1983 [DHSC0002229_085];

(ii) A letter to Clive Jenkins dated 26 August 1983 [DHSC0002331_036];

(iii) My letter to Baroness Masham dated 30 August [DHSC0002231_037];

(iv) The DHSS press release issued by Mr Clarke, accompanying the publication of the donor leaflet of 1 September 1983 [DHSC0006401_006];

(v) My letter to John Maples MP dated 16 December 1983 [ARCH0000679].

25.2. I have been asked who formulated the phrase, on the basis of what evidence and what I understood it to mean.

25.3. I have been informed that the phrase "no conclusive proof" was used in the documents circulated with a minute from Mr Parker dated 3 May 1983 [DHSC0001651]. This was before my time in office and I did not see this document at the time, but I have recently been shown a copy. It circulated a "line to take" that had been sent to the Prime Minister's Office, together with a background note written in supplementary question and answer form; all of these had, I gather, been sent for PMQs on 3 May.

25.4. The "Line to Take" stated that it was important to put public anxiety into perspective: "*there is as yet no conclusive proof that AIDS has been transmitted from 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*". The underlying Question and Answer document stated that *"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 3 in Spain ...."* [DHSC0003824_173].

25.5. The covering letter from Mr Parker proposed that the line could be reviewed once Mr Finsberg (the previous Minister with responsibility) had met the Haemophilia Society, as had been suggested. It noted that: *"Meanwhile, there seems to be little to be gained from Ministers issuing statements about a matter which has been sensationalised and, in some cases, distorted by the media and on which, with the present state of knowledge, there is no immediate action which Ministers could be advised to take".*

25.6. I would anticipate that I would have been supplied with documents in a similar format as part of the preparation for answering the PQ asked by Baroness

Dudley on 14 July 1983, and I would also have gone over the contents of it carefully with officials on the morning of 13 July. Some indication of how the briefing process worked can be seen from the note from Dr Walford dated 13 July; I had obviously asked for information on the meaning of "international units" of Factor VIII [DHSC0002229_114]. However, as I pointed out at the beginning of this statement, these documents do not seem to be available now. As a result, it is not only impossible see what information I was given, but also very difficult to recall exactly how I reacted.

25.7. Doing the best I can now, as far as I was concerned, the language represented a standard 'line to take' which I understood had been considered by officials on the basis of the clinical and scientific evidence and accepted by Ministers.

25.8. I understood the expression "no conclusive proof" to mean that there was some evidence, but, since the aetiology of AIDS was not fully understood, the evidence could not be put beyond doubt. I believe that I asked for assurance that this was a defensible line to take but do not recall detail of the discussion, other than that I accepted the advice of clinical and lay officials. For example, it is likely that I would have tested officials on this phrase when I was briefed in advance of the PQ on 14 July (see above) and I must have been sufficiently reassured that it was appropriate to use. But it is difficult for me to state, now, exactly what information was given to me at the time.

25.9. When I used the expression when (for example) answering Parliamentary Questions on 14 July 1983, I did not mention all the scientific evidence underlying the judgements made because it was not the appropriate forum for debating detailed scientific evidence. My role was to present a concise summary of the Government's position and the official advice. It may be worth explaining that, at the time, the Parliamentary format allowed for four questions to be laid and to be answered in the space of about twenty minutes. Brevity was required. Furthermore, on 14 July as a newly-appointed junior Minister, the reality is that I would not have deviated in the House of Lords from the suggested answer given to me by officials and agreed after discussion.

25.10. As I noted in the letter written on my behalf to Lord Penrose on this topic [WITN5282004], the statement that there was "no conclusive proof" was

generally balanced by a statement about what the DHSS was doing to minimise risks, and reference to "*possible risk*" or risks. I stand by what is said in that letter to Lord Penrose, including that it is important to bear in mind the context in which the phrase was used and the audience. Thus:

(i) In the debate on 14 July, I stated: "*Although there is no conclusive proof that AIDS is transmitted by blood or blood products, the department is considering the publication of a leaflet indicating the circumstances in which blood donations should be avoided.*" I set out details of the steps being taken, and also highlighted that there was no cure. As I stated at p.2 of the letter to Lord Penrose: "*Consideration of the context of the use of the expression 'no conclusive evidence' here shows that it was not likely to be misinterpreted or give a false sense of security given that further steps were being taken (in this case a leaflet about blood donations) to reduce the risk of possible transmission of AIDS by blood or blood products*";

(ii) The letter to Clive Jenkins dated 26 August 1983 stated that, first, "*there is no conclusive proof that AIDS is transmitted through blood products.*" But it continued: "*Nevertheless we are taking all practicable measures to reduce any possible risks to recipients of blood and blood products. Our scope for action in this is limited, as there is no means of testing for the presence of AIDS….*". It set out details of the leaflet and the issues related to the FDA Regulations. Again, as I stated at p.2 of the letter to Lord Penrose: "*when considering what is said as a whole, the expression of 'no conclusive evidence' was not likely to be misinterpreted or give a false sense of security given the further steps being taken to address and reduce the risk.*"

(iii) The letter to Baroness Masham, which followed on from the debate on 14 July, contained a detailed explanation of the issues, including in relation to the attitude of the Haemophilia Society: *"they accepted that the possible risks of infection from AIDS must be balanced against the obvious risk of not having enough Factor VIII."*

(iv) The DHSS press release of 1 September quoted Mr Clarke as stating, after referring to "no conclusive proof", *"Nevertheless I can well appreciate the concern that the suggestion may cause. We must continue to minimise any possible risk of transmission of the disease by blood donation …."*

(v) The letter to John Maples MP of 16 December 1983 [ARCH0000679] refers to "no conclusive proof", but then highlights the steps being taken to mitigate the risk of AIDS transmission. In the US, this entailed the introduction of stricter regulations by the Food and Drug Administration. In relation to the UK, there was explicit recognition of the need to *"minimise the possible risk"* of transmission of AIDS by blood donation and an explanation of what was being done, via the leaflet discouraging donors from high-risk groups.

25.11. I have been asked about my understanding of the degree of risk. I understood that there was a degree of risk, but that this degree was judged by clinical advisors to be acceptable at this stage in our understanding of AIDS (and was recommended as such to Ministers), and there was a need to maintain adequate supplies of US made Factor VIII, given the absence of alternative supplies.

25.12. I have further been asked if there was a tension between the statement that there was "no conclusive proof" of transmission of AIDS by blood or blood products, and other evidence of risk to haemophiliacs from blood products, or risks from blood. I accept there was a tension. But my understanding would have been that the wording of all statements about risk in this case was carefully considered by both scientific/clinical and policy officials in DHSS. They were the experts, helpfully providing advice to Ministers who did not have the necessary detailed knowledge. To reiterate, we never denied the risk of transmission, but acknowledged its possibility. We had to balance it against the counter-risk of serious injury to haemophiliacs who would suffer from not being able to accept treatment with blood products. That counter-risk is well-documented and included joint damage, intracranial haemorrhage and death. There was a fine line to be drawn on the acceptability of a degree of risk to

recipients of imported Factor VIII; and the absolute risk to those haemophiliacs who required Factor VIII.

25.13. These matters were not taken lightly by me but were taken very seriously as I could appreciate the risks. I have already explained how, for example, I asked for a meeting with my colleagues on 15 September 1983, in which I talked through the steps that were being taken and checked that there was nothing more that could or should be done. I believed the line we were taking was appropriate.

Reply to Baroness Masham, 30 August

26.1. I have been asked a series of questions about the drafting process followed to produce the letter to Baroness Masham of 30 August [DHSC0002231_037]. Dr Walford's briefing to Mr Parker (20 July) had included the sentence: "*There is no conclusive proof that AIDS can be transmitted by blood, cryoprecipitate of Factor VIII concentrates but the assumption is that such transmission may be possible*" [DHSC0002491_013] (underlining added). I have been asked why my letter omitted the underlined words.

26.2. The history in the various papers now sent to me for this Statement suggests that:

(i) On 14 July Baroness Masham asked me why we had to import blood products and whether there was a concern that AIDS could be transmitted "through anti-haemophiliac cryoprecipitate". I responded to the first part of the question and undertook to look into the second part and respond in due course [DHSC0002229_085].

(ii) Following up on this exchange, on 19 July Mr Joyce of my Private Office sent a note to Mr Parker asking him to address the issue of possible transmission through Factor VIII [DHSC0002229_096]

(iii) It is apparent that Mr Parker asked for medical input, since on 20 July Dr Walford sent Mr Parker her note [DHSC0002491_013]. It included two paragraphs in quotation marks: the first explaining how Factor VIII was derived from cryoprecipitate; the second addressing the risk of AIDS

transmission by blood, cryoprecipitate or Factor VIII concentrates. It stated that "*There is no conclusive proof that AIDS can be transmitted by blood, cryoprecipitate or Factor VIII concentrates but the assumption is that such transmission may be possible.*"

(iv) By a minute dated 26 July, Mr Parker provided my office with a first draft of a response to Baroness Masham [DHSC0002309_032]. He included what was said to be "a background note" from Dr Walford, but this included only the first of Dr Walford's paragraphs and not the second.

(v) As the suggested answer was quite short, by a minute dated 23 August, I asked for further detail to be provided, about the Medical Research Council working party on AIDS and about cryoprecipitate [DHSC0001406_001];

(vi) On 26 August, Mr Winstanley sent a revised draft to my office [DHSC0001405]. This included further information on cryoprecipitate and Factor VIII, including from the USA, but did not change the use made of Dr Walford's information.

26.3. I was not aware of the existence of the second paragraph that appears in quotation marks in Dr Walford's minute. I can only assume that the wording was edited on the advice of other officials.

26.4. I believe that including the underlined words would have been a helpful clarification and was in line with what had been written in the leaflet. But it was a change in the agreed standard line taken, and it appears that other officials did not feel that they should have been included. Had I been aware of the suggested additional words, I would have argued for their inclusion.

Correspondence with Mr Jenkins

27.1. I have been referred to my correspondence with Mr Jenkins, General Secretary of Association of Scientific, Technical and Managerial Staff (the ASTMS). From the documents, I can see the chain is as follows: on 7 July 1983 Mr Jenkins wrote to Lord Trefgarne (this is a letter referred to in the correspondence, but no copy has been provided to me); on 26 August I responded to Mr Jenkins

[DHSC0002231_036]; on 27 October 1983, Mr Jenkins replied to me [DHSC0002235_041, received 7 November]; and on 5 January 1984 I responded to Mr Jenkins [PRSE0001727].

27.2. I have been asked about Mr Jenkins' letter of 27 October, in particular the second paragraph. I am asked when I first became aware of the evidence referenced therein and whether it caused me to question or qualify the "no conclusive proof" phrase. I would not have seen the letter itself until it was sent with the suggested reply, presumably in early January 1985 since my reply was sent out on 5 January 1985. I do not recall being made aware of the detailed situation in Europe, nor of the paper to the meeting of the Advisory Committee on Dangerous Pathogens (ACDP/83/P9) (referenced at paragraph 2 of his letter) [WITN5282009]

27.3. I have been asked what steps I took to verify the evidence for the statements made. The draft reply to Mr Jenkins' letter was provided by officials for me to consider and sign. Whatever was the detail of ACDP/83/P9, which is not referred to in my reply, the 'strong circumstantial evidence…..' indicates to me that it paralleled the term 'no conclusive proof/evidence'. My response was an attempt to engage in detail with Mr Jenkins' arguments. This was the point made at paragraph 2 of my response. I do not recall taking any action personally, but I would have expected officials to examine the different terms used and the findings of ACDP/83/P9 and to advise me if there was evidence of a real conflict or cause for concern. This was the normal process within Government.

27.4. I have been asked why, given that my letter of 5 January 1984 accepted that there was strong circumstantial evidence for the transmission of AIDS through blood products, I used the "no conclusive proof" phrase, without qualification, in my earlier letter of 16 December to John Maples MP [ARCH0000679]. As I have explained, I would not have seen the October letter from Mr Jenkins until it came to me with the suggested answer in early January 1985 (or thereabouts). In December 1984, I used the phrase without qualification at a time when – as far as I can recall – I had not been advised or involved in discussions on the phrase "strong circumstantial evidence". I did so because on the basis of the suggested draft reply, I understood that this was still the

appropriate formulation. I have already commented how the phrase 'no conclusive evidence' was balanced by an account of what was being done to guard against possible risks.

Cessation of the Use of 'No Conclusive Proof'

28.1. I have been asked if I know when, why and on whose authority the "no conclusive proof" line was dropped. I do not know when it was dropped, but assume that this was on advice among officials as the phrase was no longer apt.

28.2. My attention has been drawn to a newspaper article from the Sunday Times dated 25 March 1984 [PRSE0001580] which refers to two patients who developed AIDS after blood transfusions. It states "The suspicion that the blood was to blame has now become proof". There is a handwritten note, dated 26 March, which I am told appears on the reverse of a photocopy of the article [DHSC0002239_089]. This was written by an official whose name is difficult to decipher, and is addressed to three other officials (Mr Williams, Dr Smithies and Mrs Creagh). It states: "*We dropped 'there is no conclusive proof that AIDS is transmitted through our blood or blood products" from our standard line some time ago."*

28.3. I would not have seen this informal note at the time and do not recollect any briefing on the topic. My expectation is that a change in the line should have been drawn to Ministers' attention in any briefing when relating to the use of the altered line, so that Ministers would be clear about the appropriate line to be used.

29.1. I have been asked to reflect on the use of the phrase "no conclusive proof".

29.2. From what I can recall, the phrase was very seriously considered at the time. There was much that was unknown in relation to the aetiology of AIDS and about the totality of the risk to haemophilia patients from imported Factor VIII. What was certain, however, was that haemophiliacs were in peril from unavailability of Factor VIII if foreign imports were stopped; the risk to them, though uncertain but possible, from imported Factor VIII, on balance had to be accepted. At the time the phrase was first used, I believe that it neither assisted

nor hampered public or patient understanding of the risk posed by blood and blood products, but was more a reflection of the uncertainty at the time.

The approach to the importation and use of plasma products

30.1. I have been shown a copy of a letter and short paper from Dr Galbraith dated 9 May 1983 [CBLA0000043_040], in which he recommends that *"all blood products made from blood donated in the USA after 1978 should be withdrawn from us until the risk of AIDS transmission by these products has been clarified."*

30.2. I do not believe that I saw Dr Galbraith's letter or paper at the time. Dr Walford's response to it in [DHSC0002227_047] (also not seen) is exactly what I would have expected her response to be from the knowledge I had and had received from briefings by officials.

30.3. That said, it would have been helpful to have seen Dr Galbraith's letter. Had I seen it, I would have asked for a briefing and assurance that these views had been properly considered by medical experts.

Council of Europe Recommendations

31.1. The Inquiry has further referred to the Council of Europe's Recommendation R(83)8, "on preventing the possible transmission of Acquired Immune Deficiency Syndrome (AIDS) from affected blood donors to patients receiving blood or blood products" [MACK0000307].

31.2. This Recommendation, with a covering Minute, was sent to my office in July 1982 by Mr Cumming [DHSC0002309_086]. The exact date when it was sent is not clear from the submission but I see that I replied, via my Private Office, on 22 July 1983. The minute noted the Council's recommendations and referred to an information leaflet for blood donors used by the American Red Cross. It was stated that it did not prevent the UK from continuing to import Factor VIII products from the USA, on which we relied for about 50% of our supply. There was no suggestion that specific actions were needed in response or that the UK's response was falling short of the standards recommended.

31.3. I replied to this information on 22 July [DHSC0002309_029] saying that I was in favour of accepting the European Recommendation and that it might be referred to when announcing the publication of our own leaflet to donors.

31.4. I do not recall taking any further personal action. As I have noted, the covering minute did not suggest that there were areas in which the UK was failing to meet the standards of the Recommendation. In particular:

(i) Whilst the UK remained reliant for 50% of its coagulation factors on foreign imports, the European Recommendation did not prevent these imports;

(ii) I am certain that any recommendations on avoiding products from "large plasma pools" would have been fully considered by officials including medical advisors. I do not believe that I would have taken direct action myself;

(iii) The same applies to information to be supplied to practitioners and patients such as haemophiliacs. It is difficult to remember what I would have been told, or known, about the information available. But I note that the my letter to Baroness Masham, for example, stated: *"We have been looking very carefully at our position on this matter and our medical advisors consider that the publications which have already appeared in the medical press provide sufficient and adequate guidance about this diseases for practitioners."* Equally, I cannot remember any suggestion by the Haemophilia Society, when I met with its representatives on 8 September 1983, that information for patients was lacking.

(iv) In relating to providing information to blood donors, we were already preparing an information leaflet to cover this suggestion and I made this link in my response to the submission to my Private Office.

31.5. I have been further asked about my reaction to Mr Cumming's covering minute. As set out above, it was copied to my Private Office and I can see from the documentary record that I responded to it, but I do not now recall it. As for the statement in the submission that "on the basis of present knowledge" it was assumed that AIDS was transmissible by blood, I shared the assumption and it

was the basis of the steps being taken to lower the risks so far as possible; but we remained uncertain about the degree of associated risk.

31.6. I have been asked whether the minute or the Recommendation changed my understanding of the risks to NHS patients, from the transmission of AIDS by blood or blood products. As far as I can recall, it did not; my understanding remained the same.

31.7. I do not recall any discussions with other Ministers or the CMO about the Council of Europe Recommendations. I was very unfamiliar with Council of Europe Recommendations. I have referred to the way in which they were brought to the attention of my Office, but I do not recall being briefed specifically on their importance or on any action to be taken on them.

World Federation of Haemophilia

32.1. I have been asked whether I was made aware of the "Resolutions by the World Federation of Haemophilia General Assembly regarding Acquired Immune Deficiency Syndrome (AIDS) 29 June 1983" [PRSE0001351]; and if so, whether they influenced my views or DHSS policy.

32.2. I do not recall being made aware of these Resolutions and would have expected them to be studied by my officials. I note (now) that Recommendation 1 was as follows: *"1) There is insufficient evidence to recommend at the present, any change in treatment; therefore present treatment, of haemophilia should continue with whatever blood products are available, according to the judgement of the individual physician."* I also note that it set out the ways in which US commercial producers of concentrate had taken steps to eliminate members of high-risk groups. I would have taken comfort from this, if I had seen it at the time.

32.3. I am not aware of what contact there was with the World Federation of Haemophilia. If there was any, it would have been handled at official level.

The Biological Sub-Committee of the Committee on the Safety of Medicines

33.1. I have been asked questions about a special meeting convened on 13th July 1983 of the Biological Sub-Committee of the Committee on the Safety of Medicines. From the documents I have been shown, it is apparent that the committee discussed various matters relating to the risk and benefits of the continued use of blood products within the UK, and the continued import of US Factor VIII products. I have been referred to the following documents: ARCH0001710; DHSC0003618_147; DHSC0001209; DHSC0002229_059.

33.2. I am asked if I had any knowledge or involvement in the intention to discuss these matters at a meeting on 13th July 1983, and whether I would have expected to be informed of these types of discussions in view of my responsibilities in this area of policy.

33.3. So far as I am aware, the documents referred to were not seen by me at the time. But their contents seem entirely consistent with the advice being given to Ministers. Namely, the sub-committee expressly considered the possibility of withdrawing US blood products, but rejected this on two grounds: (1) it was unfeasible on grounds of supply; (2) it was unjustified on grounds of the perceived risk of transmission, as understood at the time [DHSC0001208 at numbered point (4) of the conclusions]. I would only expect to have been informed if conclusions and recommendations were likely to have led to a change in overall policy.

33.4. I did not have any involvement in influencing or shaping the conclusions of the Sub-Committee. So far as I can recall, I was not informed of their conclusions. I have explained that I would only expect to have been informed if conclusions and recommendations were likely to have led to a change in overall policy. Otherwise, the matter was being handled at an official level.

33.5. However, that said, the documents seem to indicate a growing awareness of the substantial difficulties and uncertainties in this area, and I am surprised that a submission was not made to Ministers condensing the papers and summarising the discussion of this largely technical but possibly risky outcome, at least for information, even if this was a matter of medicines licensing.

34.1. I have further been asked what briefings or submissions were supplied on the following specific subjects over the period mid-1982 and into 1984.

(i) *Whether blood products made from pooled plasma should be withdrawn from NHS use, and whether patients should be treated with cryoprecipitate instead:* I do not recall any submissions being made on this topic, although it is evident from the papers seen that officials had considered the removal of imported pooled products, and ruled it out.

(ii) Whether blood products made from pooled plasma by companies outside the UK should be excluded from the UK. I repeat my answer as in (i) above.

(iii) *Whether blood products manufactured in the United States using plasma collected before the FDA introduced new regulations in March 1983 should be excluded from the UK.* I repeat my answer as in (i) above.

(iv) The steps that could be taken to reduce the risk of infected donors giving blood within the UK. I was aware of the preparation of a leaflet for donors to achieve this purpose.

(v) Any other steps that could be taken to reduce the risk of patients becoming infected with AIDS through the use of blood and blood products. Other than the leaflet, and no doubt consideration by medical and other experts within the DHSS and more widely, I was not made specifically aware.

34.2. Overall, I do not recall receiving such briefings or submissions, other than the policy on maintaining importation of US blood products remained current, and that we relied on these imports. That said, I refer to my statement at paragraphs 0.12 and 0.16 above; there are a number of missing briefings, in particular, which mean that I cannot be confident about exactly what I was told about policies, including the level of detail conveyed.

35.1. I have been asked whether in hindsight I consider that I should have received more briefings than I actually did. I would not have expected to have been involved in every detail. There was a substantial pool of expertise within the Department and external to it, who would have made the necessary analysis. I

would only have expected to have been more closely involved had there been recommended a substantial change in policy.

35.2. Having now read the documents, I feel that it would have been helpful for me and other Ministers to have been kept more informed about some of the more general difficult options with which officials were rationalising and in respect of which there seems to have been growing concern and uncertainty. It might have been helpful to have received a condensed submission for ministerial consideration and endorsement or otherwise; and the possibility of exploring any alternative strategies. However, many of these intractable matters were for clinicians, scientists and others with deep technical knowledge to debate and to bring forward proposals in a readily digestible form.

Importation of United States Blood Products

36.1. The Inquiry has noted that the United Kingdom continued to allow the importation of blood products manufactured from pooled plasma from the United States. I have been asked several questions:

(i) *My personal role in formulating and deciding this policy:* It was extant policy, drawn up by officials with no realistic alternative; I accepted the policy, despite the unsatisfactory nature of the choices being offered.

(ii) *If not involved in formulating or deciding this policy, why this was and whether I think I should have been:* I and other Ministers were advised by clinical and policy experts. I would have expected them to assess the merits of the policy or suggested course of action and, in particular, to advise me of any viable alternatives.

(iii) *The information that I was provided with about this matter, any submissions that were made to me, and any decisions that I took in respect of it:* I received briefings as necessary, and any alterations to the existing policy which required Minister's approval would have come to me.

(iv) *Insofar as it is within my knowledge, how this policy came to be formulated, and the reasons for it.* We were unable to produce sufficient

coagulation factors, had been reliant on imports from the US for some 50% of our need and would remain so until the BPL had been adapted to meet UK demand.

(v) *Whether I agreed with this policy*: I did. There seemed no practical alternative, other than to suddenly imperil the lives of haemophiliac patients. These were complex clinical, medical and scientific matters. Ministers did not have the qualifications to gainsay the experts, and were wholly reliant on expert advice, although they might challenge expert views in discussion.

FDA Regulations and Post-March 1983 US Products

37.1. I have been referred to my letter to Mr Jenkins dated 26 August 1983 [DHSC0002231_036], in which I stated that the Government would adopt the same position as the US Food and Drug Administration by allowing the continued use of blood products manufactured from plasma collected prior to March 1983. I have set out the full chain of correspondence between myself and Mr Jenkins at paragraph 27.1 above, noting that the first letter from Mr Jenkins dated 7 July is missing.

37.2. In response to specific questions:

37.3. This was current policy, based on the fact that, without continued use of pre-March plasma, there would have been a crisis of supply. I did not have any personal involvement in formulating this policy. It appears to have followed from the recommendation of the CSM-B (subsequently endorsed by the CSM) without being put directly to Ministers for decision or approval.

37.4. As regards the reasons for the policy, my understanding, as identified elsewhere, was that there was insufficient UK derived Factor VIII to satisfy the clinical needs of haemophiliac patients, and that the reliance on US imported material would be necessary until we were able to produce our own in sufficient quantities.

37.5. I did agree with the policy. There seemed no viable alternative and the balance of risk (as I now know, discussed and agreed by expert bodies such as the CSM-B at the time), was in favour of continuing the supply of US products.

38.1. I have been further asked about Mr Jenkins' concerns about the risks of paid donors ignoring FDA regulations and of companies "dumping" pre-March 1983 plasma on the UK, as expressed in his letter of 27 October 1983 [DHSC0002235_041].

38.2. I replied to his letter on 5 January 1984 [PRSE0001727]. As far as I can recall, my officials did not believe that 'dumping' of pre-March stock was likely; but that pre-March stock already in the UK could continue to be used to prevent a crisis in supply. My response to Mr Jenkins in answer to his paragraph 4 points out the balance of risk. The UK decision was in line with that of the US regulatory authorities, as I had previously pointed out. I have also noted that it seems that precautions to ensure the safety of these products were being taken in the US.

39.1. I have been asked whether I ever received briefings or submissions about withdrawing products made from pooled plasma and instead using cryoprecipitate as an alternative.

39.2. I do not recall such discussions or briefings (see paragraph 34.1(i) which covers the same issue). As far as I can recall, I was under the impression that cryoprecipitate was a precursor to the production of Factor VIII and held other impurities. Dr Walford had provided a Minute to Mr Parker dated 20th July 1983, on cryoprecipitate [DHSC0002491_013]. There was no suggestion that cryoprecipitate could replace Factor VIII for haemophiliacs. I was content with, and believed I understood, what was being explained. I have now been referred to a letter from Professor Bloom and Dr Rizza dated 24 June 1983 [HCDO0000270_004]. This is not something which I would had seen at the time. It sets out a series of treatment options for haemophilia sufferers, and I see that they include the use of cryoprecipitate as an option for some. There is no suggestion in that letter that intervention by the DHSS was needed to secure cryoprecipitate or other supplies.

The meeting with the Haemophilia Society, 8 September 1983.

40.1. I have been asked how I came to attend a meeting with the Haemophilia Society. It is apparent from [DHSC0001651] that on 3 May 1983 a meeting had previously been requested by the Society and organised with my predecessor, Mr Geoffrey Finsberg, who had been Parliamentary Under Secretary of State at DHSS. I presume his responsibilities included blood (Lord Trefgarne had been the Joint Parliamentary Under Secretary of State in the Lords but I am not aware of his range of responsibilities). A potential meeting had to be rescheduled due to the general election [DHSC0003824_170]. I was asked to fulfil Mr Finsberg's commitment after the General Election.

40.2. On 15 August the Society wrote to us with a list of three specific points they wished to discuss [HSOC0020344]; and on 8 September I met with the Society's executive committee [HSOC0020347]. On 28 September I followed up that meeting with a letter to the Society's chairman, The Revd Tanner [DHSC0002071].

40.3. I have been asked to describe the discussions which took place and have been supplied with a briefing note dated 8 September from the Haemophilia Society itself [HSOC0029476_028] as well as minutes of the Executive Committee of the Society on 15 September. These are not, of course, documents that I would have seen at the time. At the time, according to the records now available, I was supplied with:

(i) a briefing dated 26 August 1983 from Mr Winstanley;

(ii) a further Note dated 7 September 1983, also from Mr Winstanley, which updated the information previously made available [DHSC0002337_050].

40.4. Unfortunately, although the note of 7 September is available, the earlier "main briefing" of 26 August is not. I have also not seen a DHSS record of the meeting, although I would have expected one to be taken. My letter to The Revd Tanner dated 28 September 1983, together with any drafting material, seem to be the only records of what took place that are available.

40.5. My memory of the meeting of the meeting is fairly distinct. It was a good meeting and not an antagonistic one. I remember clearly that the Society's

officers were keen to ensure that imported coagulation factors would continue so as to safeguard haemophiliacs, despite any associated risks. The risks of not treating haemophiliacs would be life-threatening to them.

40.6. The Inquiry has noted that the Society "appears" to have been of the view that Factor VIII should continue to be imported because "the availability of treatment far outweighs any conceivable AIDS risk". That was indeed the Society's view, and I can remember that they were emphatic about it at the meeting. This was also the advice of officials and agreed by Ministers.

40.7. The Society's views can, in fact, be seen from the letter sent to Mr Green (of the DHSS) by the Society in advance of the meeting with me, where the second of the two points made was that there should be "no attempt to suspend the importation of US Commercial Products that *[presumably, without]* definite evidence that this would be necessary". The text of the letter does not make sense unless these words or similar are added, but they are consistent with the Society's briefing note (8 September) and the minutes of the Executive Committee meeting of 15 September. I am not able to comment on how the assessment of risks was made by the Society at the time, but it appears both reasonable and consistent with the advice I was receiving from DHSS officials. See also the edition of "Haemofacts" subsequently produced on 22 September 1983 [PRSE0000088].

40.8. My own understanding at the time was based upon the documents and briefings that I had previously been supplied with and which I have discussed above.

40.9. I have been asked to comment on the section in the Society's internal briefing note of 8 September [HSOC0020347], that runs as follows:

"NO SUSPENSION OF IMPORTED PRODUCTS: (This is shakier than when first put on the 'agenda'!) In spite of the recent death related to AIDS in a person with haemophilia, the Society would nevertheless hold firmly to their original persuasion that the availability of treatment far outweighs any conceivable AIDS risk. Can the Minister assure the Society therefore that there will be no suspension of the imported product?"

40.10. I believe that I, supported by officials attending the meeting, would have indicated that there was uncertainty about the safety of imported products, but

that we agreed that their importation and use should be continued. The 'shakier' term used in the internal briefing seems to imply that the Society thought that the risk might have increased, but that the alternative (stopping imports) was more dangerous. As for the weight placed by me on those views, the Department and the Society seemed to agree that there was no real alternative, although the Society seemed aware that there might be a degree of uncertainty.

40.11. I note that the minutes of the Society's Executive Committee of 15 September do not hint at any doubts [HSOC0029476_028]:

> *"Imported Factor VIII concentrates: the Society and the Department agree that factor VIII concentrates must continue to be imported from the USA. Any other course of action could only lead to people with haemophilia being exposed to even greater risks through lack of concentrates for bleeding episodes. This is still the view held by both parties in the knowledge of one recorded death at Bristol which was suspected on the day of the meeting."*

40.12. Generally, the meeting reinforced in my mind that we were on the horns of a dilemma.

40.13. As to the general impression that I had of contact with the Haemophilia Society, I am sure that officials were in regular contact with the Society, and would have recommended to me that I should meet with them again in due course, which I did in December 1984.

Mr Watters' Evidence of the Meeting

41.1. I have been referred to Mr Watters' evidence as given to this Inquiry on 10 February 2021: [WITN5282010]. [Transcript, p.49/ l.23 to p.53/l.4], specifically his viewpoint that the Society was "*possibly persuaded*", "*by the facts and possibly by Lord Glenarthur and his entourage of civil servants*", to support the continued use of pre-March plasma.

41.2. In answer to the questions posed about discussion of the continued use of pre-March 1983 products, I cannot recall the discussion of the issue at the meeting on 8 September, but I am sure the use of pre-March factors would have been raised, and our need to continue the use of existing stock.

41.3. I have been asked whether I or civil servants "persuaded" the Haemophilia Society to support, or at least not to oppose, the continued use of such products. Mr Watters' letter of 15 August shows at point (2) that – even prior to the meeting on 8 September – the Society had been keen to obtain a reassurance that there would be no suspension on the use of US blood products [HSOC0020344]. We would not have sought to "persuade" but to point to the shortages that would follow if pre-March 1983 stock was not used.

41.4. I note that Mr Watters first said that the Society was "possibly persuaded" by "the facts" and then mentioned the meeting. I expect that the Department's position was explained at the meeting. But it would be for the Society, as an independent body representing its members, to decide whether or not it agreed with the information it had been given, or actions being taken. There was no question of seeking to pressurise it in any way, if that is what is implied by the evidence for the question asked. I also note that the follow-up letter sent on 28 September set out the position on FDA imports, including on the pre-March 1983 stock. The Society had the opportunity to consider all the information that had been supplied after the meeting, and to reach its own judgements on the views expressed on behalf of the DHSS.

42.1. A note from Mr Winstanley to Mr Joyce of my Private Office on 7 September 1983 refers to a briefing being sent to me on 26 August 1983. I have been asked to supply, if I can, a copy of the main briefing. I do not have this and I am informed that it has not been found.

The Ministerial Meeting of 15 September 1983

42.2. For the sake of completeness, I should add that it was shortly after this meeting with the Haemophilia Society that I sat down with my colleagues, Mr Clarke and Mr Patten, to review the steps that we were taking and to make sure that we

had not 'missed' anything. I have described this meeting at paragraph 6.8 above.

The Revision of the Donor Leaflet on AIDS, 1984

43.1. As set out above, the first AIDS leaflet for blood donors was published on 1 September 1983. In early September 1983 I had suggested a trial period of three months (see paragraph 21.4 above) [DHSC0002309_036]. From the papers which have now been supplied to me, it seems that this was the approach adopted.

43.2. I cannot remember being provided with any further information from civil servants about the way it was distributed after its publication, although I see that my office was copied in to the response from the Minister for Health (Mr Clarke) to a submission dated 20 October 1983. A copy of the submission does not seem to be available, but it appears from Mr Clarke's response that it suggested distributing the leaflets in STD clinics [WITN5282011], a suggestion that was approved by Mr Clarke.

43.3. I cannot recollect any further information on the leaflet being provided until 17 April 1984, when a submission was sent to Ministers, including myself (see below). However, for the purpose of this Statement I have been provided with a short note [WITN5282008] summarising the actions of officials with regards to the leaflet. I would not at the time, and have not now, examined the underlying documents on which it has been based, but my understanding is that they are all in the possession of the Inquiry so the contents of the Note can be verified.

43.4. Reading the Note, it appears that action was taken after the three-month period had expired, to gather information about the distribution of the leaflets. This appears to have involved both the Regional Transfusion Directors (led by Dr Wagstaff) and the DHSS (Mr Winstanley), with discussion concerning not only the means of distribution but also the need to reword the leaflet.

<u>Letter from Dr Smithies, 14 February 1984; Submission of 17 April 1984</u>

44.1. I have been supplied with a copy of a letter from Dr Smithies dated 14 February 1984 [DHSC0002239_015], also referred to in the Note]. This expressed concern that "our current advice to donors could seem too lax. It may also be necessary to take up with the Transfusion Directors the need for more positive distribution….". I have been asked if I was made aware of these concerns or issues. I cannot remember them being raised with me and Dr Smithies' letter was not sent to my office. If there were concerns, I would have expected to be told. However, I can see from the Note that consideration was being given to a redraft and to reissuing the leaflet.

44.2. The matter came back to Ministers on 17 April 1984, when a submission was sent by Mr Cunningham to Mr Patten (PS(H)), copied to myself. It addressed the MRC's Working Party on AIDS but also recorded that:

> *"Ministers agreed last year that a leaflet should be issued to blood donors about the dangers of those at risk of contracting AIDS giving blood. There has been a 6 months' trial of this leaflet which has been successful. The leaflet and the method of distributing it are under review."*

44.3. There was a further suggestion, from the Chairman of the MRC Working Party on AIDS (Dr Tyrell) about a leaflet geared to "warning the homosexual community of the dangers of promiscuous sexual activity. This is almost certainly the most common method of transmitting AIDS." It also referred to the work of the Health Education Council (HEC) which was also planning to issue a leaflet.

44.4. I am not sure why there is a reference to a 'six-month' trial period in the Submission; the underlying documents do show that there was a general understanding that the trial period had been for 3 months (even if it was followed up by enquiries and discussions rather than any more immediate action).

44.5. The initial reaction from Mr Patten (PS(H)) was a cautious one (see the minute of 18 April). I responded on 25 April (via Mr Joyce) favouring a further leaflet and asking for "a fuller note of the successful NBTS trial", saying:

> *"Lord Glenarthur has seen your minute of 17 April covering Mr Cunningham's submission.*

He takes a somewhat different view to PS(H) – Miss McKessack's minute of 18 April – in that he favours a further leaflet, directed particularly at promiscuous gays.

Lord Glenarthur's view is based on the fact that there have been criticisms – though not widespread – from correspondents and others that the Department has not done sufficient to increase relevant public awareness. He therefore feels that we should pursue a sensible, non-alarmist course of increased public education.

He would like a fuller note on the successful NBTS leaflet trial referred to at para 4 of Mr Cunningham's submission."

44.6. I have not been provided with any documents to show that there was a response to this request, from me, for further information.

Ministerial Submission, August 1984

44.7. The promised submission (from Mr Williams, dated 8 August) was sent up to Ministers by Mr Parker (H1) on 10 August. The submission explained the need to update the leaflet, and set out the results of the monitoring exercise. There had been no fall in the number of donors and little adverse comment, but wide variation in the manner in which the leaflet was distributed by the Regional Transfusion Centres (RTCs). The recommendation was now that the leaflets should be sent to all donors at their next recall.

45.1. I have been asked a number of questions about this submission. As can be seen from the chronology set out above, this was the first substantive information that I received about the effectiveness of the leaflet and the methods of distribution prior to this minute. There had been some limited information provided in April 1984, but there seems to be no record of a written response to my request for further information about the NBTS trial.

45.2. I have been asked if I would have agreed with Mr Parker's statement, on the covering letter for the submission, that the AIDS leaflet should be reproduced as a matter of priority. Mr Parker observed:

> *"In addition, Ministers may wish to know that we are likely to require up to 1,500,000 leaflets which can be printed at a cost of approximately £15,000. This can be met from within Information Division's budget in the current financial year, although this is likely to lead to the postponement of more routine publicity in relation to the National Blood Transfusion Service. Officials believe, however, that it is vital that the AIDS leaflet should be reproduced and that it should be accorded this priority."*

45.3. I am sure that I did agree with this judgement about importance and competing priorities. I indicated as much in my response to the submission, when I set out my support for the proposed revisions and the recommendation for a more uniform distribution system. See my response on 21 August 1983 [DHSC0002309_046]. Specifically, I said: "*We must take all sensible steps to prevent this disease being transmitted, and I support the recommendations…*"

45.4. I am sure that I would also have agreed that the Department would be open to criticism if it failed to take all reasonable steps to discourage high-risk donors.

Further Steps Taken

46.1. I have been asked to consider the steps that followed this approval and the time that it eventually took for the revised leaflet to be redrafted and published; the publication did not take place until 1 February 1985.

46.2. Tracing my own involvement through, the documents provided by the IBI and others show that:

(i) As set out above, I responded positively to the need for a new leaflet on 21 August [DHSC0002309_046].

(ii) A hand-written annotation on my response shows that on 14 September 1984, the submission and my response were sent to MS(H) (then

Kenneth Clarke) seeking comments on the leaflet's content: [DHSC0002309_046].

(iii) On 16 October 1984, Mr Naysmith (Assistant Private Secretary, Mr Clarke) wrote to Mr Williams saying that MS(H) had seen the submission and was content for the leaflet to be revised and distributed as suggested, adding, 'sorry this has taken so long to clear' [DHSC0002309_050].

(iv) By that time, the leaflet looked like: see [WITN5282012]

(v) A briefing note dated 19 November sent by Dr Smithies for the Secretary of State and copied to my office, referred to the leaflet as having been revised and stated that it was "being printed now" and would be given to every donor. The DHSS would issue a circular advising on distribution when it was ready [DHSC0002309_053].

(vi) However, a minute from Ms Hewlett-Davies dated 22 November 1984 to colleagues refers to further recommended changes: DHSC0002323_014. This minute was copied to (amongst others) Ms Bateman, who was Mr Clarke's private secretary; and to Ms McKessack, who was Mr Patten's private secretary. Ms Hewlett-Davies stated that she was attaching a revised version of the leaflet "drafted by my Publicity Branch" (i.e. Information Division). It is apparent that this was the second revision to the leaflet – she refers to making changes to the "first revise" having to be looked at again in the light of "recent developments and ministerial statements" (presumably, a reference to Mr Patten's press statements on 18 and 19 November 1984, see below). It seems that the second revision was to secure a more strongly worded version and she felt that need had been met. She wanted to secure urgent approval, production and distribution [DHSC0002327_127].

46.3. Documents which follow include:

(i) 23 November: a minute following a briefing session with the MS(H) suggested that the Minister was content to hold up the donor leaflet until after the NBTS Working Group meeting – but he was obviously satisfied with it as it is at present; [DHSC0000435].

(ii) On 27 November, 1984 a minute seeking approval of the revisions of the leaflet was sent following consideration by the NBTS Working Group on AIDS;

(iii) Mr Patten responded to the minute of the 22 November on 30 November, stating that he was content if I and the Minister of State for Health were;

(iv) A minute of 3 December [PRSE0000898] explained that the printing of the leaflet had been delayed to allow the NBTS Working Group on AIDS to discuss the draft leaflet on 27 November. However, the Group had only minor comments to make.

46.4. On 3 December, a revised version of the leaflet, with modest changes approved by the NBTS Working Group on AIDS was sent to the Minister of State for Health under cover of a minute from Dr Abrams; this was copied to Mr Joyce of my office: [DHSC0002309_058].

46.5. On 4 December 1984, I sent clearance for the revised leaflet [DHSC0002309_117]. This referred back to Hewlett-Davies minute of 22 November, so there was something of a crossing of minutes, as the further minute sent by Dr Abrams had not, it seems, yet reached me.

46.6. Thereafter:

(i) A letter from me to the Haemophilia Society dated 12 December 1984 referred to the fact that the leaflet had been revised, with wider definition of the 'high risk' categories; RTCs would be asked to ensure it was received on an individual basis by all donors [DHSC0002249_015];

(ii) a response from the Minister of State for Health was 'chased' on 14 December; [DHSC0002309_060].

(iii) Detailed comments were provided by the Minister of State for Health on 20 December (again copied to my office). The minute from his office records that he commented on the need to ensure that the leaflet took into account the publicity surrounding the two cases of AIDS from blood transfusions. He also felt that the Information Division version of the leaflet had conveyed the message more effectively. The minute noted that although the need to produce the revised leaflet as soon as possible

was appreciated, the Christmas break would inevitably delay printing to the New Year, and that being so, the Minister should be given the opportunity to comment on the agreed version (i.e. a further revision) before it went for printing.

46.7. A revised draft was circulated the next day, on 21 December 1984, to take account of comments made by Mr Clarke. The handwritten comments on the document [WITN5282013] show how Mr Clarke responded, querying the accuracy of statements on the risk of contracting AIDS from blood transfusions (was it still true to say that there was only a "remote chance" of contracting AIDS?). He "remained wary" of promising blood screening tests and heat-treated products [DHSC0002309_063]. Those comments were recorded in a minute from his office dated 31 December, copied to my office [DHSC0002309_064].

46.8. A handwritten note (copied to my office) dated 2 January 1985 shows the detailed response to the Minister of State for Health's questions or comments and the changes that were made to the final version of the leaflet as a result. [WITN5282014].

46.9. On 3 January 1985, approval was sought for a draft Health Circular asking Regional Health Authorities to implement the decision to distribute the revised leaflet to all blood donors [DHSC0002309_065].

46.10. On 15 January 1985 I approved the Circular as drafted and Mr Joyce confirmed this in a minute to Mr Williams. He wrote a further minute to Mr Williams confirming that "Lord Glenarthur and PS(H) are content with the draft as 'finally' revised accompanying your minute of 3 January and that PS(H) is content to revert to the wording 'serious' rather than 'killer' disease." [DHSC0002482_010] [DHSC0002482_011].

46.11. A draft press statement dated 1 February 1985 refers to the creation of the Expert Advisory Group on AIDS, evaluation of screening tests for AIDS and the publication of the revised AIDS leaflet [DHSC0002311_053]. I suspect that the gap between early January and the 1st of February is accounted for by the need to print and distribute copies of the leaflet.

46.12. It is apparent from the chronology above that I responded positively to requests for approval of the revised leaflet at various stages.

46.13. I have been asked if I had any concerns about the length of time taken to get a revised version of the leaflet into the public domain and if so, if I took any action.

46.14. I agree that it does seem a very long interval. I cannot recall the reason other than that the Department and Ministers were always rightly keen to ensure as much accuracy and sensitivity as possible in published leaflets. There was a strong wish to publish the up-to-date advice, but papers do not seem to indicate exactly what the hold-up was other than that a large number of people were involved in providing comment.

46.15. In response to the question about my views now, I have set out why it seems to have taken so long. I agree that ideally it should have been achieved more quickly.

Methods of Distribution

47.1. My statement has already referred to my comment in August 1983, that there was a need for a "really positive approach". I have been asked if I think that the Government had been "really positive" in its approach to the issue of AIDS and the blood supply in the 18 months that followed that minute.

47.2. My comment was in fact about the need to discourage blood donors, not the wider issues of AIDS and the blood supply. Focussing on that issue, I think that the Government was probably as positive as it could have been in view of increasing knowledge about AIDS on the one hand, and the sensitivity of donors on the other.

47.3. I have been asked if the concerns I raised in this minute were borne out by the events that followed in the subsequent 18 months, or feel (then or now) any sense of frustration that my proposal for direct distribution of the leaflet in August 1983 was not followed.

47.4. As to the first, conceivably events did bear out those concerns. As to whether I felt (or feel) any sense of frustration, others decided that they did not wish to

follow my advice, but perhaps at the time I was unaware of all the sensitivities publication entailed.

48.1. I do not have any further comments to make on the subject of the revised leaflet, save to say that public statements or publication of leaflets were always addressed with much care, often with much redrafting or amendment. An ill-considered document could give rise to press sensationalism and increased public concern.

The Screening Test for HTLV-III in blood donors

49.1. On 31 August 1984, M H Arthur sent a briefing note, prepared in collaboration with Dr Smithies, to Mr Joyce of my Private Office, referring to publicity concerning the results of a blood screening tests for "AIDS antibody" developed at the Middlesex Hospital [DHSC0000443]. Since the paper was copied to my office, I am sure I would have seen it.

49.2. The paper stated that "*Ministers are aware from the AIDS leaflet submission that a blood test for AIDS antibody is under development at the Middlesex Hospital and the Institute for Cancer Research".* The AIDS leaflet submission in question was that sent under cover of Mr Parker's minute of 10 August 1984 [DHSC0002309_044]. At paragraphs 7-8 of that minute Mr Parker had stated that development of a test was still in research stage; that it was hoped that trials would start in October; and that it would be some time before the results could be properly evaluated. It envisaged that a working party would be set up by the Advisory Committee of the NBTS. Again, I believe I would have been aware of this as it was such an encouraging development.

50.1. The paper of 13 August 1984 stressed that the implications of a positive test were still unknown:

"The results of the tests seemed to confirm that individuals suffering from AIDS and a high percentage of those who may be developing AIDS itself, or a milder form of the disease, carry an antibody in their blood. Other groups known to be at high risk of AIDS also show a high percentage of individuals with the antibody. It is not yet known what this means. It may mean that they have been infected with the agent; or have overcome it but still retain evidence of immunity

to it. It could mean that they have recently been infected with the agent and have yet to develop resistance to it; or they may be incubating it … and will succumb to the disease at some time in the future. There is no way of knowing whether those people with antibody, but who are otherwise in good health will necessarily develop the disease…."

50.2. The paper continued:

"*The proportion of haemophiliacs amongst the relatively small total number tested is high. It must be stressed that at present the significance of this finding is not yet clear. However, in all the studies carried out on groups of patients so far there does seem to be evidence that haemophiliac patients are a group at risk presumably because of the therapy they require with Factor VIII most of which is derived from human blood*."

50.3. I have been asked by the Inquiry if I was surprised by this finding. After much thought, it seems to me that I cannot reliably say now (when the infections that sadly resulted are well-known) how this would have struck me in August 1984, (almost 40 years ago). I would have known, however, (e.g. from the earlier submission of 10 August) that officials and the scientific community were working to identify a screening test for the causative agent in blood/blood products and also to find a way of neutralising the agent without damaging the blood/blood product.

51.1. The paper also recorded that until a screening test was developed, "no guarantee can be given that donations [of blood] are free from the AIDS agent." I believe I would have been aware of this, as this was not new.

52.1. The preliminary reports of the UK tests on blood donors were described as "very encouraging in that they showed that none of the 1000 UK blood donors tested carried any antibody to AIDS." It was hoped that the test could be extended to a larger number of donors. My reaction to this information would have been to have been very encouraged by these indications of potential progress.

53.1. On 13 November 1984, a meeting took place to discuss provision of central funds from the DHSS for various projects in the financial year 1985/1986

[DHSC0002309_052]. The meeting was attended by the Minister of State for Health, Mr Lillywhite, and Mr Staniforth. It discussed a submission put forward by Mrs Banks on 31 October 1984 [DHSC0002309_051]. Among the matters considered was the possibility of central funding being made available for the testing of blood donations for AIDS (or the agent causing AIDS). A provisional figure of £2 million was attached to this. Mrs Banks' submissions recorded officials' view that central funding would be "potentially difficult to resist." But the minutes of the meeting record an agreement that such expenditure should be for the regions and not for "Central pre-emption". The justification recorded that the test was "Hypothetical", as well as being for the regions rather the centre.

53.2. I was not at this meeting and do not believe I was aware of these submissions. Complex financial matters (such as balance between releasing funds from Hospital and Community Health Services, and retaining them centrally, within the Central Reserves) were invariably handled by the Minister of State for Health.

54.1. The priority which I attached to securing progress in this area can be seen by the question I asked for information on, on 15 November 1984. The minute of my request reads *"Lord Glenarthur has queried whether we are now screening all blood for AIDS. If we are not he would like to know when we will be able to and whether there are any problems associated with such an idea, if the technology exists"* [DHSC0002309_116]. I wished to be informed about progress and was seeking to find out if there was follow-up of the developments reported (for example) in August of that year and in other papers circulating.

55.1. In reply, I received a minute from Mr Williams, dated 26 November 1984 [DHSC0000436]. This stated that:

"*The NBTS is not yet screening blood for evidence of AIDS infection. A test has been developed and will be in use in a pilot trial at on Regional Transfusion Centre very shortly. At the same time arrangements are being made with industry to scale up production of test reagents so that a British test is available for use as soon as possible…* "

55.2. The minute recorded the decision of the Minister of State for Health that funding from central reserves would not be appropriate (see above). The technical and ethical implications of such testing were being considered by the Working Party on AIDS set up under the Advisory Committee for the NBTS.

55.3. I would have been encouraged by this development that technical and ethical implications were being considered by the Working Party. There was no request for Ministerial action.

55.4. The minute refers to the Minister of State for Health's decision that Regional Health Authorities, and not the Central Reserve, would have to meet the costs of the tests. I cannot now recall whether I knew about this decision before. I was probably aware, but as I have previously explained, decisions on finance were generally handled by the Minister of State. I was generally aware of the pressures on central funding, and it would have seemed reasonable to ask for regional contribution in whole or in part. I have noted below how in February 1985, RHAs were asked to set aside funds for 1985-85, to enable the introduction of these tests in their Blood Transfusion Centres. I cannot recall changing my mind on this at a later stage.

56.1. Between the minutes of 15 and 26 November 1984, a note for the Secretary of State was produced. This was circulated by Dr Alison Smithies on 19 November 1984, including to Mr Joyce in my private office [DHSC0002309_053]. I will have seen it as a result. It was a useful summary of the situation, which the Secretary of State might not have been aware of in detail. I do not think that it contained anything that I was unaware of, or feel that I should have been advised of earlier.

56.2. The note refers to the first meeting of an expert Working Group, which was due to take place on 27 November 1984. I have been asked why no such group had been established at an earlier stage. As to that:

(i) The MRC had set up an informal group in the autumn of 1983; this was co-ordinating research, as the note from Dr Smithies stated;

(ii) A CBLA Ad-hoc Working Group on AIDS was set up under the chairmanship of Dr Gunson, on 27 July 1983;

(iii) It would primarily be for the CMO or medical advisors to advise if further gatherings of experts would be useful, to bring together expertise on AIDS. I would assume that it was thought that the existing structures and Committees had been sufficient, to that point.

Press Briefing by Mr Patten, 18 and 19 November 1984

57.1. John Patten gave a statement to various media organisations on 18 and also 19 November 1984 [PRSE0002251 and MACK0002638_029]. I suspect that the context for these statements was the news that (i) 13 people including a baby had died in Australia after receiving a contaminated blood transfusion and (ii) a patient in the UK who had received a blood transfusion with blood contaminated with AIDS had died. See the briefing to the Secretary of State dated 19 November 1984 [DHSC0002309_053] as well as the minute from Mr Arthur dated 21 November 1984 which also refers to press interest in these matters.

57.2. I cannot now recall why Mr Patten, rather than me, made these statements. It is possible that ministerial colleagues preferred public announcements to be made by House of Commons Ministers. Mr Patten had an interest in AIDS; see for example his involvement in the AIDS leaflet.

58.1. On 30 November 1984, a minute was sent to Mr Joyce of my Private Office reporting that three UK blood donors had been found to be HTLV-III positive, and that their donations had been used in blood donations and the production of Factor VIII concentrates. The batch of Factor VIII concentrate had been given to 38 people with haemophilia [DHSC0002309_057]. The minute did not state when the infected donations had been given.

58.2. Further and fuller details were subsequently set out in a public statement from the CMO, Dr Donald Acheson dated 20 December 1984: [BART0000814]

58.3. Turning back to the minute of 26 November, I am sure I would have seen it; it had been sent to my office. The minute set out the steps that were being taken:

(i) Revision of the AIDS blood donor leaflet to dissuade high risk groups from donating;

(ii) Developing a screening test and carrying out pilot studies of the test;

(iii) Considering the use of heat-treatment of Factor VIII in reducing the risk of HTLV-III transmission.

58.4. Overall, the minute would have reinforced in my mind the importance of developing and implementing the necessary tests.

Introduction of a screening test for HTLV-III for blood donors

59.1. I have been asked to describe my role in the further decisions concerning the introduction of a screening test for HTLV-III for blood donors in the United Kingdom. The Inquiry has referred me to a number of papers regarding this issue:

(i) I have been shown a copy of Dr Smithies' minute and draft submission on screening of 11 January 1985: [DHSC0000562]. The note was addressed to the CMO, but it included a draft submission for Ministers. It appears from Mr Clarke's minute of 22 January 1985 (below) that a submission to Ministers was made on 15 January 1985, but this document has not been made available to me.

(ii) The draft submission from Dr Smithies detailed the proposed introduction of the screening test for AIDS. It was already being used at Middlesex Hospital and at Colindale, but production of the reagent needed to be scaled up before the test could be rolled out more widely.

(iii) A reply from Mr Clarke (copied to my office: Mr Joyce) dated 22 January gave approval for the plans and posed certain questions: [DHSC0002482_012]. Dr Acheson responded on 31 January, providing answers to the questions and enclosing a draft letter to RHA chairmen and a draft press release. His covering minute is at [DHSC0002311_050 and PRSE0004280]; the substantive answers to Mr Clarke's questions are at [DHSC0002311_050] and the enclosed draft letter to RHA Chairmen and draft press release are at [DHSC0002311_088] and [DHSC0002311_053].

(iv) There was then a follow-up minute from the CMO dated 1 February 1985 [DHSC0002327_028], providing fuller answers to Mr Clarke's questions. He explained that the antibody screening test was being produced by the private sector (in particular, by Welcome in conjunction CAMR). He

explained that heat treatment remained advisable because neither the leaflet nor the screening test could completely eliminate the risk of AIDS transmission.

(v) A press release was issued by the DHSS on 20 February 1985 [DHSC0101892], in which Mr Clarke outlined steps taken generally to control the spread of AIDS, including reference to the development of screening tests for HTLV-III antibodies.

59.2. In response to the particular questions asked by the Inquiry:

(i) With regard the introduction of the screening test, I believe that I was kept aware of all developments, but I notice that many of these documents were not copied to me;

(ii) If I did make any decisions on these issues, none seem to have been recorded and decisions on funding would have been handled by the Minister of State.

(iii) I cannot now recall whether I had a role in deciding which tests should be used in the UK, or when. I doubt that I did. The announcement of steps made by Mr Clarke on 20 February 1985 [DHSC0101892] was to the effect that tests would be introduced within the NBTS, when a reliable test was available. The issues regarding their introduction, including the evaluation of tests, post-dated my time in office in the DHSS.

60.1. It appears from the contents and distribution lists of the documents listed above that my role in respect of decisions on the donor screening test was limited.

60.2. It is difficult to say why this was so. But it may have been due to my other work in DHSS taking pre-eminence, not least because I was due to be abroad in the week from 9 – 16 February 1985, attending Arab Health '85 and Arab Lab '85 as the Minister responsible for Healthcare Exports. I could not easily have contributed to detail whilst in the Gulf, or preparing for the trip and may have agreed that it should have been handled by other Ministers.

60.3. I have been asked whether I agreed with the policy in respect of donor screening that was pursued. The answer is yes. With regards to funding (and

whether it would be centrally-provided or a matter for regional budgets to cover), funding was largely left to the Minister of State for Health to deal with. The process whereby the testing would be introduced after the evaluation of available tests was driven by scientific advice.

Heat Treatment of Blood Products

61.1. I have been asked to describe, in broad terms, the knowledge that I had, during my time as Parliamentary Under Secretary of State, about the way in which blood and blood products were regulated and licensed for use within the United Kingdom; to identify the sources of my knowledge; and to describe my role, if any, in such systems.

61.2. It is not possible to recall now, exactly what I knew about these regulatory systems then. I obviously had some involvement with BPL, its redevelopment and its finances; I have referred elsewhere to visits to it. I was aware that there was a system of product licences for commercial imports of Factor VIII (see for example the record of the Hansard debate on 14 March 1985). But I cannot now recall the detail of my knowledge and I do not believe that I played any part in the regulatory system, which I would expect would have relied on medical expertise for decision-making.

61.3. I was aware that heat treatment of blood products was a desirable goal which might eliminate the agents in the product which could cause the transmission of AIDS and hepatitis. But I was also aware from briefing that there was a risk associated with heat treatment which could damage either whole blood or blood products; that such treatment would require thorough research; and that if it proved viable it would require trials, regulatory approval and subsequent licensing. I understood that this was a topic being addressed by research, whether by scientists at BPL or the Protein Fractionation Centre (PFC), or other centres of fractionation expertise and would not have expected either the DHSS or Ministers to have played any direct role in this.

61.4. The primary source of my knowledge was briefings from officials.

62.1. I have been asked what role, if any, I played in respect of the following:

a. Decisions relating to the prioritisation and/ or development of heat-treated Factor VIII by the Blood Products Laboratory, and/or the Protein Fractionation Centre.

b. Decisions relating to the licensing/ regulation and use of imported heat treated blood products by NHS patients (including by allowing the use of unlicensed heat treated products on a named-patient basis).

62.2. In relation to both of these, I do not recall being specifically involved. These were both technical areas being addressed, in essence, by clinical experts. I believe that advancement in this field would have been left to expert bodies. I would have expected to be informed of any issues in respect of which Ministerial decision or intervention would have assisted.

63.1. On or around 19 November 1984, the Blood Products Laboratory announced that all of its Factor VIII products would be heat treated from April 1985: see the brief prepared by Dr Smithies at [DHSC0002309_053, paragraph 9]. I have been referred to the newspaper article and Dr Smithies' note to the CMO on this topic: [WITN5282015]

63.2. A brief to the Secretary of State dated 19 November, copied to Mr Joyce of my Private Office, set out that the announcement had been made that day, and continued: *"At present heat treatment cannot guarantee that Factor VIII will not transmit AIDS although heat treatment is likely to do so according to recently-published research. Heat treatment of Factor VIII may solve the problem for haemophiliacs but it will not do so for recipients of blood donations (admittedly at less risk because they are receiving single donations not a product from many pooled donations)."*

63.3. A memorandum by Mr Patten sent 21 November 1984 suggests that the Government were not given prior notice of this announcement [DHSC0002327_126]. I cannot recall when I personally first became aware of the Blood Products Laboratory's decision, but I have no reason to think that I was in any better a position than Mr Patten's office.

63.4. I would have expected to have been informed of these plans by the CBLA at an earlier stage. It is very probable that I shared Mr Patten's concern that this had not happened. This was not because I thought that Ministers should have been

involved in its approval, but more from the perspective of handling parliamentary and press questions.

64.1. The Revd Tanner wrote to me on 28 November 1984 [DHSC0002251_016]. I met him and his colleagues from the Haemophilia Society on 7 December 1984 and wrote a follow up letter on 12 December 1984 [DHSC0002249_015]. The Society was concerned about the introduction of commercial heat-treated Factor VIII. I addressed this in the second paragraph of my letter, where I noted that providers would need to be apply for variations to their licences and that regulatory authorities would need to ensure that heat treatment would not introduce new toxic risks. I also noted that the cost would be borne by Health Authorities and that DHSS had not been made aware of any difficulties in that regard.

64.2. With regard to the various questions asked by the Inquiry:

(i) Given the passage of time, I am unable to recall when I became aware of the effect of heat treatment in inactivating the causative agent for AIDS infection.

(ii) I cannot recall what steps I took in respect of the provisions of heat treated blood products to NHS patients, other than I expect that I was generally kept aware of developments. There was activity at official level. As far as I can see now, there are no records of any request for interventions or decisions on my part being sent to me by civil servants. The development and introduction of heat-treated products was, in the first place, for the CBLA/BPL and PFC (in respect of UK products) and also for commercial manufacturers and the Licensing Authority, when applications licences for heat-treated products were made. The importance of the technology was well-known. See also paragraph 66 below.

(iii) Matters regarding the costs of imported heat-treated blood products and who should bear them (in the event of applications for further funding) would probably have been addressed by the Minister of State for Health. I might have been made aware of general details.

(iv) However, to the best of my recollection, I had not been made aware by officials that Regional Health Authorities were limiting the supply of imported heat-treated blood products on financial grounds (i.e. leaving aside the fact the Haemophilia Society raised that concern with me), or of an application by the RHAs for additional funds on such a ground. I did have a general awareness of the significant pressure on costs driven by the general policy of Government, and of the maintenance of decisions reached in the Public Expenditure reviews. But I have no reason to doubt the information in the letter that was sent to the Society in December 1984. However, I do note that further information on this subject was provided in the letter from Professor Bloom sent to me on 4 February 1985, to which I have referred below.

65.1. I have been referred to the minute of 30 November 1984 sent to Mr Joyce [DHSC0002309_057]. It reported that three UK blood donors had been found to be HTLV-III positive, and that their donations had been used in blood donations and the production of Factor VIII concentrates, which had been given to 38 people with haemophilia. I suspect this minute, with its worrying news, would have reinforced in my mind the need to develop safe heat treatment as soon as possible, as well as reinforcing the need to screen blood donations as soon as that technology was available for use within the NHS.

66.1. A press release [DHSC0000684] dated 20 December 1984 was issued by the Haemophilia Society in response to the news that Factor VIII produced in Scotland had been found to be contaminated with HTLV-III. The press release stated that the Society was "disappointed that there appears to be a lack of urgency in the attitude of both the Department and some of those who treat people with haemophilia which means that heat treated concentrates are only available to a limited number of patients."

66.2. Addressing the various questions:

(i) I was not aware of any lack of urgency, whether on the part of government or clinicians, to provide for the use of heat-treated Factor VIII in this period. The development of heat treatment required full and proper evaluation and testing, including by the licensing authorities.

'Named-patient' use would I think have been a matter for the relevant clinician. Any 'lack of urgency' was, in my view, perceived; lack of *progress* to satisfy licensing etc. was simply due to the procedures to be undertaken which could not be ignored in order to be compliant.

(ii) Insofar as the press release was intended to be a criticism of the DHSS, I consider it was unfair. The Haemophilia Society would perhaps not have been fully aware of the details of the approval steps which had to be taken.

(iii) Although I was not copied in at the time, I now note the correspondence from Professor Bloom to Dr Smithies on 21 November 1984 regarding the licensing of heat-treated blood products [DHSC0001211] and the response from the Department on 29 November 1984 [DHSC0002251_021]. In this, Dr Smithies noted that the Committee on Safety of Medicines *"recently discussed the subject of heat-treating Factor VIII concentrates and advised that the Licencing Authority should actually approach the appropriate manufacturers in order to prompt them to make applications for abridged Product Licences or variations so that the heat-treated product would be available on formal licences. This is, as a high priority item, in hand and the Senior Medical Officer dealing with it is Dr Mary Duncan. The Supplies Division of the DHSS is also fully alert to the problem."*

67.1. In relation to that same press release, I have been asked to speculate about the Society's "understanding" that additional funding could be made available to Regional Health Authorities who were facing problems over the additional costs involved in purchasing heat treated products. Addressing the various questions:

(i) I cannot recall whether I personally had told the Society, or given them the impression, that such funding would be available. I do not think I would have conveyed such a message in my meeting with the Society, but there is no minute of the meeting. I assume that officials would have had regular dialogue with the Society and perhaps this issue had been discussed.

(ii) I daresay that there would have been processes to make additional funding available to RHAs if necessary, but financial issues were generally a matter for the Minister of State for Health.

(iii) I do not know whether any claims for additional funding were in fact made by any Regional Health Authority.

68.1. A press release was issued on the same day (20 December 1984), this time by the Scottish Office: [WITN5282016]. It stated that the Scottish National Blood Transfusion Service had announced that all Scottish produced supplies of Factor VIII would be heat treated. (This apparently followed the news that 15 Scottish patients had tested positive for antibodies to HTLV-III). I shall do my best to address the various questions about it:

(i) I do not recall having been given advanced information by the Scottish Office of this step or this announcement. I would assume that officials in both the Scottish Office and DHSS were in dialogue;

(ii) So far as I recall, I was not involved in considering the use of Scottish facilities to produce heat treated Factor VIII products for patients in England and Wales, nor did I discuss such a possibility with the Scottish Office or the Scottish National Blood Transfusion Service.

69.1. I have been asked about an exchange of questions put by the Minister of State on 22 January 1985 [DHSC0002482_012] and responses received. The responses are contained partly in a minute from Dr Smithies on 31 January [DHSC0002311_050] and partly in a minute from the CMO dated 1 February 1985 [DHSC0002327_028]. Both appear to have been copied to my office. Addressing the various questions:

69.2. I do recall the Minister of State for Health's minute of 22 January 1985, but do not seem to have been on the circulation list for the CMO's minutes. I was, however, aware of the 'science' which the CMO described in both these minutes.

69.3. Although the Minister of State questioned the need for both a screening test and heat treatment, as set out in the CMO's responses, they addressed rather different targets. The information in the CMO's responses did not come as a surprise to me. Testing and heat treatment did not seem mutually exclusive as

they had different roles. I do not believe either minute would have caused me to change my approach, as I would have wanted to see both precautions taken.

The Letter of Professor Bloom, 4 February 1985

70.1. I have been asked about a detailed letter to me [MPNI0000037] dated 4 February 1985 from Professor Bloom, Chairman of the UK Haemophilia Centre Directors Organisation. He wrote that, *"The data on HTLV III seroconversion in British haemophiliacs are tending to confirm that a high proportion of severely affected patients have already been infected. Since the tests available do not detect all carriers, it seems prudent to conclude that all haemophiliacs who have been treated with large pool blood products should be considered to be potentially infectious."* He spoke about the pressures, including financial ones, engendered by new treatment needs. There is a handwritten comment from me at the top, asking for advice and an updating briefing on AIDS, so I think I must have been shown the letter.

70.2. Addressing the various questions:

(i) Looking at the letter now, together with the note I made, the broad thrusts of Professor Bloom's letter regarding potential infection would, I think, have been familiar (see the briefings I had received on HTLV-III testing in August 1984) but on re-reading it the emphases seemed rather different, so I passed it to officials for advice.

(ii) I do not believe this letter would have changed my risk assessment in respect of patients with haemophilia who were using blood products. The risks were well appreciated, as were the risks associated with a lack of supply. The emphasis was now upon securing access to heat-treated products.

(iii) The letter makes the point that the continuing shortfall at BPL Elstree meant that there had been increased reliance on buying imported blood products from the United States. I have been asked if, setting the cost implications of this aside, I was concerned about the risks of transmission of AIDS created by this increased reliance. However, this question seems not to take into account the reason why the imported products

were now being preferred – they were heat-treated, so they were thought to be safer than the non-heat-treated products available from BPL, Elstree. I believe that clinicians (together with the Licensing Authority) should have been able to assess the relative risks.

(iv) However, as I have stated, a number of complex issues were raised by the letter and I passed it to officials for advice and an update on the AIDS situation. There is no record of a response that I have seen, before I left the DHSS.

71.1. A minute from Mr Williams dated 26 March 1985 [DHSC0103282_091] with attachments [DHSC0103282_092], [DHSC0103282_093] may represent the response to Professor Bloom's letter. The minute recommended a meeting with Professor Bloom and other Haemophilia Centre Directors. It was sent to Baroness Trumpington, who succeeded me as Parliamentary Under Secretary of State at the DHSS [DHSC0103282_085] and I believe that a meeting was subsequently arranged.

71.2. As I left DHSS on 26 March 1985. I would not have seen these minutes when they were circulated. During my time as Minister, I was not aware of any complaints about working conditions or understaffing at the Haemophilia Reference Centres. It seems likely that such issues were being addressed or raised at an official level. As for the availability of heat-treated Factor VIII, this had been discussed in – in particular – Professor Bloom's letter and I had asked for advice and information from officials.

House of Lords debate, 18 March 1985

72.1. I have been referred to my speech in the House of Lords debate on 18 March 1985, as recorded in a Hansard extract [HSOC0018710 at pp.33-37]. I believe that the measures I outlined represented a short summary of the Government's efforts to protect recipients of blood and blood products against the risk of HTLV-III/AIDS transmission. It is simply impossible within the time constraints of a reply to what was then called an Unstarred Question, with no introductory remarks by the Minister, and no right of reply by the original questioner, to answer or encompass every detail, or the rationale for decisions. The speech

would have been drafted by officials, possibly amended by me with officials' approval, and I would have had a full oral briefing.

Self-sufficiency and related issues

General questions

73.1 I have been asked to provide a chronological account of my involvement in, and knowledge of, the efforts of the DHSS to achieve self-sufficiency in blood and blood products throughout my time as Parliamentary Under-Secretary of State.

73.2 When I took office on 14 June 1983, I had no knowledge of the previous efforts of the DHSS to achieve self-sufficiency in blood and blood products. This would not have been unusual for a newly appointed minister. I have already explained how when I took office, a general briefing would have been prepared by officials about the areas for which I had responsibility. However, I do not now have access to that briefing and I cannot recollect what it would have said.

73.3 A minute dated 22 June 1983 states that I had asked the CMO Sir Henry Yellowlees for information on AIDS [DHSC0002309_123]. Again, I have explained in Section 2 how I had requested this briefing very shortly after taking up my post.

73.4 In response to my request, I was sent a paper prepared by Dr Walford [DHSC0002309_124]. Amongst other things, Dr Walford provided information on the steps which were being taken by the DHSS to prevent the spread of aids in the UK. This included the information that the BPL was being redeveloped over the next three years at a cost of £21 million to achieve national self-sufficiency in blood products. From what I can recall this would have been the first occasion I received any information on the subject of self-sufficiency, but I did understand from this that the Government policy was to attain self-sufficiency.

73.5 I believe that I was provided with both a written and, on 13 July 1983, an oral briefing on the issue of self-sufficiency, before Baroness Dudley's Parliamentary Question was answered by me on 14 July 1983. However, I cannot say what these might have added to the information that I gave to the House of Lords on 14 July.

73.6 Following on from this initial briefing, my knowledge of the efforts of the DHSS to achieve self-sufficiency would have been derived from written and verbal briefings from DHSS officials. This would have been the case throughout the term I served as a minister. I received papers fairly regularly, either for my own information; or when decisions were required; or Parliamentary matters required handling, over the entire period I served as Parliamentary Under-Secretary of State. This history is covered more fully below, in response to the successive questions raised.

74.1 I have been asked about my understanding of the Government's policy on self-sufficiency in respect of blood products when I took office as Parliamentary Under-Secretary of State. I have been specifically asked to comment on my sources of understanding for this policy, and whether the policy changed during my time in office.

74.2 Please see my answer above. As Parliamentary Under-Secretary of State, my sources of information came from written and verbal briefings by DHSS officials. The methods of receiving information did not change during my time in office. Throughout my time in office the Government's policy remained achieving self-sufficiency in the production of Factor VIII blood products as soon as possible and this was supported by the continued investment in rebuilding the Blood Products Laboratory.

Knowledge of Previous Statements

75.1 The Inquiry has asked whether I was aware of statements made by ministers in previous governments about aspirations towards self-sufficiency in Factor VIII blood products.

75.2 I do not believe I was made aware in detail of statements made by ministers in previous governments.

75.3 The Inquiry has referred me to a DHSS press release of 29th April 1976 [LDOW0000044]. This press release provides a summary of the speech given by Dr David Owen to the World Federation of Haemophilia Congress on 29 April

1976. Dr Owen indicated in this speech that following a special allocation of £500,000 in the previous year, there had been significant progress made in building up NHS production capacity, and self-sufficiency was expected to be reached by mid-1977. Furthermore, I have been referred to statements made by Dr Owen to Parliament on 22nd January 1975 [DHSC0000274] and 7th July 1975 [DHSC0000281], which outline the UK's objective of becoming self-sufficient.

75.4 I was not aware of Dr Owen's statements to Parliament on 22nd January 1975 and 7th July 1975, or the DHSS Press Release of 29th April 1976.

75.5 I know there is a constitutional convention regarding access to, in particular, the papers of a previous administration. Please see Section 1, which sets it out. Whilst it would not prevent such access as was properly needed (or access to previous records of Parliamentary debates), it is possible – although I speculate - that the convention played a part in how information about the actions of previous administrations was generally framed. But this was a matter for the officials who provided briefings. In 1983, it may simply be that the previous history was not thought sufficiently relevant to be drawn to my attention, not least as government was committed to the same policy.

75.6 Although knowledge of the previous history might have helped in replying to matters such as the letter from Dr Owen (see below), by the time I arrived at the DHSS the policy of redeveloping BPL was already in train and I do not think that knowing more about the previous history would have made much difference.

Letter to Dr David Owen

76.1 I have been referred to a letter from Dr David Owen, dated 19 October 1983, to the Minister of State for Health, Kenneth Clarke, in which he indicates that during his time as Minister of State for Health he had "set in train a capital investment programme to make us self-sufficient in blood and all the factors". Dr Owen queried what stage this programme had reached [DHSC0000209].

76.2 On 10 November 1983, I sent a letter to Dr David Owen in reply. My reply indicated that £2 million had been spent on improving production facilities at BPL Elstree. Furthermore, a 3-year redevelopment programme was under way. Upon completion, the Central Blood Laboratories Authority will have a new lab of a size capable of meeting the demands of England and Wales for blood products [DHSC0000208].

76.3 The reply to Dr Owen's letter sent by me on 10th November 1983, was prepared and drafted, as was always the case, by officials and sent for me to consider and sign. The draft sent to me seemed a brief but adequate answer to the general question on progress which Dr Owen posed. I do not recall any discussions with DHSS officials about Dr Owen's Capital Investment Programme at the time, or further information being provided.

Visit to the Blood Products Laboratory, July 1983

77.1 On 21st July 1983, I visited the BPL at Elstree. The purpose of my visit to BPL on 21st July was to familiarise myself with the work undertaken there, to understand the processes and to meet the staff. I would have had a written brief beforehand, about any issues likely to be raised and possible responses to them. I personally hold no documents about the visit and I have not been supplied with a copy of any briefing I might have received.

77.2 I have been referred to the Minutes of the CBLA's Seventh Meeting held on 27 July 1983 [CBLA0001732], but these are fairly uninformative:

> *"The Chairman reported the visit of Lord Glenarthur, Joint Parliamentary Under-Secretary of State, to BPL on Thursday 21 July accompanied by Dr EL Harris, Mr J Parker and Dr Diana Walford. Lord Glenarthur had toured the manufacturing unit with Dr Lane and met the Chairman, Dr Gunson, Mr Jerwood and the Secretary. It was noted that Lord Glenarthur had subsequently said that he had very much enjoyed his visit to BPL."*

77.3 Now in 2021, I do not think that I can add anything more.

The financing of BPL

78.1 I have been asked to consider the following documents, whose contents are summarised below:

a) *Letter from David Smart, Chairman of the CBLA*, 8 August 1983 [DHSC0001663]. This letter from Mr David Smart to me argued that the financing of BPL should be approached on the basis that it was a revenue-sparing and profit-producing manufacturing operation, and asked for a meeting to discuss these issues. This letter would have been passed to officials for their advice on the complex financial matters involved, but it was obviously part of the background to the meeting that subsequently took place in November 1983.

b) Minutes from Miss A M O'Carroll to Mr Winstanley, 13 October 1983 [DHSC0002235_085]. A minute from Miss O'Carroll dated 13 October records concerns about the outcome of an inspection visit by the Medicines Inspectorate (late July / early August 1983) of BPL. Ms Carroll notes that I had agreed to meet the Chairman and Deputy Chairman of the CBLA in November to talk about "financial difficulties" and offered briefing, but did not add any further details about these issues.

c) Financial briefing supplied ahead of a meeting with the CBLA dated 1 November 1983 [DHSC0046951_042]. I was supplied with a fairly detailed financial briefing in advance of the meeting planned for 22 November.

d) Minutes of a meeting between myself and representatives of the CBLA, 22 November 1983 [DHSC0001669]. The note of the meeting with CBLA on 22 November 1983 records the discussion that took place. I believe that this meeting was largely concerned with funding of the CBLAs requirements. I would have listened to the CBLA's case, given the Department's views on the issue, and asked for officials and the CBLA to take matters forward. The minute seems to reflect this and I do not now recall any further details.

78.2 The Inquiry has asked me to provide an outline of the arguments being made at the time concerning the way in which BPL should be funded, and in particular whether it should charge NHS bodies for the products it supplied.

78.3 I cannot add to the information in these documents about the arguments being made at that time concerning the way in which BPL should be funded, and in particular whether it should charge NHS bodies for the blood products it supplied. The financial briefing paper outlines the difficulties in introducing a charging system. It noted that the "present system of free supply of plasma and products" was not "conducive to a healthy cost-consciousness in this multi-million-pound service". On the other hand, the administrative and clinical implications within the regions were considerable and there was unlikely to be any enthusiasm within the NHS "for anything that adds to the administrative burden at a time of manpower and management cuts". There was reference to a trial being run in Wessex RHA to determine the administrative costs. This trial was not raised with me again during my time in office.

78.4 As far as I recall, the funding issue, under what I recall as very tight cost pressures, was passed to officials at DHSS and CBLA to resolve. I had indicated in the meeting between the representatives of CBLA and myself that DHSS could agree to the provision of a further £0.5m in revenue funding. Some would of this be provided by BPL's additional sales of RIA tests (for the screening of blood for Hepatitis B) and the rest would be found by the DHSS.

78.5 With regards to my own knowledge of the "worrisome and disturbing" report that followed an inspection, by the Medicines Inspectorate, of BPL in July and early August 1983, I was not made aware of Miss O'Carroll's minute of 13 October 1983 and assume this was not thought to require ministerial intervention. It was not copied to my office. I do not think that these issues were raised by Mr Smart when we met on 22 November 1983; the matter is not referred to in the minutes referred to above at paragraph 79.2(d). I would have asked officials for further information about these difficulties and what was being done to address them, if I had been made aware.

Approach to self-sufficiency in England and Wales

79.1 I have been referred to my letter, dated 28th September 1983, to the Haemophilia Society. Specifically, this letter was sent to the Chairman of the Haemophilia Society, The Revd Tanner after our meeting earlier that month.

Amongst other things, I indicated that the CBLA had embarked on a £21 million redevelopment programme. I stated that the target date for the completion of the redevelopment of BPL was the end of 1985, by which time "the Authority aim to have a new laboratory of a size capable of meeting the demands of England and Wales for blood products" [DHSC0002071]. The inquiry has also referred to my letter, dated 10th November 1983, to David Owen, where I used a similar phrase [DHSC0000208].

79.2 I have been asked whether my understanding was that this target, if met, would allow for self-sufficiency in blood products for England and Wales by the end of 1985, or only that there would be the laboratory infrastructure in place at that time to allow for self-sufficiency. I believe it was my understanding that the new plant would be complete but not fully operational.

79.3 I have further been asked whether I was concerned that other elements required for self-sufficiency would not be in place by the end of 1985. I recall that the increased volume of product in the new facility would be dependent on commissioning and testing of the new facility, a sufficient supply of plasma from the regions and work-up. By this I mean that if the new facility was finished by the end of 1985, it would still take a further period of time for it to start up its processes, to carry out any necessary tests and to start production and to get up to full capacity. I believe that DHSS officials were aware of these points, and if there was any cause for concern, I would have expected to have been briefed on the situation.

Future Plasma Supplies

80.1 I have answered questions 80 and 81 together.

1983

80.2 I have first been referred to minutes from a meeting of the Executive Committee of the Haemophilia Society on 15 September 1983. Specifically, the minutes provide a report of the meeting held with me on 8 September 1983, about which it is said that "it was clear that the Government had committed funds (£21m) to the development of BPL". The view of the Committee was that achieving self-

sufficiency within the above timescale was "unlikely to be a reality, not least due to the difficulty which could be foreseen in procuring adequate supplies of plasma" [HSOC0029476_028].

80.3 I have been asked about the extent I shared those concerns about the future plasma supply. As to this, I believe that if officials at the DHSS shared the concerns of the Executive Committee of the Haemophilia Society, I would have been briefed about this. I cannot recall being briefed about any such concerns in September 1983.

1984.

80.4 It may be useful if I lay out the documents which I have seen on this topic for the purpose of this statement, before returning to the Inquiry's questions.

80.5 On 5 January 1984, I sent a letter to Clive Jenkins [PRSE0001727] in response to his letter of 27 October 1983. I have referred to the correspondence with Mr Jenkins in Section 2, above. In relation to the issue of self-sufficiency in blood products, I referred to the new laboratory under construction at BPL which would enable England and Wales to become self-sufficient. I made the point that the existing laboratory at BPL is "capable of fractionating all the plasma currently available". I indicated that should the situation arise where the plasma supply builds up beyond the fractioning capacity of the existing laboratory, we would need to examine whether any surplus capacity at the Protein Fractionation Centre (PFC) could be used. However, presently PFC did not have the storage, filling and packaging facilities to handle a substantial amount of extra plasma, even if it were available.

80.6 I have now been shown a letter from Dr Harold Gunson, Director of the NTBS, dated 13 February 1984, to Dr E L Harris, the Deputy Chief Medical Officer [DHSC0001966]. This letter outlines Dr Gunson's concerns about plasma supply for the redeveloped BPL. He attaches a report to this letter which is an analysis of options to address this issue of future plasma supply for self-sufficiency [DHSC0001967]. On 15th February 1984, Dr E L Harris responded to Dr Gunson. Dr Harris indicated that DHSS was taking the matter extremely seriously, and following discussions amongst senior DHSS officials it had been

decided that a submission to Ministers would be required [DHSC0046942_114].

80.7 Whilst this response suggests to me that DHSS officials were taking steps to address concerns, I have not been supplied with a copy of any Ministerial submission on the issue. I would have expected to have been briefed, with options if there was real reason to believe that, in due course, a sufficient supply of plasma could not be obtained.

80.8 A DHSS press release, dated 23 March 1984 [DHSC0002239_088], referred to the laying of the foundation stone for the new production unit at the BPL by the then Secretary of State for Health and Social Services, Norman Fowler. I attended this ceremony as well. The press release stated:-

> *".. when the redevelopment is complete, BPL will have the capacity to satisfy the needs of England and Wales for blood products. However, as with any production process, the unit cannot function without the basic raw material – in this case blood plasma. Efficient operation of the new unit will require three times as much plasma as it currently processed. For this we shall look to Regional Health Authorities through their Regional Transfusion Centres."*

80.9 My letter to Mr Jenkins dated 4 April 1984 set out information about the rebuilding of BPL and added [DHSC0001674]:

> *"We are aware of the need for an increased supply of plasma from the National Blood Transfusion Service to feed the new BPL units, and Regional Health Authorities have been set increased plasma production targets. I recognise this has resource implications for Health Authorities in the short term, but the longer term returns will benefit the NHS".*

80.10 A DHSS letter dated 10 August 1984, addressed to all Regional Administrators [CBLA0001870]. This DHSS letter, signed by Mr J A Parker, outlined the concerns that several Regional Transfusion Directors had expressed; they were "pessimistic about their chances of attaining the continued growth in

plasma growth so as to reach the targets set for 1988". Mr Parker stressed the importance that ministers attached to the matter of self-sufficiency. The action required was that the RHAs were to reconsider the steps that were being taken to attain the procurement targets, by 1987-88 now. Mr Parker asked for comments by the end of September 1984. This is not a document that was copied to Ministers.

80.11 A Ministerial submission seeking approval for the increased costs of the BPL redevelopment was sent to me on 20 September 1984; this is covered at paragraph 85 below. This did not discuss plasma supplies, but assumed for the sake of financial analysis that there would be no need for commercial products by 1986/87.

80.12 On 27 September 1984, I gave a speech to the newly formed British Blood Transfusion Society [DHSC0004764_103]. On the topic of plasma supplies, I said:

> *"The Government has accepted the World Health Organisation's recommendation that countries should become self-sufficient in blood and blood products. Our commitment to the importance of self-sufficiency is shown by our current investment of over £24 million in the redevelopment of the Blood Products Laboratory at Elstree. My Department is asking Regional Health authorities to ensure that the Blood Transfusion Service is provided with the resources to increase their collection of blood plasma – this is essential to the success of the Elstree project…."*

80.13 I have been shown a copy of the minutes of the CBLA's meeting held on 28 November 1984 [DHSC0001101], which illustrates how consideration of the topics of plasma supply continued at the official/NBTS/CBLA level. The minutes record that the DHSS representative stated that all RHAs had replied to the departmental letter about plasma supplies sent in August 1984 (see Mr Parker's letter, above) and three or four Regions had been unable to give any commitment in terms of either finance or time to plasma supply. The RHAs would have to be approached individually.

80.14 Later that year, I sent a letter, dated 12th December 1984, to the Chairman of the Haemophilia Society, the Revd Alan Tanner [DHSC0002249_015]. In this letter, on the topic of self-sufficiency, I confirmed that the new production unit at BPL was still on target for completion in January 1986. Furthermore, DHSS was aware of projected shortfalls in plasma procurement in certain regions and officials were discussing the matter with the Regional Health Authorities concerned.

80.15 Finally in early 1985, I sent a letter to Tony Benn MP dated 22 January 1985 [DHSC0003997_101]. I informed Mr Benn that redevelopment of BPL was on schedule for completion by its original date of January 1986 and there had been no delay through the reduction of financing. Furthermore, regions had been reminded of the need to ensure they meet plasma procurement targets set by DHSS in 1981.

80.16 All this material would suggest to me that I had been briefed about concerns regarding plasma supply and I was aware that steps were being taken, at an official level, to address the issue. See further below.

81.1 I have been asked to explain the role that I played in seeking to ensure that the supply of plasma to BPL increased sufficiently to allow for self-sufficiency in England and Wales to be achieved. It would have been for officials, in the first place, to work out a method for ensuring sufficient supply, and Ministers would have been alerted had there been significant risks of failure. From the correspondence and documents above, it does not appear to me that any particular concerns about increasing plasma supply were regarded as requiring Ministerial intervention or decision or were brought to my attention.

81.2 I have further been asked to explain, from my own experience, how the decentralised structure of Regional Transfusion Centres and Regional Health Authorities affected the efforts to increase plasma supplies; and the potential impact of a more centralised system. At this point in time, I am not able to recall the tensions which might have existed between the Regional Transfusion Centres and Regional Health Authorities, or between these bodies and the CBLA/DHSS, as to increasing plasma supplies. I do not think that I can usefully

comment on the advantages or disadvantages of introducing a less decentralised system. I do not think that the topic was considered during my time in office.

81.3 I have also been asked how I and/or the DHSS could influence how Regional Health Authorities and/or Regional Transfusion Centres used their funding to harvest plasma.

81.4 There would have been a dialogue at official level on funding and its use. The letter sent by Mr Parker on 10 August 1984 (see above) is an example of the sorts of pressure or interventions that the DHSS was able to apply or make, and it was (it seems) followed up by discussions with individual RHAs. I have explained that I do not recall being alerted to difficulties requiring ministerial intervention.

81.5 I have been asked whether I was aware of, and did I support, the pro-rata system of plasma supply and distribution to the regions. Furthermore, the Inquiry wishes to know what considerations informed my position and the DHSS's position on this issue. However, I cannot recall the pro-rata system of plasma supply. It does not appear to have been a matter that was considered at a Ministerial level, from the papers I have seen.

81.6 I have further been asked if I was aware of, and did I support, a cross-charging system of plasma supply and distribution to the regions.

81.7 The topic of 'cross-charging' was, I believe, covered at least in part by the financial briefing supplied ahead of a meeting with the CBLA dated 1 November 1983 [DHSC0046951_042] that I have referred to above. If my understanding of the Inquiry's use of the term is correct, 'cross-charging' would presumably have involved (a) charges being levied by the regions for their supply of plasma to BPL and (b) charges being levied by BPL for the blood products supplied in return. The complexities of introducing even a part of such a scheme within the administrative structures of the NHS as they were at that time were outlined in that paper. I have not been supplied with any information to clarify the results of the work done by Wessex RHA and as far as I can now recollect the matter was not further progressed whilst I was in office.

81.8 I have been shown a copy of the minutes of the CBLA's meeting held on 28 November 1984 [DHSC0001101], which illustrates how consideration of the topics of plasma supply and also of charging continued at the CBLA level. I have already set out the discussion on the topic of plasma supply by the Regions, above. There was also a reasonably detailed discussion on the topic of charging for supplies:

"The Chairman subsequently raised the question of charging for products but it was confirmed that this had not been accepted by either DHSS or RHAs at the present time. Dr Harris referred to the last meeting of the National Advisory Committee on the NBTS when it had been agreed to try and establish a charging system within Regions but this was still very much at an elementary stage. The Secretary emphasised the need to have a national discussion with Regional Treasurers on this issue.

The Secretary referred to a recent meeting he and the Director held with officers from the Northern RHA in Newcastle which had not proved too helpful basically because of the Region's lack of knowledge about BPL's range of product and their outdated information on costs.

Dr Gunson expressed the opinion that even the more committed Regions would only provide finance for plasma supply in respect of their own population and he felt that there should be some kind of national integration. Dr Lane [the Director of BPL] felt that plasma procurement could be speeded up by promoting the growth of plasmapheresis, which Dr Gunson had highlighted in his report to the CBLA in January 1984. After further discussion it was agreed that a paper should be prepared within the next two weeks, which would be audited by Dr Gunson, outlining plasma requirement, various options and costs which could be presented to the Policy Division of DHSS with a view of [sic] the preferred option being presented by the Chairman to Ministers as soon as possible."

81.9 There is a reference to a paper being submitted to ministers, but no paper was not sent to me, as far as I can see.

Allocation of resources by Regional Health Authorities and Regional Transfusion Centres

82.1 I have been asked to describe my general experience as Parliamentary Under-Secretary of State on how much influence I, or the DHSS more generally, had on how Regional Health Authorities and Regional Transfusion Centres allocated their resources, and how that influence was exercised.

82.2 I recall in very general terms that there were tensions between on one hand the DHSS and on the other hand Regional Health Authorities and Regional Transfusion Centres. This was to be expected given that the DHSS allocated finite funds. However, I have no recollection of the detail of any tensions. The Minister of State for Health, Kenneth Clarke, led on financial matters and would have had more experience of any tensions that existed.

Time Estimates for the Redevelopment of BPL

83.1 I have been referred to a briefing note on screening tests that was sent to my Private Office on 31 August 1984. The subject of the note, which was detailed, was that of screening tests for HTLV-III, for blood donations. However, the note states as follows at p2: "As Ministers are aware, building of the plant required to extract Factor VIII from blood donations given in this country is going ahead at Elstree and it is expected that self-sufficiency will be obtained by 1987/88" [DHSC0000443].

83.2 I have been asked whether I was aware that the expected date for self-sufficiency to be achieved was 1987/1988, before I received this briefing note.

83.3 As mentioned above, the press release issued on 23 March 1984, when Mr Fowler laid the foundation stone for the new BPL, stated that the project was on time and that completion was due by the end of 1985. I attended this event with Mr Norman Fowler. I understood that to mean completion of the building work; it would take a further period of time to commission the facility fully and start production (see paragraph 79.3 above).

83.4 I have now seen a letter from Mr Alun Williams [BPLL0011039] dated 22 June 1984 to the Secretary to the CBLA. The letter concerns escalating costs and I

would not have seen it at the time. It refers to a "current completion date of 1 January 1986." Whilst not identical to Mr Fowler's date of "by the end of 1985", it is a similar timeline. Absolute precision on a completion date would have been practically impossible.

83.5 I have not been shown any further material relating to slippage in the date for completion of BPL, and therefore the attainment of self-sufficiency, before August 1984. I would therefore assume that the mention, in the Submission about screening tests dated 31 August 1984, was the first time this topic had been raised with me and that I would have become aware of it shortly afterwards. But the submission did not highlight that information in any way, and I do not have any recollection of any slippage in the expected timescale Please see further paragraph 84, below.

Discussions with the Haemophilia Society, December 1984

84.1 I have been referred to a letter that I sent to The Reverend Tanner, dated 12 December 1984, in which I outlined the discussions that I had held with the Haemophilia Society on 7 December 1984. I indicated that the new production unit at Elstree was still on target for completion in January 1986 [DHSC0002249_015].

84.2 Before turning to the Inquiry's questions, it is worth noting that on 18 and also on 19 November 1984, Mr Patten had issued a press announcement in which he said that Britain should be self-sufficient in blood products by late 1986 [PRSE0002251]. He said:

> *"Our multi-million pound development project at Blood Products Laboratory, Elstree, is on target for completion early in 1986 and this should enable us to become self-sufficient in blood products, such as Factor VIII which is a clotting agent required by haemophiliacs, by the end of that year. This will mean that we no longer have to import Factor VIII from abroad." (underlining added)*

84.3 This information was repeated in the submission to the Secretary of State from Dr Smithies dated 19 November 1984, which was copied to my office [DHSC0002309_053]. Dr Smithies noted that "Self-sufficiency in blood products (mainly Factor VIII) will be achieved once the new blood products laboratory (BPL) at Elstree is completed and sufficient plasma is supplied by the regions. This is hoped to be by the end of 1986." She also noted that the CBLA had just announced that all Factor VIII produced at BPL would be heat treated "from next April".

84.4 I have been asked by the Inquiry why I did not give the estimate of achieving self-sufficiency "in 1987/1988" in my letter to The Revd Tanner of 12 December 1984. Moreover, I have been asked if I did otherwise make him or the Haemophilia Society aware of the 1987/1988 estimate (which, to recap, is sourced from the ministerial submission on screening dated 31 August 1984).

84.5 Mr Patten's announcement was, of course, made publicly and Mr Watters of the Haemophilia Society was plainly aware of it. See the minute from Mr Arthur dated 21 November 1984 [DHSC0000217] which indicates that it was Mr Patten's statement that was the trigger for the Haemophilia Society seeking a meeting with me (I agreed via a minute sent on 26 November 1984, [DHSC0001409]). Thus, the information given by Mr Patten on 18/19 November 1984 formed the 'backdrop' to the meeting in early December.

84.6 Also relevant was a letter from the Haemophilia Society dated 28 November 1984, which set out the topics which the Society wished to raise with me [DHSC0002251_016].

84.7 I can see that the response from my office dated 26 November set up a verbal briefing shortly before the meeting with the Haemophilia Society. I do not have any papers recording what was said to me in advance of the meeting, or the suggested information to be supplied to the Haemophilia Society about its concerns, as set out in its letter. The usual practice would have been for a written 'handling' brief, and possibly an oral briefing for this meeting to be supplied by officials, but no copy has been provided to me now. I cannot recall whether the 1987/1988 date possibility was contained in any briefing received.

84.8 However, I would refer the Inquiry to the Departmental statement about completion of the redevelopment of BPL contained in the press announcement from Mr Patten on 18 and 19 November 1984 (see paragraph 84.2 above), and the submission to the Secretary of State from Dr Smithies, dated 19 November 1984, which was copied to my office (see paragraph 84.3 above). As indicated above, both the press announcement and submission state that Britain should be self-sufficient in blood products by late 1986. This is a more reliable time estimate than the submission of August 1984 which addressed this issue only tangentially.

84.9 I have been asked to consider whether there was any tension between the information contained in my letter to the Haemophilia Society, and the estimate contained in the internal minute of 31 August 1984.

84.10 Considering the relevant documents, as outlined above, the most recent information, at the time of the letter I sent to The Reverend Tanner in December 1984, was that Britain should be self-sufficient in blood products by late 1986. This information superseded the internal minute of 31 August 1984. Furthermore, the Haemophilia Society was aware of the announcements of 18/19 November 1984, which spoke of self-sufficiency being attained by the end of 1986. As far as I can see, there was no tension.

Ministerial Submission, BPL Costs Escalation

85.1 I have been referred to a submission sent to Ministers dated 20 September 1984, seeking approval for a substantial increase in the capital cost for the redevelopment of BPL. The submission was sent to my Private Office as well as to the Minister of State for Health. Three options were presented in this submission: abandon the project; redesign to the original budget, suitably inflated to £25.3m; or accept the revised design solution at £38.8m [DHSC0002309_047]. It was noted that, although a decision was needed urgently, construction work had not been halted. The date of completion or any possible slippage were not explicitly mentioned, but I can see that Table 3 on Option C (concerned with the revised, more costly proposals) assumed that

self-sufficiency would be attained in 1986/87 (when the costs of "bought-in products" drops to zero).

85.2 I have further been referred to a minute sent to Sir Kenneth Stowe (the Permanent Under Secretary of State) by Mr Clarke; this was copied to Mr Joyce in my Private Office. This records the Minister of State's response to the submission described above. He made comments about the "fairly woeful lack of cost control" in relation to the redevelopment of BPL. However, he felt that there was "little practical alternative to seeking Treasury approval" [DHSC0002309_114].

85.3 In turn, on 25 September 1984 Sir Kenneth commented: "This is all news to me – which perhaps reveals a lot". He asked for an official to investigate and to report back to him [WITN5282017].

85.4 The Treasury expressed its concern when the situation was raised with it; see the letter from Mr Peet of HMT dated 25 October 1984 [DHSC0002247_105].

85.5 I have been asked to comment about my role, if any, in overseeing the ongoing redevelopment project, and in particular the costs and timetable of that project. These matters would ordinarily have been overseen by officials. Details of the arrangements that had been agreed when the project was set up are set out in the documents I refer to at paragraph 85.7 below. I would expect to have been kept aware of developments that required Ministerial attention.

85.6 In relation to the Ministerial submission of September 1984, I am sure that I agreed that there was no option but to proceed with Option C in the submissions, specifically, to accept the revised design solution at £38.8m. However, I have not been shown a minute recording my response at the time. The correspondence between Mr Clarke and Sir Kenneth reflects the much greater involvement of Mr Clarke in relation to financial matters. That said, I am sure that I shared his views about costs control, as set out in the minute of 25 September 1984.

85.7 I have been asked for my views on why the cost of the redevelopment of BPL expand so greatly during my time as Parliamentary Under-Secretary of State. The cost of the redevelopment expanded for the reasons which were identified

in the submission made to Ministers. Specifically, it was due to the fast track "design and build" scheme which carried considerable risk, and poor estimation and cost control. See further the letter from the Treasury which provides further insight, as well as the briefing sent by Mr Williams on 6 November 1984 [DHSC0002323_131 and DHSC0003615_032] and further notes sent to Sir Kenneth Stowe on behalf of Mr France on 7 November [DHSC0003964_029]. There is a briefing for a Departmental meeting with the CBLA Vice-Chair dated 22 November 1984 [DHSC0002323_015] and a subsequent account of the meeting from dated 23 November 1984 from Mr France [DHSC0002323_016]. I do not believe that these documents were copied to me at the time, but they provide further insight into what had happened.

85.8 A letter from Mr France to Mr Jerwood indicates that Mr Jerwood was due to see the Minister of State for Health in December 1984 [DHSC0002323_098]. The Minister of State for Health met Mr Jerwood in January 1985. Mr France's letter to Mr Jerwood of 28 February 1985 [DHSC0002323_027] sets out that the Minister of State for Health informed Mr Jerwood at this meeting that he expected the cost of the BPL rebuilding project, including the warehouse and quality control facilities, to be met within a total budget cost of £35.3 million. The letter sets out the DHSS's expectations on costs and made it clear that there needed to be early reports of any further difficulties.

85.9 The Inquiry has noted that in a letter to Tony Benn MP, dated 22 January 1985, I stated that there had been "no delay in the project through any reduction in financing", and that it was still on schedule for completion at its original target date of January 1986 [DHSC0003997_101].

85.10 I have been asked whether, to the best of my knowledge, it was correct to say that while the costs of the project had increased by January 1985, this had not caused any delay. That was my understanding at the time, as far as I can recall. A target completion date of January 1986 is consistent with the information in the most recent ministerial submission of 19 November 1984, which did not highlight any slippage in the works. I have noted how, above, the submission of September 1984 on escalating costs does not highlight any slippage. It appears to suggest that self-sufficiency would be attained by

1987/88, but that was in the context of making financial calculations on costs-savings.

Reflections on BPL Redevelopment

86.1 I have been asked to comment on whether I think more could and should have been done to ensure that the redevelopment of BPL was achieved at an earlier point in time, and at less cost.

86.2 It would have been very difficult to have achieved both a quicker completion of the redevelopment and to do so at a lower cost. It is, perhaps, easy with hindsight to criticise the process. But I recall the urgency in the need for the development and hence, presumably, the 'design and build' procurement decision. But perhaps the risks of this process, from a costs perspective, were not well understood by the DHSS.

86.3 I believe that I was not aware of the escalating costs until the submission of September 1984, and I am sure that I fully endorsed the tone of the minute to Sir Kenneth Stowe, as Accounting Officer. I do not believe that I was made aware of the escalating costs issue when I visited Elstree in July 1983 or in March 1984, when the foundation stone was laid.

Co-operation with the PFC and the Scottish authorities

87.1 I have been asked whether I was involved in, or if I had knowledge of, any proposals for the Scottish facilities at the Protein Fractionation Centre (PFC) to be used to produce blood products from plasma supplied from England and Wales. I cannot recall any such proposals.

88.1 I have also been asked whether I was aware of the financial contribution made to the costs of establishing the PFC by the DHSS, referred to in the document at [DHSC0003715_171]). This is an undated document; its contents suggest that it was probably written in around early 1978. It provides an outline of how the PFC was established and the discussions between BPL and PFC with regards to whether Scotland should fractionate any plasma from the North of England up to that date. It shows that DHSS made a financial contribution of

£400,000 to the SHHD towards the cost of establishing the PFC in the early 1970s.

88.2 This financial contribution was made long before I came into office; therefore, I was not personally aware of this contribution. Furthermore, I was not informed by officials about it.

89.1 I have been referred to correspondence between Mr Clive Jenkins and myself in relation to the PFC, and co-operation England and Wales for fractionation of blood products:

a. Mr Jenkins' letter to me dated 27 October 1983 [DHSC0002235_041];

b. My reply to Mr Jenkins dated 5 January 1984 [PRSE0001727];

c. Mr Jenkins' further letter to me dated 14 February 1984 [DHSC0001672];

d. My reply to Mr Jenkins dated 2 April 1984 [DHSC0001674];

e. The letter from John MacKay, Minister for Health and Social Work at the Scottish Office to Mr Jenkins dated 14 May 1984 [MACK0002271_012];

f. An internal Scottish Office minute regarding this correspondence dated 10 May 1984, and the minute of 4 October 1983 to which reference is made [SCGV0000118_007 and SCGV0000118_011];

g. Mr Jenkins' letter to Mr MacKay, 31 August 1984 [SCGV0000118_012].

89.2 In response to the specific questions I have been asked about these documents:-

89.3 I have been asked, first, why I was of the view that the blood products needed for England and Wales should be provided solely by the redeveloped BPL, rather than through the use of PFC. As I indicated in my letter of 2 April 1984, the intention was that the redeveloped BPL would meet the needs of England and Wales, and the PFC would concentrate on the needs of Scotland and Northern Ireland [DHSC0001674]. I understand that capacity at the new BPL had been designed on that basis.

89.4 Further, as I indicated in my letter of 5 January 1984, my understanding at the time was that PFC would not have the storage, filling and packaging facilities to handle a substantial amount of plasma [PRSE0001727]. This would suggest to me that PFC would not have had the capacity to assist England and Wales, without further redevelopment at PFC. (Mr Jenkins' letter of 27 October asserted that PFC "could increase its capacity" – he did not suggest that the capacity was there, without the need for further development).

89.5 I have further been asked whether I gave any consideration to exploring the possibility of PFC producing at least some product for England and Wales as a short-term measure; and if not, why not.

89.6 I am sure that this would have been discussed at official level. I believe that given the urgency of the need for Factor VIII, I would have asked officials about the possibility of PFC producing some product for England and Wales. But I note that my letter to Mr Jenkins stated: "At present however the existing laboratory at Elstree is capable of fractionating all the plasma currently available. Should the situation arise where plasma supply builds up beyond the fractionating capacity of the existing laboratory, we should need to examine whether any surplus capacity at the Protein Fractionation Centre could be used." I then went on to make the point already discussed, about PFC's inability to handle a substantial amount of plasma, even if it were available.

89.7 I have been asked whether the growing knowledge of the risks associated with imported blood products in 1983 and 1984 altered my thinking or approach and if not, why not.

89.8 I was always concerned about the balance to be struck between the possible risk of transmission by contaminated blood products, on the one hand, and the certainty that not providing Factor VIII could be life-threatening, on the other. I understood the former risk to be small, particularly when compared to the latter risk. My concerns are demonstrated in the letter I sent to the Revd Alan J Tanner, dated 28 September 1983 [DHSC0002071]:

89.9 However, I do not recall being advised by officials that there was a real possibility that plasma supplies could have been increased to such a point that BPL would have a notional 'surplus' that could not be processed by it; and which therefore could or should have been processed by PFC instead.

89.10 I have been asked if, reflecting on these matters now, I consider any further or different steps could have been taken at that time in respect of co-operation with the PFC and the Scottish authorities to advance the achievement of self-sufficiency in England and Wales.

89.11 This question demands a full knowledge of the investigations that had been carried out by officials into transferring production to Liberton, before I took office, and of the reasons why it was not thought to be feasible. These are not matters I was involved in, and when I was in the DHSS, I never received advice suggesting that this was a possibility that needed to be explored further. I am sure that officials would have kept this possibility in mind, when considering BPL in the years that followed. For example, I have been shown a note from Dr Oliver in October 1983, when he 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]. But I think that the question of whether "more could have been done" is a matter that would need to be considered by those who were familiar with what would have been required, within PFC and in the blood service more generally, to have shifted production.

Section 4: Other Matters

Hepatitis and Blood Products

90.1. I have been asked what, if any, advice or information or briefing was provided to me when I first took office about the risks of transmission of hepatitis in blood and blood products.

90.2. All the advice and information I received, including about the risks of the transmission of hepatitis in blood and blood products, was from written and verbal briefings by officials. However, as I have explained, there are no copies now available of the initial written briefings that would have been provided to me on arrival in office, and it is impossible to recall now what was said. In general, I would have been given written briefs on some issues, verbal on others, and more in-depth briefings when particular issues arose (e.g. Parliamentary Questions).

90.3. I have been further asked if I was given any advice, information or briefing(s) about the nature and severity of different types of blood borne hepatitis (in particular what was then called Non-A, Non-B hepatitis) and the relative risks of infection from the use of commercially sourced blood and blood products, and how this changed during my time in office.

90.4. I can remember, in general terms, that one of the drivers for self-sufficiency was the belief that US products were more likely to be a source of viral infection; but by the time I was in office, the reasons behind the policy of attaining self-sufficient were not necessarily spelled out in submissions. See, for example, the submission of 20 September 1984 [DHSC0002309_047]; the BPL costs escalation is discussed with little reference to underlying reasons for adopting the policy initially. There is merely a short statement, at the bottom of p2, that "The need for self-sufficiency has been emphasised by the association of AIDS with imported blood products". In general terms, my knowledge and understanding grew throughout my time in office, and my source of knowledge was drawn from briefings by officials in what was a technical, scientific and clinical area.

90.5. It is impossible to be more definite without referring to specific documents. For example, I note that in a press release from the DHSS dated 27 September 1984, reporting my speech on the "Changing Demands on the British Transfusion Service" [DHSC0004764_103], I likened the progress in research regarding the detection of AIDS in blood to that of the research of the detection of hepatitis, commenting there is 'much work yet to be done'.

91.1. I have been asked how my knowledge developed during my time in office. This is a question that can now only be answered by reference to any submissions or other written information supplied to me at the time. See question 92, below.

Steps to Protect against Hepatitis Risks

92.1. I have been asked to provide, insofar as I am able to do so from the documents provided or available to me, and from my own recollection, a chronological account of any involvement and knowledge I had of the steps taken by, or at the request of, the DHSS during my tenure as Parliamentary Under-Secretary of State to address the risk of people being infected with hepatitis, and in particular Non-A and Non-B hepatitis, as a consequence of treatment with blood and blood products.

92.2. I have already provided information about the progress towards self-sufficiency, by the redevelopment of BPL. As the Inquiry will be aware, a major impetus for the decision to rebuild BPL was the concern about hepatitis infection risks associated with the import of foreign plasma.

92.3. Further work on hepatitis risk reduction would have related to research efforts, into matters such as heat-treatment. These matters were essentially complex scientific and medical matters, which required expert understanding and input. I received some information about research work, but it was not work in which the DHSS had a direct involvement – that is, it did not itself carry out research work. Thus I can see that:

a) In my letter to the Haemophilia Society in September 1983 [DHSC0002071], I commented that research into genetically engineered Factor VIII (which would not carry the risks associated with human plasma) was being "intensively researched" but it could not be estimated when such material might be available;

b) I received information about the development of heat-treatment at BPL, again covered above, but submissions focussed on AIDS rather than hepatitis; see for example the update on AIDS received on 19 November 1984 [DHSC0002309_053].

92.4. Looking at the documents now, it seems that concerns and information to me were focussed on the issue of AIDS. This does not mean that officials lost sight of hepatitis risks. I understand that the Inquiry will have access to information about research efforts continuing at BPL or amongst commercial manufacturers. But I have been shown a note dated 20 November 1984, for example, from Dr Smithies (Med SEB) to Dr Alderslade. She noted that:-

> *"Commercial heat-treated Factor VIII is not licensed in this country and prescriptions for its use have to be on a name[d] patient basis.* ***Pilot trials have shown that heat treatment does not inactive the non-A, non-B hepatitis agent against which the heat treatment was originally developed.*** *Dr Lane [the Director of BPL] has now been asked to provide a programme of the intended introduction of heat treated Factor VIII in order to let us know how soon the first batches will be available to haemophiliac patients in the UK." (bold emphasis added).* [DHSC0002249_034]

92.5. It seems to me that this shows that the issue of hepatitis had not been forgotten by Medical Officers, but there was nothing which they considered it necessary to ask Ministers to intervene upon.

92.6. I believe I may have understood that heat treatment to prevent Non-A and Non-B hepatitis was different to that of heat treatment for AIDS, but I cannot now be

sure. As I have commented above, discussion of the introduction of heat-treatment tended to focus on its protective effect against AIDS. See for example my statement to the House of Lords in the exchanges following the unstarred question on 18 March 1985.

Correspondence with A.W. Barrell, December 1984 and January 1985

93.1. I have been referred to a letter of 7 December 1984 from A.W. Barrell of the pharmaceutical company Travenol that was addressed to me [DHSC0002335_054] and asked if I knew Mr Barrell personally. I can confirm, I did not know Mr Barrell personally.

93.2. I do not remember having a "brief chat" with Mr Barrell at the Carlton Club, as he claims in his letter and I do not remember meeting him. I have checked through my personal diary, but it does not help. I can only speculate that I was there, and he saw me and raised the issue of his products. However, as set out this is not something that I recall.

93.3. I do not remember any earlier correspondence Mr Barrell refers to in his letter and this has not been supplied to me. I see that in a letter to me from Mr Eric Deakins MP (14 January 1985, [WITN5282018]), Mr Deakins refers to a previous letter from Travenol dated 8 November 1984; but I have not been supplied with a copy of that letter and so it seems that it never reached me from the Ministerial Correspondence Unit. It seems to have been unavailable to officials at the time [WITN5282019]. As a result, my reply (23 January 1985) referred only to the letter of 7 January.

93.4. I have been asked to explain the assertion that Travenol had previously "...offered every conceivable supportive measure we could think of to accelerate the introduction of newer methods of blood collection and processing to assist the Transfusion Service and the [CBLA] to move to self-sufficiency". I do not know what was meant by this assertion, nor do I know what support, if any, was offered and when.

93.5. My response was to pass the details of the letter to officials to pursue, as my letter dated 23 January 1995 [MACK0002659_016] indicates; see below.

Response to Mr Barrell

94.1. In response to Mr Barrell, I sent a letter dated 23 January 1985 [MACK0002659_016] saying that Dr Alison Smithies (a Senior Medical Officer in Med SEB) would contact him shortly about the matters that he raised. I replied in this way because I regarded this as a matter to be handled at official level.

94.2. I do not believe I was kept informed of any further contact Dr Smithies had with Mr Barrell.

94.3. I can see from my letter to Mr Deakins MP dated 19 February 1985 [DHSC0002261_077] that Dr Smithies organised a meeting with various officials from Travenol. I have now been shown a copy of the letter sent by Travenol's Business Manager to Dr Smithies following their meeting: see DHSC0001477, not in bundle], letter dated 18 March 1985. These were matters that were being handled at official level and would have come to ministers only with submissions and further explanation, if decisions were required.

95.1. I do not think I can add anything more.

DHSS relationship with pharmaceutical companies

96.1. I do not believe that I was involved with any interaction between ministers and officials in DHSS, on the one hand, and pharmaceutical companies, on the other. I have explained above how my letter to Travenol's Mr Barrell came to be sent. I am aware that officials within the DHSS would have been required to collaborate with the industry on many matters (e.g., on licensing matters). I do not recall being aware or concerned about such companies exerting excessive, undue or improper influence on policies or decisions.

Role of the Chief Medical Officer

97.1. I have been asked my understanding of the role of the Chief Medical Officer (CMO). My memory is that he had a substantial body of staff reporting to him. Responsibilities in different fields would have been delegated to his staff, some of whom would have worked in my areas of responsibility. I do not expect that the CMO would have been involved in every detail. He would have relied on his staff.

97.2. I have seen a few documents that help to illustrate the role of the CMO during my tenure as Parliamentary Under-Secretary of State.

97.3. For example, in a minute from Robert Oates to Miss Edwards providing Dr Harris' comments on HEC AIDS health education leaflet dated 22 August 1984 [DHSC0002245_038], Dr Harris, who was acting CMO at the time, says he is content for officials to discuss with the Health Education Council their production of a health leaflet on AIDS. He also provided suggestions for amendments to the leaflet.

97.4. As already mentioned in this Statement, the CMO set up an Expert Advisory Group on AIDS in late 1984. Its first meeting took place on 29 January 1985: see [WITN5282020]

97.5. I have referred to the advice the CMO sent to Mr Clarke, in response to the latter's questions about HTLV-III screening (see the minute of 31 January 1985, [WITN5282021]).

97.6. I have also seen a press release from the DHSS dated 20 February 1985 [DHSC0101892], which notes that the CMO "will shortly be writing to all doctors giving guidance on the clinical features and public health implications of the disease", i.e. AIDS. This Circular was ultimately issued after I had left the DHSS, on 15 May 1985: see [DHSC0105232, attached].

98.1. I have been asked whether I personally gave consideration to asking the CMO to issue guidance, advice or instructions, etc., on issues such as (i) the risks of infection from blood or blood products, (ii) the information to be provided to patients regarding such risks or (iii) the circumstances in which patients should or should not receive treatment with blood or blood products. In practical terms, the response to AIDS was generally – although not exclusively, see above - being handled at DCMO level, or even below that, and the advice I received seemed full and cogent, and did not suggest that such steps were needed. I cannot reliably say now whether any one of these issues might have been raised or debated by me with Senior Medical Officers - it would be speculation now, after so much time has passed.

98.2. As to the question of advice to clinicians on testing patients with haemophilia for HTLV-III, the testing for HTLV-III was just being developed during my time in post. See further paragraph 99.6 below.I have been asked whether it was part of the role of the DHSS to issue guidance, advice or instruction to clinicians and health bodies as to (i) the risks of infection from blood or blood products (and in particular the risks associated with AIDS); (ii) the information to be provided to patients regarding such risks; (iii) the circumstances in which patients should or should not receive treatment with blood or blood products; or (iv) the approach to be taken to testing patients with haemophilia for HTLV-III/AIDS.

99.2. The Department did, at times, issue advice of various types, to different groups. Examples of this are:

- **For blood donors:** The 'AIDS and how it concerns blood donors' leaflet, issued in 1983 and revised in 1984 and addressed to donors. This was done in conjunction with the Regional Transfusion Directors;
- **For NHS employees/managers:** The Health Circular HS(85)1 which contained interim guidelines to safeguard medical, nursing and other healthcare staff from exposure to AIDS at work. These were drawn up by the Advisory Committee on Dangerous Pathogens (see my speech to the House of Lords on 18 March 1985, [HSOC0018710].

- **For doctors and clinical staff more generally**: circulars giving information about public health or about public health initiatives: the roll-out of vaccines might be an example, or the CMO circular on AIDS referred to above. This drew together a number of pieces of information on AIDS. It is interesting that Dr Acheson wrote in the introduction:

  "I take the liberty of sending this information because AIDS is a new disease (the first UK case was diagnosed in 1981) about which information has not yet got into textbooks but which has been widely discussed by the media often in an inaccurate and misleading way. Although at the time of writing only 159 cases have been reported, AIDS will undoubtedly become substantially more frequent in the immediate future and cases will occur more widely throughout the country."

99.3. Since the DHSS as Licensing Authority would have had a role in the licensing of blood products, staff working in this area may have had some role in considering information carried on any product labels or information leaflet. This was a very specialised area in which I had no involvement at all when at the DHSS. I do not remember any discussion of this issue with officials at the time and think that the work of the Medicines Authority and Licensing Division was separately handled.

99.4. In relation to direct advice from the DHSS to clinicians (or their patients) about the risks of blood products, I do not think that this would have been considered appropriate. Again, the treatment of haemophilia was a specialised area of expertise, and the Department was in the position of receiving information and advice from the clinicians concerned (for example, Dr Gunson was the Department's Consultant Advisor on Blood Transfusion; or the CSM-B provided advice in July 1983, as I have discussed). As far as I am aware, the Department did not have any information about risks that was not available to those clinicians, and I do not think that the Department would have felt it appropriate to have offered guidance in those circumstances.

99.5. I can see that one of the documents which was sent to me, for information, whilst I was at the DHSS was the booklet "AIDS and the Blood" published by the Haemophilia Society in February 1985, but written by Dr Peter Jones [HSOC0001554]. Pages 26 – 27 and pages 42 – 43, for example, gave advice on treatment and demonstrate the complexities of the choices to be made. As far as I can now recall thinking at the time, I would have expected the DHSS to take the view that it was the expert practitioners at the Haemophilia Centres who would be best placed to advise their patients about risks and appropriate treatment. I cannot remember any suggestion being raised that guidance was needed, or that the DHSS should provide it.

99.6. As to the approach to be taken to testing patients with haemophilia for HTLV-III/AIDS, this was an issue which was handled primarily, as far as I can remember (or see now) by the medical advisors in the DHSS. I have referred to the first meeting of the Expert Advisory Group on AIDS, on 29 January 1985. I would not have been sent those minutes at the time. But looking at them now, I can see from paragraph 23 (p4) that a sub-group of clinical experts was set up to consider "the various aspects of screening tests for AIDS, in particular the best way of introducing the service when the tests became available." [WITN5282020]. I would have expected groups like this to consider whether or not guidance on any issues relating to the test were needed.

Response to Baroness Masham, 14 July 1983

100.1. I have already referred to the answer I gave to a parliamentary question from Baroness Dudley in Parliament on 14 July 1983 [DHSC0002229_085]. Amongst other things, I stated that the Medical Research Council had established a working party to coordinate research into the disease.

100.2. I made this statement because it would have been in my briefing papers. See my previous explanations about the nature of these answers and how I was briefed.

100.3. I have seen the letter of 15 July 1983, sent by Sir James Gowans (secretary of the MRC) to the Chief Medical Officer, Sir Henry Yellowlees, which suggests that my answer was "untrue" [MRCO0000439_158]. I was certainly unaware that any statement I made was inaccurate or not true.

100.4. The reason why I was briefed in this fashion probably emerges from a record of a departmental meeting held on 3 June 1983 [DHSC0002229_030, attached]. This is not a minute that I was sent or would have seen at the time, but I have been shown it as part of the preparation for this statement. I can see that there were a large number of senior officials attending, both from the Department but also from the National Institute for Biological Standards and Control (NIBSC). It is apparent that Dr Joseph Smith, the Director of NIBSC, reported that a Medical Research Council (MRC) group on AIDS was shortly to be established.

100.5. Although there is no copy of the briefing I was given for the Parliamentary Question on 14 July 1983, the protests of the MRC suggest that Dr Smith's statement (or, perhaps, any further follow-up information obtained by officials) was somewhat premature. The letter from the MRC states that there had been an invitation issued for an "informal discussion" (on 29 July 1983) only.

100.6. With regards to the note of 19 July 1983 reporting on further discussions [MRCO0000439_147], I was not aware of it. This note was never bought to my attention. I can see from it that Sir Henry raised the matter with Sir Kenneth Stowe (the Permanent Secretary at the DHSS), who in turn was advised on what the MRC wanted to see conveyed to the press if there were any enquiries.

100.7. As I was not made aware of any error or misstatement, I never attempted to correct the statement or record. If I had known, I would have sought advice on whether a correction should have been made in the Parliamentary record. Looking at the correspondence, it appears that Sir Kenneth did not consider that further action was needed. I am not aware of his reasoning, but I note that

an MRC Working Group on AIDS was set up as a result of the informal discussion that took place at the end of July 1983; its first meeting took place in October 1983.

Later roles

101.1. As Minister of State for Scotland, from September 1986 until June 1987, I had responsibility for health under the Secretary of State for Scotland, Mr Malcolm Rifkind. I do not recall detail about blood or blood products per se, but I do recall being advised to, and agreed to, needle exchange in order to prevent cross-contamination of AIDS, hepatitis and other diseases by drug abusers. I recall press criticism of this announcement.

102.1. At the time, I would have had overall responsibility for blood, blood products and related matters, and recompense and support for people infected and affected by HIV and hepatitis as a result of transfusions of blood and blood products, but I am now unaware of the detail and have no records.

102.2. My personal diary notes that I had a meeting with, or about, Gavin Strang MP in relation to AIDS on 7th January 1987, but there is no other reference to AIDS or blood/blood products in my diary. I do not recall visiting the PFC.

102.3. I recall that I did attend the Cabinet Home Affairs and Social Affairs Sub-Committee on AIDS at their London meetings on occasion, in particular about the warning films for public broadcasts highlighting the danger of AIDS and the importance of minimising risk. This would have been at the time when wider public health campaigns on AIDS were taking place.

102.4. Thus, I can see that that in my capacity as Minister of State for Scotland I attended a meeting of the Cabinet Home Affairs and Social Affairs Sub-Committee on AIDS on 9 April 1987. There were several agenda items including discussion of the memorandum H(A)(87)12: "AIDS: Improving the database". My contribution to the discussion focussed specifically on the spread of HIV amongst drug users in Edinburgh and Dundee. I informed the committee

of the proposal to set up a system of voluntary antenatal screening in those cities. For clarity, the issue here was not the use of donated blood products as such, but rather the specific risk of mother-to-child transmission during pregnancy and involved voluntary participation only.

Section 5: Reflections on relevant events

103.1. I have been asked whether I believe that the Government responded to the risks posed by infected blood and blood products in a timely manner.

103.2. My own belief is that, when judged by the information that was available at the time and the policy options available, the response to the risks posed by infected blood and blood products was as timely as it could have been. The lack of knowledge about AIDS, our lack of self-sufficiency in blood products and a host of other factors, including the increasing prevalence of drug misuse and needle sharing that ultimately proved to contribute to the spread of AIDS within the population (including in those who gave blood in the UK), seriously hampered our ability to respond.

104.1. I do not believe that, given the weight of expert opinion with which I was briefed at the time, there was much more that could have been done. With hindsight, it would have been ideal to have had our own full availability of blood products, first mooted in the 1970s, but progress there was obviously far too slow. But dealing with the reality that faced Ministers when I came into office in 1983, I was aware throughout, as were officials on both the policy and medical sides, that there were a series of risks which had to be balanced. I gave those risks careful consideration – as I have tried to explain, I was worried and troubled by the situation, and I tried to press for a speedy response when actions were suggested to me for the Department to take. But I was advised that there were no viable alternatives to reliance on imported blood products; and this seemed to be the general view, shared by a patient body such as the Haemophilia Society.

105.1. Reflecting more generally, and drawing on my wider experience of government, perhaps the major decision that could and should have been made was to improve the BPL facilities at an earlier stage and to remove our reliance on imported blood factors. But I am not in a position to comment on the history of that matter.

106.1. I am not aware of any structural difficulties or failings within the way in which health policy in the United Kingdom was administered that either increased the risk of infected blood and blood products being used in any part of the country, or prevented a more effective response to those risks.

107.1. There are almost certainly lessons that can be drawn from the events with which the Inquiry is concerned with that are applicable today. But this is a matter for the Inquiry, which will have a broader oversight than I possess.

108.1. I have been asked if I have anything more to add. I believe that I have covered as much as I can in relation to a matter with which I was dealing some 38 years ago, and in which I had no prior knowledge or experience. It is without doubt that the decisions taken at the time have had tragic consequences for many: this is deeply troubling. However, the decisions taken were on the best scientific, clinical, administrative and well-meaning advice available at the time, and it is very difficult to use contemporary attitudes and scientific advances to gainsay the decisions taken at the time.

Parliamentary interventions

109. I have been asked to provide a chronological list of all Parliamentary contributions made during my tenure as Parliamentary Under-Secretary of State for Social Services on matters relevant to the Inquiry's Terms of Reference. I have listed in the table at Annex A those which have been brought to my attention for the purpose of providing this Statement. I have provided the links to Hansard online where available. The list is complete to the best of my understanding.

Annex A

Date	Hansard Reference	Topic	Link	Exhibit number where applicable
14 July 1983	HL Deb 14 July 1983 vol 443 cc894-6	AIDS: Incidence and Control	https://api.parliament.uk/historic-hansard/lords/1983/jul/14/aids-incidence-and-control	
09 November 1983	HL Deb 09 November 1983 vol 444 cc802-917	The National Health Service	https://api.parliament.uk/historic-hansard/lords/1983/nov/09/the-national-health-service	
05 December 1983	HL Deb 05 December 1983 vol 445 cc873-5	Blood: Licensing Requirement	https://api.parliament.uk/historic-hansard/lords/1983/dec/05/blood-licensing-requirements	
08 February 1984	HL Deb 08 February 1984 vol 447 c1261WA	Notifiable Disease	https://api.parliament.uk/historic-hansard/written-answers/1984/feb/08/notifiable-disease	
18 March 1985	HL Deb 18 March 1985 vol 461 cc358-87	AIDS: Prevention and Control	https://api.parliament.uk/historic-hansard/lords/1985/mar/18/aids-prevention-and-control	

Statement of truth

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

Signed GRO-C

Dated 8th July 2024