Witness Name: Kenneth Clarke
Statement No.: WITN0758001
Exhibits: WITN0758002 – WITN0758011
Dated: 1 July 2021

INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF KENNETH CLARKE

Contents

Opening Comments, Statement Structure and Exhibits

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006, dated 18 December 2020.

I, KENNETH HARRY CLARKE, will say as follows: -

0.1. I have been asked by the Infected Blood Inquiry to provide a witness statement regarding my involvement in the issues covered by the Inquiry's Terms of Reference during my period of office as the Minister of State for Health in the Department for Health and Social Security ("DHSS"), from March 1982 to September 1985. A further request has been sent to me addressing later periods of my career in Government; these are not, therefore, covered in this Statement.

Opening Comments

0.2. I would like to make the following comments before I address the Inquiry's questions.

0.3. The infection of men, women and children with HIV and other blood borne diseases, including hepatitis, through the blood and blood products they were treated with is one of the worst tragedies in the history of the NHS. It has obviously had fatal and disastrous effects on the lives of very many people and their families. I offer my sincere condolences to all those who have suffered as a result of this disaster.

0.4. My time as Minister for Health coincided with the emergence of the AIDS crisis, which was a major issue for the DHSS at the time. I have reflected on the issue of HIV / AIDS in haemophiliacs in particular and asked myself, with all the benefit of hindsight and the knowledge that we now have, what might have made a difference to the outcome for the haemophiliacs who were tragically infected. It appears to me that there are two crucial issues in this respect. The first is whether the NHS should have, at any stage, stopped prescribing Factor

VIII to haemophiliacs. This was essentially a question to be addressed by specialist doctors who treated haemophilia and I think they, together with their patients, were faced with the desperate problem of balancing risk. Whilst there were concerns about Factor VIII, the specialist doctors obviously decided that the balance of risk did not justify the detrimental effect that withdrawal of Factor VIII would have on their patients' lives. The Haemophilia Society, I now see from the documents, seems to have agreed with this at the time. The second is whether heat-treatment of Factor VIII or other blood products, which proved to be the solution to the problem for haemophiliacs, could have been developed more quickly. This is ultimately a matter of scientific opinion, but I have no reason to suspect that the breakthrough could have been achieved earlier.

0.5. As Health Minister, I was not personally involved in either of these two issues, which were clinical rather than political in nature. I have given an account of those matters in which I was involved in this Statement, as explained further below.

0.6. I would also like to note that since the events addressed in this Statement took place approximately 40 years ago, or a little less, I have only limited memory of the events about which the Inquiry asked and certainly no detailed recollection of them. I am very heavily dependent on the documents that have been brought to my attention, whether directly by the Inquiry or by further documentary searches conducted by my legal advisors. Their contents have been summarised in this Statement. If it is apparent that the documents that I have seen or been referred to are incomplete or partial, I have tried to draw attention to this in this Statement. If further material is brought to my attention, I will revise the Statement as needed.

0.7. In addition, when I was Minister of State for Health, the areas of responsibility for which I had primary Ministerial responsibility did not include matters of blood policy. I have explained this in more detail below. But, as a result, I saw only a small amount of the detailed work that was done on the areas of Departmental policy which fall within the Inquiry's Terms of Reference.

0.8. My understanding is that the Inquiry is seeking my personal account and my personal recollections of events, in response to the questions that have been asked. As a result, this Statement concentrates on those matters that were brought to my attention and into which I had input. It does not attempt to set out a broader account of the DHSS' response or its actions as a whole. If I have been asked such broader questions, but was not personally involved, I have indicated this in response to questions. These are the matters on which I cannot provide any additional insight. I hope that this Statement will nevertheless contribute to an understanding of events, if read with the documents and information that others involved at the time are also able to provide.

0.9. I understand that my Statement, and the information available to the Inquiry, is or will be supplemented not only by the extensive disclosure of the DHSS documents of this period (including by those transferred to the National Archives), but also by further detailed accounts from those who were more involved in the areas covered by this Statement.

Structure of the Statement and Exhibits

0.10. A Table of Contents has been included at the outset, for ease of navigation. I have adopted the same section numbering as that used by the Inquiry in the Rule 9 Request of 18 December 2020.

0.11. Where a document has been drawn to my attention by the Inquiry in the Rule 9 Request and is already available on the Inquiry's Relativity Database, I have included the Inquiry's Relativity document ID number in the body of this Statement. All other documents that I refer to are exhibited (exhibits WITN0758002 to WITN0758011).

Section 1: Introduction

1.1. My name is Lord Kenneth Harry Clarke of Nottingham. My professional address is the House of Lords, London SW1A OPW.

Career Within Government

1.2. I have been asked to set out details of my career.

1.3. I was born on GRO-C 1940. After obtaining a scholarship to Nottingham High School, I studied law at Cambridge University. On leaving university, I initially worked as a barrister, being called to the Bar in 1963. I first entered parliament as the Member of Parliament for Rushcliffe in June 1970. I held that seat until 6 November 2019. I held the title of the Father of the House of Commons from 26 February 2017 to 6 November 2019. At that point, I decided not to seek re-election in the General Election that was called. I was subsequently made a Member of the House of Lords and have sat in the Lords under the title of Lord Clarke of Nottingham since 17 September 2020.

1.4. I have held the following positions within Government:

a) Assistant Whip (HM Treasury): 1 January 1972 – 1 January 1974;
b) Whip (Lord Commissioner, HM Treasury): 1 January 1974 – 1 March 1974;
c) Parliamentary Secretary (Ministry of Transport) and later Parliamentary Under-Secretary (Department for Transport) (Roads and Motoring): 7 May 1979 – 5 March 1982;
d) Minister of Health (Department of Health and Social Security): 5 March 1982 - 1 September 1985. (I was preceded in this role by Dr Gerard Vaughan and succeeded by Barney (later Lord) Hayhoe);
e) Minister of State for Employment: 2 September 1985 – 13 June 1987;
f) Paymaster General (HM Treasury): 2 September 1985 – 12 June 1987;
g) Minister of State (Department of Trade and Industry): 13 June 1987 – 24 July 1988;

h) Chancellor of the Duchy of Lancaster (Duchy of Lancaster Office): 13 June 1987 – 24 July 1988;

i) Secretary of State for Health (Department of Health): 25 July 1988 – 1 November 1990;

j) Secretary of State for Education and Science: 2 November 1990 - 9 April 1992;

k) Home Secretary (Home Office): 10 April 1992 – 26 May 1993;

l) Chancellor of the Exchequer (HM Treasury): 27 May 1993 – 1 May 1997;

m) Lord Chancellor and Secretary of State for Justice (Ministry of Justice): 12 May 2010 – 6 September 2012;

n) Minister without Portfolio (Cabinet Office): 6 September 2012 – 14 July 2014.

1.5. I have been asked to describe my roles and responsibilities in each position. Given the number of positions I have held within Government, and the detail that a description of my roles and responsibilities in each position would require, generally relating to areas that are not of relevance to the Inquiry's work, I have limited the description of my roles and responsibilities to my period as Minister for Health, addressed in response to the Inquiry's Q7 below.

Q3: Membership of Committees, etc

1.6. I have been asked about membership of or involvement with any committees, associations, parties, societies, groups or organisations relevant to the Inquiry's Terms of Reference. I have not been involved in any such groups.

Q4: Business Interests

1.7. I do not have any private or business interests which are relevant to the Terms of Reference.

Q5: Involvement in Inquiries and Litigation

1.8. I have been asked about any other inquiries, investigations, criminal or civil litigation that related to HIV, to Hepatis B or C infections, or variant Creuzfeldt-Jakob disease (vCJD), including in the HIV litigation that was settled in 1991.

1.9. I confirm that at the time of the HIV litigation (and specifically, from 25 July 1988 to 1 November 1990) I was the Secretary of State for Health. The topic of my involvement, until I left the DHSS for the Department of Education and Science on 2 November 1990, is addressed in my Second Statement. As explained in that statement, I was not involved in the case thereafter.

1.10. I would need to review papers to confirm whether I had any further involvement in any later matters related to any other inquiries or investigations, etc, and am happy to do so if this information is provided to me.

Section 2: Decision-Making Structures

Q6: Function of the DHSS

2.1. I have been asked to describe my understanding of the functions and responsibilities of the DHSS during my tenure as Minister of State for Health. The Inquiry will be aware that at the time, the DHSS was responsible (in England) for the administration of the National Health Service (NHS). In addition, it was responsible for the social services provided by local authorities to the vulnerable in society, and for some aspects of public health. It was responsible (throughout Great Britain) for the payment of benefits and the collection of contributions under the National Insurance and Industrial Injuries scheme, and for the payment of various social security or welfare benefits.

2.2. Perhaps it is obvious, but it is worth noting that the DHSS was not responsible for treatment decisions relating to individual patients. These lay in the hands of the treating doctors, whose clinical freedom to make such decisions was carefully guarded.

2.3. The breadth of the health issues being dealt with by the DHSS when I was Minister of State for Health should not be underestimated. I have made brief comments on some of the immediate challenges at the time, below.

Q7: Role of the Minister of State for Health

2.4. From the point of view of Ministerial responsibility, at that time the DHSS was split into two, with a Minister of State for Health and a Minister of State for Social Security.

2.5. I have explained in my autobiography 'Kind of Blue', first published in 2016, how at the time of my appointment, Mr (now Lord) Norman Fowler, the Secretary of State for Health, was handling massive welfare reforms with his social security Minister, Tony Newton. I was left to be the Minister with day-to-day responsibility for the NHS for most of the time. Whilst I had considerable

autonomy and discretion, the range of issues and conflicts was huge, and the service was in a state of continuous national and local crisis. I became persuaded of the need for reform, something I took up when I later became Secretary of State for Health.

2.6. The immediate crisis on my appointment was the national strike within the NHS which started 4 days after my appointment and was not resolved until the end of 1982 (the longest strike of the century, at that point). The dispute was provoked by the Government's move to a system of strict cash limits for all departments and led to bitter confrontations across hospital picket lines throughout the country.

2.7. I have described in my autobiography how the more general underlying task was:

"to get hold of this Leviathan [the NHS] and seek to deliver the service, whilst at the same time trying to reform it. And to get growth in the service delivered out of the money we had available, we had to constrain cost in some way that didn't damage the service.

We had two fundamental problems as we set about this task. One was that there wasn't a management system worth the name. There was next to no management information of any kind ... The other was that we could not have a grown-up debate about reforms, because the constant mantra that everything wrong with the NHS was down to Tory cuts drowned out anything sensible we tried to say." [1]

2.8. By the 1980s the NHS had become the biggest employer in the country, but lacked any coherent system of management. The "consensus management" introduced in the mid-1970s had totally failed. As I said in my autobiography:

[1] *Kind of Blue: A Political Memoir*, (Electronic Edition, Pan Macmillan, 2017), Chapter 9, pp. 125-126

"The country was divided up into over 190 district health authorities who all did their own thing with varying degrees of success and attributed to the centre any problems or failings that arose. The machine at the centre tried to help me to field all the flak and persistently tried to advise and intervene on all the difficult issues. The new system of cash limits brought all of this into sharp relief." [2]

2.9. It was against this background that Roy Griffiths was appointed to examine NHS management (see further below).

2.10. I have set out these very brief, personal and necessarily subjective recollections of my time as Minister of State for Health as, in my view, the political context helps to explain both (i) the cash and management constraints under which the system operated; and (ii) the limited involvement which I had, at the time, in the matters with which this Inquiry is concerned. This is not to downplay their importance. But the firefighting on individual issues ranging from hospital closures and waiting lists to industrial relations and pay settlements dominated my three years in the Ministry, with most of my efforts concentrated, of necessity, on industrial relations and pay bargaining, the cause of the worst conflicts. I was also often the Minister who was asked to handle press interviews or public announcements on these issues.

2.11. The point about limited involvement that I have made is underlined by the fact that Lord Fowler intervened to take direct charge of policy on AIDS, and, in particular, the high-profile public health campaign on the disease. He rightly championed the message that people of any sexual orientation could contract HIV and that everyone should be taking precautions against it. In addition, I was not the Minister responsible for blood products, which was regarded as a specialist area of activity and was handled by, first, Lord Trefgarne (6 April 1982 – 14 June 1983); then Lord Glenarthur (14 June 1983 – 26 March 1985) and finally Baroness Trumpington (30 March 1985 – 13 June 1987). Each served, in turn, as the Parliamentary Under-Secretary in the Lords.

[2] *Ibid*, Chapter 9, p. 128

2.12. Against this backdrop, I have tried to explain the involvement that I did have over these years, as evidenced in the papers to which I have been referred. Whilst the detail is covered in the Statement, it seems that I was often most closely involved if there were press interviews or announcements to be made. In addition, I can remember having perhaps two informal discussions with Lord Glenarthur, when he spoke generally about the policy responses to AIDS and on blood products. I cannot remember the dates or details of those conversations, which were not formal policy-making ones with civil servants or minuted, but informal 'catch-ups' between colleagues. My general recollection is that the actions that Lord Glenarthur described seemed reasonable and that I was not able to identify other steps that should be taken instead, or different directions of travel.

Q8: Other Ministerial Figures

2.13. Secretary of State: Lord Norman Fowler was Secretary of State throughout my tenure as Minister for Health.

2.14. Minister of State for Social Security: Between 1982 and 1985 ('the relevant period'), the position of Minister of State for Social Security was occupied by:

a) Sir Hugh Rossi (5 January 1981 – 12 June 1983),
b) Dr Rhodes Boyson (12 June 1983 – 11 September 1984); and
c) Tony (later Lord) Newton (11 November 1984 - 10 September 1986).

2.15. The Parliamentary Under Secretaries of State for Social Security during the relevant period were:

a) Tony (later Lord) Newton (5 March 1982 – 11 September 1984); and
b) Raymond Whitney (11 September 1984 – 2 September 1985).

2.16. Parliamentary Under Secretary for Health:

a) Geoffrey Finsberg (15 September 1981 – 14 June 1983) (now sadly deceased);
b) John (now Lord) Patten (14 June 1983 – 2 September 1985).

2.17. Parliamentary Under Secretary of State (Lords) during the relevant period were:

a) Lord Elton (15 September 1981 – 6 April 1982),

b) Lord Trefgarne (6 April 1982 - 14 June 83);

c) Lord Glenarthur (14 June 1983 - 26 March 1985);

d) Baroness Trumpington (30 March 1985 to 13 June 1987).

2.18. My private office staff during my tenure of Minister of Health consisted of Robert W D Venning (my Principal Private Secretary or PPS), Paul D Hastings (an Assistant Private Secretary or APS), Stephen J Alcock (my PPS after Mr Venning), Robert Oates (APS), Robin Naysmith (APS), Gary Franklin (APS) and Sarah Bateman (my PPS after Mr Alcock). These individuals were "my only arms to pull the levers and my only ears for the mood in the system"[3]; in those days we did not have personal political advisors to supplement the Private Office civil service staff.

Q9: Organisation of the Department of Health and Social Security

2.19. I have been asked to describe my understanding of the functions and responsibilities of the DHSS during my tenure as Minister of State for Health.

2.20. The DHSS was at that time responsible for both health and social security policy making; it was not until 1988 that the two departments were separated. As a result, and as I have explained above, there were two Ministers who, under the overall leadership of the Secretary of State for Health, split the responsibilities for these policy areas between them.

2.21. I have set out my views above about the absence of proper management within the NHS when I was Minister for Health. A programme of change had been embarked upon in 1979, with the start of the implementation of the recommendations of the Royal Commission on the National Health Service (June 1979, the Commission having been set up by the Wilson government). But it was not until Roy Griffiths was asked, in February 1983, to lead an inquiry

[3] Ibid, Chapter 9, p. 126

into NHS Management, and the Griffiths Report was published in October 1983, that a recommendation was made that general, rather than consensus, management in the NHS should be introduced. The Griffiths Report gives a good account of the functioning of the DHSS as well as the NHS more broadly at about the time when I took up my post.

2.22. Mr Griffiths proposed that the DHSS should establish a Health Services Supervisory Board to oversee policy and strategy, and an NHS Management Board with responsibility for implementation. The idea in relation to the latter was to remove the DHSS from the more 'day to day' running of the NHS and Mr Griffiths intended that it would be multi-disciplinary, drawing members from the NHS, the private sector and the civil service. The proposals were accepted, and supervisory and management boards were established by Lord Fowler in October 1983 and April 1985 respectively. The process of embedding the concept of general management was an ongoing one however, and I was responsible for introducing further reform during my tenure as Secretary of State for Health.

2.23. When I was Minister of State for Health, the DHSS employed both administrators and medical advisors, at that time arranged in a parallel hierarchy. The medical advisors reported ultimately to the Chief Medical Officer, who – together with his staff – provided input and advice on clinical issues. It was then the practice that a medical officer attended every policy meeting of any significance. We relied on the medical officers for their clinical expertise and we would not have done anything that they did not think was in the interests of patients. Sir Donald Acheson was the Chief Medical Officer for the larger part of my time as Minister of State for Health. As I described him in my autobiography, he was "a splendid man: quite quiet, self-effacing but an absolutely dedicated public servant in the pursuit of his own particular interest and expertise in health education".[4]

[4] *Ibid*, Chapter 9, p. 127

2.24. It is important to stress that Ministers did not have the requisite clinical expertise to go behind the expert advice provided by the CMO and his team. Moreover, even the CMO and his team did not provide specific instruction on, or intervene in relation to, clinical decision-making, which was properly a matter for individual doctors and their patients. In my view, many of the terribly difficult treatment decisions that had to be made in relation to haemophiliacs in the early 1980s fell into this category.

2.25. Ministers were consulted by civil servants about significant policy issues or matters with political implications, often by means of a written submission being sent to the Minister's Private Office, with the issues that required decisions being set out. Depending on the topic, the submission might go to the other Ministers in the DHSS as well. There are examples of this in this Statement below. Not every submission or minute that was sent to a Minister's Private Office staff would have been seen by the Minister in question. One of the roles of the Private Office staff was to filter out from the large volume of documents received by them the documents that really mattered to their Minister and that their Minister should have sight of.

2.26. What is not immediately apparent from the documents I have been provided with is the amount of time that I and other Ministers spent in Ministerial meetings. Whilst straightforward issues could be dealt with in written submissions to Ministers and written responses from Ministers (sent out most often through a Minister's Private Office staff), more complex or controversial matters falling within a Minister's areas of responsibility were discussed with that Minister in meetings attended by Departmental officials and medical advisors. When I was Minister of State for Health my diary was full of such meetings. At these meetings, policy matters falling within my areas of responsibility were debated fully and robustly. Really significant decisions were taken by Ministers to Cabinet. With perhaps one or two exceptions, such as the meeting I attended with Lord Glenarthur to discuss the principle of the production and distribution of a leaflet on AIDS for blood donors in 1983 (see paragraph 7.9 below), I do not recall having such meetings on policy matters relating to blood, blood products or HIV/AIDS when I was Minister for Health

because, as I have already explained, these areas did not fall within my areas of Ministerial responsibility.

2.27. As a Minister, I received a significant amount of correspondence from Members of Parliament and members of the public. Draft replies to Members of Parliament would be provided to me by the Ministerial Correspondence Unit, which I would check and amend where necessary before signing. I would also be involved in answering Parliamentary questions from Members of Parliament. In relation to written answers, I would be provided with a draft answer and a short background brief from a civil servant, usually those involved in the policy areas in question, on which input would have already been sought from medical advisors. I would consider such drafts to ensure I was content, making any changes I thought were necessary, before they were printed in Hansard.

Q10: Senior Civil Servants

2.28. The names of my Private Office Staff are outlined above at paragraph 2.18. The identity of the key figures providing advice on particular issues would be evident from the names on the submissions that were received by me; it is likely that looking at these documents will be more helpful or accurate than the provision of a general list, especially after this period of time.

Q11-Q16: Devolved Administrations in the 1980s

2.29. Q11 – Q16. I have been asked about the roles of the governments in Scotland, Wales and Northern Ireland, and my involvement with these devolved administrations. At least in relation to matters related to blood policy, I did not have any involvement with the devolved administrations, although I have no doubt that some submissions on matters such as, for instance, the redevelopment of the Blood Products Laboratory (BPL) would have been copied to the health departments of the devolved administrations.

Q17 – 18: Relationship with the Haemophilia Society

2.30. I have been asked about the DHSS' relationship with the Haemophilia Society. To the best of my recollection, I had no personal involvement with the Haemophilia Society at all during my time as Minister of State for Health.

2.31. Lord Glenarthur and Baroness Trumpington were the Ministers who, it appears from the papers I have been provided with, had contact with the Haemophilia Society for the DHSS during the relevant period. This arose out of their role as the Ministers responsible for blood products. I understand that the Inquiry has been provided with all the papers relevant to this subject.

Section 3: Safety of Blood and Blood Products

Q:19: Briefing on Taking Office.

3.1. I have been asked about my knowledge of the National Blood Transfusion Service, the safety of blood and blood products and the risks of infection on taking office. I do not think I would have received any briefing on these issues when I took office as they did not fall within my Ministerial areas of responsibility and there were so many issues that did fall within my areas of responsibility that had to be covered.

3.2. During the relevant period, Lord Glenarthur held ministerial responsibility for the National Blood Transfusion Service. It can be seen from the documentary record that on 28 June 1983 a minute was sent to Mr Patten's Private Office (Mrs Walden) - Mr Patten had by this time succeeded Mr Finsberg as Parliamentary Under Secretary for Health - by Mr Winstanley of the Health Services Division [DHSC0002309_022]. Mr Winstanley noted that Mr Patten had "expressed interest in AIDS ... although Ministerial responsibility for the National Blood Transfusion Service now rests with Lord Glenarthur". Mr Winstanley attached a recent brief from Dr Walford to Lord Glenarthur about AIDS and noted that a further submission would be going to Lord Glenarthur shortly on the AIDS leaflet mentioned in the brief. The involvement of Mr Finsberg, Mr Patten and Lord Glenarthur in these issues is noted below, where it coincides with my own limited involvement.[5]

Q20: Development of Knowledge

3.3. I have been asked how my knowledge and understanding of these issues developed, during my time in office. I acquired some information and

[5] I can see from the record of answers I gave to Parliamentary questions when I was Minister of State for Health (see the table at Annex A, explained at paragraph 8.6 below and provided in response to Q83) that I did from time to time have some involvement in other issues that are less relevant to the Inquiry's Terms of Reference but do relate to the Blood Transfusion Service (for example, I provided a number of written answers on the issue of blood handling charges for non-NHS hospitals and also about standards for stock and record keeping within the Blood Transfusion Service). I have erred on the side of inclusion in the table in relation to Parliamentary contributions such as these.

knowledge in relation to this area from my involvement in issues such as the production and distribution of the AIDS leaflet and the introduction of routine screening of blood donations for HTLV III, dealt with fully below at paragraphs 7.5 to 7.39 and 7.40 to 7.96 respectively. I would also have had an appreciation of the general public concern about AIDS in general and about the safety of blood and blood products from reading the newspapers. AIDS was a very high-profile concern and the Inquiry will, no doubt, have seen a selection of newspaper articles from the time. There was a daily cuttings service for Ministers (and others) that highlighted health-related stories. I received the advice from officials that is shown in documentary records such as submissions, or was given in meetings and other discussions, and took relevant decisions based on this advice.

3.4. I do not feel I can properly assist the Inquiry with the remaining questions under this heading, which ask for broad accounts of the structures and processes in place within the DHSS in relation to risks arising from blood or blood products (Q21), the system and DHSS's role in relation to the regulation and licensing of blood and blood products (Q22) and the steps taken by or at the DHSS's request in relation to Non-A Non-B Hepatitis (Q23) during my time as Minister of State for Health. I did not have personal involvement in or any particular knowledge of these areas at the time.

Section 4: Self-Sufficiency and the Redevelopment of the Blood Products Laboratory

4.1. The Inquiry has asked me (Q24) about my understanding of the Government's commitment to self-sufficiency in blood and blood products when I took office in 1982. There is no suggestion from the documents provided to me for this Statement that I was provided with any briefing when I first took office that related specifically to this issue.

4.2. I have been asked (Q25) about the Government's attempts to achieve self-sufficiency in blood and blood products, during the time when I was in office. I have answered this question by reference to the involvement that, from the documents that have now been provided to me, I can see that I personally had. This relates to my involvement in the redevelopment of the Blood Products Laboratory ("BPL") which I have discussed below.

4.3. I am asked to explain (Q26) how, and from whom, the DHSS obtained or received estimates in relation to (a) plasma supply, (b) demand for Factor VIII and (c) demand for other blood products. I would not, as a Minister, have been apprised of this level of detail in relation to the DHSS's work in pursuit of self-sufficiency and I did not have at the time, nor do I have now, the requisite knowledge to assist the Inquiry with this question.

4.4. I have also been asked (Q27) to reflect on the Government's attempts to achieve self-sufficiency, and how successful they were (or were not). I became aware in 1982 that there was a need to commission and build a new factory at Elstree; once in action, this would enable England and Wales to meet self-sufficiency targets. As I have explained below, the financial commitment to achieve this target was made, and it was maintained even though the costs escalated enormously. During the period when I held office, therefore, financial commitment was not the issue. I have no first-hand knowledge of the preceding period and do not feel that I can comment upon the decisions made before 1982.

Q28: The redevelopment of BPL – 1982 to 1985

BPL Decision-Making

4.5. In the autumn of 1982, approval was given to redevelop the BPL at a size capable of achieving self-sufficiency. I can see from the records that the Minister with primary involvement was Mr Finsberg, then the Parliamentary Under-Secretary.

4.6. I have been asked what the decision-making process was within the DHSS for decisions relating to the BPL. Whilst I did not have policy responsibility for decisions relating to the BPL, I did become involved from time to time with issues across the DHSS where concerns had arisen about project management and cost control. The redevelopment of BPL was one of these issues. Ensuring proper project management and cost control was important. There were always excellent bids being made for more expenditure on matters that would improve patient care coming in from across the service. If one project exceeds its budget, the funds that might have been available for another project may no longer be available.

4.7. I see from the documents that:

a) BPL itself was managed by the Central Blood Laboratories Authority ("CBLA"), a Special Health Authority established in December 1982.

b) My understanding is that the project was managed, by the CBLA, via contractors, Matthew Hall Norcain ("MHN").

c) Oversight over the CBLA was provided by DHSS officials, and specifically by officials in the Health Services Division, Branch 1, Division A (HS1A). The DCMO, Dr Edmund Harris, had been appointed as the DHSS representative on the CBLA in December 1982, I understand.

d) Ministers were responsible for giving approval to the case for rebuilding BPL, and for approving the decision to submit the case to HM Treasury; the Treasury's approval was ultimately needed.

4.8. As will be seen below, at times I expressed concerns about the poor costs management of the project, whether by the CBLA or by the DHSS officials. The problem of costs overrun in large public sector building projects was not a new one in 1982 and has not ended since then. I do not consider that it was unique to the exercise of redeveloping the BPL.

4.9. Whilst I was only involved in this issue from time to time, I have attempted to assist the Inquiry by setting out below a more detailed account, with summaries of events drawn from the documents.

The decision on redevelopment in 1982

4.10. On 22 September 1982, Mr Godfrey (HS1A) sent to Mr Finsberg's Private Office (Mrs Walden) a Ministerial submission seeking decisions with regards to the redevelopment of BPL, and specifically (a) the size of the new laboratory; (b) the scale of production and (c) its cost [DHSC0002309_017, DHSC0002309_108 and DHSC0002309_018]. This submission was not sent to me or my Private Office. The economic analysis had concluded that the most economic option available to meet the NHS's demand for blood products was to redevelop BPL at a size capable of achieving self-sufficiency. It would be capable of extracting all therapeutic material from the plasma it received and selling surplus materials to the pharmaceutical industry, with the income retained by the NHS. The planned laboratory would cost £21.03 million plus a contingency allowance of £1.5 million (£21 million in 1982 would be a sum worth about £74 million today[6]) [DHSC0002309_108, para 16(i)(c) of the submission]. The underlying economic appraisal of the proposed project gave further detail, including on why the Scottish fractionation centre, PFC Liberton, was not

[6] https://www.in2013dollars.com/uk/inflation/1982?amount=21 (accessed 26 January 2021).

capable of fractionating English plasma [DHSC0002309_018, para 3 of the economic appraisal].

4.11. On 7 October 1982, Mr Finsberg attended a meeting with officials to discuss this submission [DHSC0002309_019]. I was not at this meeting. Mr Finsberg agreed that the investment appraisal should go to the Treasury seeking approval from the Treasury, save that: (a) the cost limit should be set at £21.1 million, i.e. there should be no contingency allowance; and (b) the investment appraisal should be amended to reflect a lower expected production level in the new BPL's first year of production, given the complexity of commissioning a plant of this size. The economic appraisal was duly revised following this meeting [DHSC0002319_031].

4.12. There is a minute dated 20 October 1982 from Mr Finsberg to Sir Kenneth Stowe (now sadly deceased, but at the time the Permanent Secretary in the DHSS) [DHSC0002321_065]. Mr Finsberg noted that he had authorised officials to submit the investment appraisal to the Treasury and asked for advice on whether the DHSS should be represented on the project steering group that would be set up by the Central Blood Laboratories Authority (the CBLA) which was to be constituted as a SHA on 1 December 1982. Mr Finsberg noted his views, that it should be for the SHA to manage the project and that the DCMO (Dr Edmund Harris) would be representing the DHSS within the CBLA itself.

4.13. On 21 October 1982, Mr D. Harris sent the economic appraisal to Jeremy Colman at the Treasury, seeking its approval for the project [DHSC0002319_012]. He noted that although Ministers had directed that the budget cost to the contractor should exclude any additional margins for contingencies, the project steering group wished to ensure that there was flexibility to accommodate improvements that might emerge in the design stage. As a result, "In the light of this professional opinion we would like to have authority to seek Ministers' approval in the future, should it be necessary, for additions to the budget cost within this contingency figure (i.e. up to a maximum of £22.6m at November 1981 prices)".

4.14. It appears from a note dated 8 November 1982 from a Mr Muir to Mrs Walden (Mr Finsberg's Private Office) that I had by this point seen and noted Mr Finsberg's minute of 20 October (summarised at paragraph 4.12 above). [DHSC0002321_059].

4.15. I can see from the documents that approval was received from the Treasury on 11 November 1982 [DHSC0002319_013]. The overall cost of £22.6 million was also approved, with the DHSS to make its own arrangements with BPL if it wished to exert additional financial discipline. There is a note from Mr Godrey (HS1A) to Mrs Walden dated 26 November 1982 "Mr Finsberg will wish to know that the Treasury has confirmed approval to proceed with redevelopment of the Blood Products Laboratory..." [DHSC0002309_020]. This minute was copied to my Private Office (Mr Venning) but I cannot say now whether or not I had sight of it at the time.

Developments in 1983

4.16. The topic of BPL does not appear to have come to my attention again until about July 1983. I can see that on 5 July I provided a written answer to questions from Mr Hamilton MP on the amount of Factor VIII imported from the United States of America, which included reference to the redevelopment of the BPL over the next three years at a cost of £21 million and explanation that "when completed the laboratory would be of a size capable of making England and Wales self-sufficient in blood products" [WITN0758002]. As was normal practice, I had been provided with a draft of this written answer by officials [DHSC0000188], which I would have checked before approving and I would also have been given a short explanatory brief. A similar question was answered by me on 11 July 1983 [DHSC0006401_005]. I was answering these questions and others referenced in this section below because Lord Glenarthur, who had responsibility for blood products, was, as a member of the House of Lords, unable to answer questions in the House of Commons.

4.17. I can see that the Guardian had published an article on 6 May 1983, reporting that union officials had suggested that the Government had "restricted the

budget of the only laboratory in England producing the vital blood clotting factor for haemophiliacs" [MDIA0000024]. Mr Clive Jenkins, general secretary of the Association of Scientific Technical and Managerial Staffs, had said that supplies of the comparatively safe home-produced Factor VIII were being threatened, and the programme to make Britain self-sufficient by 1985 was being delayed. It was not true that funding for the programme to rebuild BPL in pursuit of self-sufficiency was being restricted - Ministers and the Treasury had approved funding for this project - but Mr Jenkins' comments seem to provide some of the context for Mr Hamilton's questions. However, Mr Finsberg was the Minister who would have dealt with CBLA budget issues.

4.18. On 19 October 1983, I received a letter from Dr David Owen asking for an update on progress towards self-sufficiency [DHSC0000209]. Lord Glenarthur replied to this letter on 10 November 1983, being better placed to do so as he had responsibility for this area [DHSC0000208]. He offered reassurance that the Government was committed to making the country self-sufficient in blood products. Over £2 million had already been spent improving the production facilities at the BPL and a major 3-year redevelopment programme was underway. Once complete, the CBLA would have a new laboratory of the size capable of meeting the demands of England and Wales for blood products.

4.19. On 14 November 1983, I answered a question from Edwina Currie MP about the use of imported Factor VIII [PRSE0000886]. I responded:

"There is no conclusive evidence that acquired immune deficiency syndrome (AIDS) is transmitted by blood products. The use of factor VIII concentrates is confined almost exclusively to designated haemophilia centres whose directors and staff are expert in this field. Professional advice has been made available to all such centres in relation to the possible risks of AIDS from this material."

4.20. This response is discussed further below at paragraphs 7.115 to 7.118.

Escalating Costs in 1984

4.21. Progress on the BPL redevelopment is apparent from a DHSS press release dated 23 March 1984 [DHSC0002239_088]. This noted that the Secretary of State for Health (Norman Fowler) had laid the foundation stone for the new BPL. Investment was now stated to be £24 million. The project was said to be on time and completion was scheduled for the end of 1985.

4.22. Ministers were updated in a submission provided in September 1984 notifying them of a substantial increase in costs: from £25.3 million to £35.3 million in 1984 / 1985 prices ([DHSC0002309_048]; what appears to be a near final draft appears at [DHSC0002309_047]). The submission set out the history of the approval given by Mr Finsberg in 1982, and the "design and build" approach that was adopted in order to fast-track the project and to enable it to be flexible enough to respond to change in high technology equipment and processes. The increased costs that were now apparent were discussed. The increases to the capital costs would be considerable, but there would be savings in the ongoing revenue costs. Ministers were asked to accept the revised design solution and agree that officials could seek Treasury approval.

4.23. I responded to this submission in a minute to Sir Kenneth Stowe dated 25 September 1984 [DHSC0003964_035] in which I expressed dismay at the poor costs control exercised by DHSS officials. Whilst I agreed that there was little alternative but to seek the additional funding from the Treasury, I was highly critical of the project management approach that had been taken, and felt that the Special Health Authority (i.e., the CBLA) had been left in sole charge and given a blank cheque. I asked to be kept in touch with what was being done, and to be told "where we are going to find the money from."

4.24. I have been shown a minute from Sir Kenneth in response to my note; it seems that the Permanent Secretary's response was "This is all news to me – which perhaps reveals a lot". He asked an official to investigate and to report back to him [DHSC0002309_113]. One of Sir Kenneth's principal duties as Permanent

Secretary was as the Accounting Officer for the DHSS and he was accountable to the National Audit Office and the National Audit Committee.

4.25. Perhaps predictably, the Treasury reacted with concern to the news about the costs increase: see the letter of 25 October 1984 from Mr Peet of the Treasury to Mr Harris (DHSS) [DHSC0002247_105]. Again, there was resignation about the need to continue with the revised design, despite the overrun.

4.26. It is apparent that officials prepared explanations of what had occurred in response to the concerns that I had expressed to Sir Kenneth [DHSC0003615_032, DHSC0002323_131 and DHSC0002323_132].

4.27. On 28 November 1984, I answered further written questions on blood products and self-sufficiency from Mr Brown MP and Mr Chris Smith MP [DHSC0002251_014]. The former related to the rebuilding of BPL; I noted that it was due to be completed by January 1986. To the second question, about self-sufficiency and US imports, I answered:

"The Government decided in 1982 that self-sufficiency in all blood products, including Factors 8 and 9 should be achieved, and that the Blood Products Laboratory at Elstree should be rebuilt to provide the capacity to manufacture the blood products needs of the National Health Service in England and Wales. Work commenced in May 1983 and the project is presently on time for completion in January 1986."

4.28. My answer referred to the decision taken in 1982 to redevelop BPL at a size capable of achieving self-sufficiency (see paragraphs 4.10 to 4.15 above). As far as I can remember now, I do not think that I was aware at the time that the policy of achieving self-sufficiency pre-dated 1982.

Developments in 1985

4.29. I can see from the documents now provided to me that I met with the Mr Jerwood, the Deputy Chairman of the CBLA, in January 1985, as I wished to

call them to account for their failure to control the escalation of costs of the BPL redevelopment and to discuss their application for increased funding of £35.34 million plus an extra £3.35 million for additional buildings. I was provided with a briefing in advance of this meeting [DHSC0002323_127, DHSC0002323_128]. I can see from Mr France's letter to Mr Jerwood of 28 February 1985 that I made it clear at the meeting that I 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 [DHSC0002323_027]. The letter set out the DHSS' expectations on costs and made it clear that there needed to be early reports of any further difficulties.

4.30. In early 1985, I answered further Parliamentary questions on the topic of blood products, namely:

a) 5 February 1985: a question about the availability of British heat-treated Factor VIII and whether the output of heat-treated Factor VIII from the BPL was sufficient to meet domestic demand on 5 February 1985. I responded as follows:

"At present the blood products laboratory, Elstree manufactures almost half of the National Health Service consumption of Factor VIII. BPL has started to heat treat its factor VIII, and limited amounts will be distributed to the National Health Service for clinical trials within the next two weeks. Heat treatment capacity is being increased, and it is hoped that, by April this year, all BPL factor VIII will be heat-treated.

The major redevelopment of BPL is on schedule to open in January 1986. This is intended to provide the capacity to meet the forecast demand on the National Health Service in England and Wales for factor VIII. The heat-treatment process however reduces product yield and the consequences of this for the timetable for achieving self-sufficiency in factor VIII is being examined." [CBLA0002020]

b) 19 February 1985: a question about whether the economics of self-sufficiency in Factor VIII had been studied by the NBTS and whether the results were to be published. I replied that an economic appraisal of the BPL building project had demonstrated that the policy would be cost-effective. The appraisal had been prepared for internal purposes and was not in a form that others would find helpful without the addition of further explanatory and background material. [MACK0000067_007; draft answer at PRSE0003968]

c) 20 February 1985: I answered two questions, announcing in particular the formation of an expert advisory group on AIDS, chaired by Dr Abrams (DCMO) and comprised of leading experts on the disease. The Group had already met, and a series of meetings and working groups were scheduled to take place the next few weeks, with the first priority being to advise on all measures necessary to control the spread of the disease. I summarised the steps that had been taken to safeguard members of the public including haemophiliacs, such as the steps being taken to introduce heat-treated Factor VIII blood products. I also referred to the steps being taken to achieve self-sufficiency, referring in particular to the £35 million investment in the BPL, which I said should begin to come into production in 1986. [DHSC0002261_043]

4.31. I note now that in the second written answer I again used the formulation that a decision had been taken in 1982 that the country should become self-sufficient in blood products, addressed at paragraph 4.28 above.

4.32. On 29 March 1985, John James (DHSS) wrote to Mr Peet (Treasury). Mr James reassured Mr Peet that closer monitoring of the project by the DHSS was being put in place [DHSC0101506]. Reference was made in this letter to my meeting with Mr Jerwood in January.

4.33. Despite these steps, requests for further funding were received in July 1985, by which time the cost of the project had risen to approximately £38 million, which included a figure of £0.4 million stemming from the introduction of the heat-

treatment process. A submission dated 10 July from Mr Harris asked me for approval of a cash limit for the CBLA of £38 million [DHSC0002311_024]. A covering note from Mr France dated 11 July noted that the intervention in January/February had helped to "bring the CBLA under control and to make them take the management of the project seriously" [DHSC0002311_026]. There was no realistic alternative to approving the extended cash limit of £38 million. The benefits of the project, "economic and for health, remain, and have been enhanced by the AIDS crisis."

4.34. A handwritten note made it clear that I was expected to take a decision before the summer recess, but I can see from a letter dated 23 July 1985 that the matter was being brought to the attention of the Treasury (Mr Peet) in the interim [DHSC0002273_011]. There is a note dated 25 July from my Private Office (Mr Naysmith), showing that I had seen the two documents of 10 and 11 July, and was asking questions about whether possible savings could be accepted [DHSC0002311_061]. A response was made, justifying the officials' advice, on 2 August 1985 [DHSC0002333_045]. I can see from the note of my views dated 8 August [DHSC0002311_059] that I pushed back on this advice, observing: "*We appear to be undermining CBLA by preferring the contractor's claims for costs and fees! I think CBLA should be taken at their word and allowed to make the savings they offer. CBLA <u>should</u> be in charge – <u>not</u> the DHSS.*"

4.35. However, a further submission from Mr Harris dated 9 August 1985 [DHSC0002311_058] gave further details of why he felt that agreeing a realistic cash limit was the way forward, and why holding the CBLA to the "savings" that they proposed would merely pass to Minsters the responsibility for any failure to complete the facilities on time. The recommendation in the submission from Mr Harris of 10 July 1985 was endorsed.

4.36. A letter from Mr Peet of HM Treasury dated 20 August 1985 indicates that the Treasury had accepted the revised costs limit of £38 million [DHSC0002275_081].

4.37. I have been asked at Q31 a number of specific questions about the letter of 29 March 1985 from Mr James of the DHSS to Mr Peet [DHSC0101506]. The answers should, to a large extent, be apparent from the history that I have set out above. I was not aware of this letter at the time and I was not involved in its drafting. I am therefore unable to comment on the detail of the letter but it appears to me to summarise the position in a reasonably accurate way.

CBLA Review

4.38. I have been shown a copy of a minute dated 5 August 1985, which refers back to proposals that I had apparently received in June 1985, for an accountability review of the CBLA [DHSC0002311_032]. They were described as apolitical and non-controversial, and welcomed by the CBLA chair. I was asked to approve the proposals, with a reference being made to the efforts being made to "tighten up" on the CBLA and the specific problems with the BPL project (the context of the note making it clear that this was a reference to the costs overrun).

4.39. On 20 August 1985, some handwritten annotations were made on a minute dated 13 August from M A Harris, suggesting that my Private Office had been reminded of the need for my agreement to take the proposals for an accountability review forward [DHSC0002311_057]. It is unclear to me whether I approved these proposals before I moved to become Secretary of State for Employment on 2 September. I cannot imagine, however, that I would have had any objection in principle to such an accountability review taking place.

Conclusion

4.40. Since I left the DHSS in September 1985, I believe this represents the end of my involvement, as Minister for Health, in the matter of the rebuilding of the BPL and the CBLA's or DHSS's management of this major project. Plainly the issue continued (see for example the position paper at [DHSC0002303_018] dated 12 June 1986, which recorded further costs escalation and a projected completion date of mid-January 1987).

4.41. I deal below with the outstanding questions raised by the Inquiry under this heading, insofar as I am able to.

Q29: Establishment of the Central Blood Laboratories Authority ("CBLA")

4.42. I have been reminded that on 18 May 1982, Lord Fowler announced the setting up of a Special Health Authority to run the Central Blood Laboratories at Elstree and Oxford. This became known as the Central Blood Laboratories Authority (CBLA). I can see from the documentary record that the CBLA was formed by the CBLA (Establishment and Constitution) Order 1982, coming into force on 1 December 1982.

4.43. Mr Finsberg was the junior Minister with primary responsibility for and involvement in the establishment of the CBLA. I was not so involved and cannot therefore assist the Inquiry with the background to this.

Q30: Reference to discussions with the SHHD about a reciprocal arrangement for the fractionation of plasma in times of shortage in a meeting of the Policy Steering Group for the Redevelopment of BPL

4.44. I am asked to comment on an extract from minutes of a meeting of the Policy Steering Group for the Redevelopment of BPL dated 27 April 1982 [DHSC0002217_010]. I was not a member of the Policy Steering Group or at this meeting and to the best of my recollection the question of whether there could be any reciprocal arrangements for the fractionation of plasma in times of shortage was never raised with me. I cannot therefore assist with this question.

Q32: "Bad Blood" Documentary – July 1985

4.45. I have been asked about my interview as part of the World in Action programme "Bad Blood" broadcast on 22 July 1985 [transcript at HSOC0008599].

a) I was briefed before appearing on this programme. A written briefing was sent on 10 July 1985 by Mr Williams to Ms Bateman [DHSC0002337_008] and it is likely that I also had an oral briefing; this was offered by Mr Williams. I can only assume that the source of my information that haemophiliacs would run a greater risk without commercial Factor VIII products remaining available to them was either an oral briefing before the interview or an earlier briefing or Ministerial submission on the AIDS situation.

b) In relation to the consideration that had been given to increasing cryoprecipitate production as an alternative to Factor VIII concentrates, I do not think this is a matter that I would ever have been involved in during my time as Minister of State for Health. I was not the Minister with specific responsibility for blood products. It may also reflect the fact that the production of cryoprecipitate was – I now understand – primarily a matter for the Regional Transfusion Centres. It was not something that was covered in the written briefing provided to me by Mr Williams in advance of the programme.

c) As to other alternatives to the importation of blood products, I explained in the interview that we were driving on with the investment in BPL to achieve self-sufficiency, but that in the meantime no alternative source to the imported products was available. That is not to say that other steps to reduce the risk had not been taken. As is apparent from Mr Williams' written briefing, by this point both commercial imported products and all BPL's current output of Factor VIII were heat-treated to reduce the risk of AIDS transmission, steps had been taken to dissuade high risk donors from giving blood (see further below at paragraphs 7.5 to 7.39 in relation to the AIDS leaflet in particular) and the DHSS was funding an urgent evaluation programme by PHLS and Blood Transfusion Centre experts so that a reliable screening test could be introduced as soon as possible (again, see further below at 7.40 to 7.96).

d) I have been asked when I first understood that commercial products were from "dubious donors". As noted below, in the context of HIV/AIDS, I may have known from my involvement in the redevelopment of the BPL that it was important to ensure self-sufficiency in blood products, at least in part because they were considered to be safer than imported products. I may also have been aware of the issue from reading about it in the newspaper.

Q33: The importance of plasma supply to self-sufficiency

4.46. As with Q26, whilst I was from time to time provided with some information about plasma supply in the context of the goal of self-sufficiency (see, for example, the explanation that plasma targets had been set for the Regions and that DHSS was involved in monitoring Regions' actions to achieve those targets in Mr Williams' written briefing provided to me ahead of the "Bad Blood" documentary [DHSC0002337_008]), I did not at the time and do not now have the requisite knowledge of the detail of how plasma was supplied to the BPL, or what impact plasma supply had on progress towards self-sufficiency, to assist with this question.

Q34: Whether special funding was made available, outside the RHAs' allocation, for the purchase of commercial factor products

4.47. I cannot assist with this question, having had no involvement with this issue when I was Minister of State for Health.

Section 5: Hepatitis B Vaccinations

5.1. I have been asked (Q35) to describe my knowledge of, and involvement in, the DHSS's decisions and actions with regards to Hepatitis B (HBV) vaccinations.

5.2. On 21 April 1982, Albert Angel, the Managing Director of the company Merck Sharpe and Dohme Ltd (MSD), wrote to me about its production of a new Hepatitis B vaccine [DHSC0001728]. MSD offered to supply to the United Kingdom, from the autumn, up to 300,000 doses of the vaccine. The letter referenced an earlier briefing MSD had provided to the Secretary of State for Health, Norman Fowler, at which time the vaccine was yet to be approved and the DHSS was awaiting expert advice on the vaccination policy.

5.3. The letter referenced circumstances preventing the planned visit of the Secretary of State to the United States, which was to include a visit to MSD's manufacturing plant. I have been asked to explain the purpose of the Secretary of State's planned visit to the plant and why the Secretary of State was unable to attend (Q36(a) and (b)). I am also asked whether the Secretary of State met with the President of MSD (Q36(c)). Since these questions relate to the Secretary of State's diary plans and not my own, I would not have been involved. I certainly cannot now recall having had any particular knowledge of them. I am asked (Q36(d)) whether I or any other Minister visited or met with any other pharmaceutical companies during my time in office and to provide details of any direct interactions I had with pharmaceutical companies when I was Minister for Health. I cannot recall having had dealings or meetings with pharmaceutical companies or their representatives in my capacity as Minister of State for Health, although no doubt I would have encountered people who worked in this industry from time to time, as I would with other industries. I cannot speak for other Ministers.

5.4. On 24 May 1982, a holding response was sent on my behalf, explaining that the DHSS was still considering the points raised by Mr Angel and promising a full reply from me as soon as possible [WITN0758006].

5.5. On 26 May 1982, Dr Geffen, a DHSS official, sent a minute to Mr Venning, my Principal Private Secretary, attaching a submission to Ministers on the Hepatitis B vaccine and a summary of the recommendations of the Joint Committee on Vaccination and Immunisation (JCVI) [DHSC0001724 and DHSC0001726].

5.6. I have been provided with a copy of this minute which has annotations in my hand and underlining added [DHSC0001724]. It was my practice to mark up documents as I read them with underlining and this indicates to me that I considered Mr Geffen's minute carefully. I would have considered the underlying documents with equal care.

5.7. Dr Geffen's minute summarised the DHSS's recommendation at paragraph 3:

"In view of the high cost of the vaccine in relation to the prevention of serious cases of the disease and of difficulties of ensuring that the available supplies are used for those with the highest priority, it is not thought that it has a strong claim for scarce NHS resources. However the vaccine has been licensed for use and will be available on prescription if the manufacturer decides to make it generally available in this country. It is suggested that the agreement of the manufacturer be sought to limit the quantity and distribution of the vaccine in order to contain the cost and to ensure that it is used only for the high priority groups."

5.8. The submission itself highlighted in the first paragraph that MSD had written to me offering to make 100,000 courses of the vaccine available for the United Kingdom and that an urgent decision in response to this offer was required – the Secretary of State was due to meet the President of MSD on 9 June and the issue would no doubt be raised then.

5.9. The summary at the top of the submission included the following observation:

"This vaccine will be very expensive, in short supply for at least a few years, and subject to competing claims from groups of individuals considering that

they should have priority in its use. Decisions as to its purchase, distribution and use are therefore likely to create serious problems." (para 1)

5.10. It appears from the submission that MSD was, at the time, the only manufacturer producing the vaccine, although attempts were being made to develop new methods of producing the vaccine, by research workers in the United Kingdom and pharmaceutical firms and research workers elsewhere:

"It is too early to say whether this research will succeed in producing a much cheaper vaccine, but there is some possibility of success within the next three to five years. The Department has given considerable financial support to research in hepatitis B vaccines, and has recently given some money towards developmental work on a new British vaccine; it is hoped that this work can be carried out at the Public Health Laboratory Service Centre at Porton Down." (para 5)

5.11. The JCVI's advice that the vaccine should be given to certain groups was summarised in the submission:

"In general the groups have been allocated to two levels of priority – category 1 (higher priority) and category 2 (lower priority). In practice supplies of vaccine likely to be available for the next two years would not cover both categories. The JCVI recognise that their recommendations would involve considerable expense, and that it is for Ministers to decide whether the expense could be justified at present." (para 8)

5.12. The possibility of a system of central purchase and distribution was addressed in the submission and characterised as impracticable:

"A bid for extra resources in 1983/84 to cover the cost of immunisation category 1 is included in the draft PESC chapter but even if the bid is successful it will come too late to solve present problems. There are no central reserves of funds which could be used to purchase a supply of the vaccine nor any central mechanism for distribution." (para 12)

5.13. The costs and benefits in relation to the vaccine were set out in the submission as follows:

"The vaccine is highly effective in preventing hepatitis B infection, but its use in the two priority groups would only prevent a small fraction of all cases of hepatitis B. Although individuals in the priority groups have an increased risk of contracting hepatitis B, the great majority of reported cases do not occur in the two priority groups. Because of this, and because the vaccine is so expensive, the cost of prevention is very high; possibly £25,000 to prevent each case of hepatitis, £500,000 to prevent each case of chronic liver disease and £3 million to prevent each death." (para 13)

5.14. The submission asked for decisions from Ministers on a national policy for use of the vaccine and on the response to MSD's offer. The policy options open to Ministers were set out and in summary were as follows:

a) Because of the high cost of the vaccine, Ministers could decide to discourage MSD from making supplies available in the United Kingdom.

b) Ministers could decide to discourage the use of the vaccine on the basis that its high cost in relation to the number of cases likely to be prevented made it a poor candidate for scarce NHS resources.

c) The manufacturer could be asked only to make supplies of the vaccine available to hospitals on an equitable geographical basis and to limit the total distribution of the vaccine to a pre-determined number of doses (for example, sufficient to immunise category 1 individuals only). The JCVI advice would then be sent to health authorities and the decision on whether to seek supplies would be left for local consideration as would the local policy on its use.

d) The JCVI advice on the use of the vaccine could be published with or without a Government recommendation that the vaccine be used for one or both of the category 1 / 2 groups. (para 14)

5.15. The recommendations made to Ministers in the submission were as follows:

"In view of the high cost of the vaccine, the lack of unanimity over the medical indications for its use, and the widespread concern about hepatitis B infection among health service staff and unions, it is inevitable that any of the policy options outlined will give rise to criticism and difficulties. Option (iii) – attempted limitation and control – would seem the most attractive option but would be dependant on the co-operation of the manufacturer and the health authorities." (para 15)

5.16. On 7 June 1982, Mr Venning sent a minute Dr Geffen [DHSC0001723], reporting my comments on the submission of 26 May 1982, which were as follows:

"The whole thing strikes me as far too expensive. I am impressed by a cost of £3.3 million in the first year only to cover a limited number of high priority cases. Even then we will not prevent the majority of hepatitis B cases apparently. £3 million to prevent each death is given as the cost of full use of the vaccine. No PESC or other financial provision appears to have been made for the use of the vaccine.

I would like to say "no sale" in the friendliest possible way to the Company marketing the product. We should do everything possible to discourage its use in this country. The positive policy must be to press on to produce a British product at a more realistic price."

5.17. I have been asked some questions by the Inquiry about this minute (Q37):

a) As explained above, these were my comments being reported.

b) The difficulties posed by new high-cost vaccines and treatments are now considered by the National Institute for Clinical Excellence ("NICE"), but this used to be a task for Ministers. NICE employs cost / benefit analysis in its considerations and I think it unlikely that it would approve today a

vaccine equating to the cost of £3 million to prevent each death from a disease (also, £3 million would be equivalent to in the region of £8 million today). It was clear from Dr Geffen's submission that there was no provision for funding from central reserves for the vaccine and that all of the policy options set out presented difficulties.

c) My reasoning is largely apparent from my comments as reported by Mr Venning. My wish to discourage use of the MSD vaccine in this country stemmed from concern, in light of the content of Dr Geffen's submission, about the cost implications if the vaccine were to be prescribed without restraint (it is worth remembering that at the time there were no limits on GPs' clinical freedom to prescribe as they saw fit, with the NHS meeting the cost; the battle which I had subsequently when trying to introduce only a modest Limited List of prescribable drugs in 1985 was one of the fiercest during my time as Minister). High expenditure in one area invariably means having to cut back in another or budgets being exceeded. I was keen that efforts were made to produce a British vaccine because I considered that a British product was likely to be more reasonably priced.

d) As Ministers, we relied on the advice of medical advisors such as Dr Geffen. Dr Geffen's advice was that use of this vaccine in the two priority groups would only prevent a small fraction of all cases of Hepatitis B. I trusted that our medical advisors, in advocating for attempted limitation and control in relation to the vaccine, had properly taken into account the interests of patients. I would not have been involved in or apprised of consideration by the medical profession of risk reduction measures in relation to Hepatitis B in general.

e) As set out above, Dr Geffen's submission indicated that there was some possibility of research resulting in production of a cheaper vaccine within the next three to five years. It also explained that the Department had given considerable financial support to research in Hepatitis B vaccines,

and had recently given some money towards developmental work on a new British vaccine.

5.18. I can see from documents provided to me now that Miss Stuart, a DHSS official, sent Mr Venning a draft letter of reply to Mr Angel on 22 June 1982 [DHSC0001701 and DHSC0001702]. It appears from Miss Stuart's minute that officials planned to follow up on the letter with a phone call to MSD to establish whether its plan would be to market its product in the United Kingdom.

5.19. The draft letter underwent some minor amendments before it was sent out in my name on 29 June 1982 [DHSC0001715 and DHSC0001716] I would have ensured I was content with the letter before I put my signature to it. The letter conveyed our position as follows:

"Whilst the disease can in some instances be a very serious one, it has a low overall risk incidence in this country and, though several groups with increased risk can be identified, there is no group with an exceptionally high risk. In order to stand a good chance of reducing the number of cases contracted in this country we would therefore need to vaccinate extremely large numbers of people and the cost of preventing a small number of cases would be very considerable.

We are grateful to you for offering a supply of the vaccine and for being helpful in explaining what quantity we might expect to be made available in the near future. I am afraid however that we must decline since we do not feel that the purchase of the vaccine could rank highly amongst the many claims on limited NHS resources at present."

5.20. I have been asked by the Inquiry (Q38) about the reference in my letter to there being no group with an exceptionally high risk. I cannot now recall the basis for this statement, which was included in the draft letter provided to be, but I assume the basis for it would have been the information provided in Dr Geffen's submission and by the JCVI. In relation to the consideration given to the priority

groups identified by the JCVI, I would only have been aware of considerations set out in Dr Geffen's submission of 26 May, addressed in some detail above.

5.21. On 13 July 1982, Mr Angel replied to my letter of 29 June 1982 [DHSC0001711]. MSD regretted our decision and hoped to discuss it further at a later date. Given the decision however, they had taken steps to release the greater part of the intended United Kingdom allocation to other European countries. The letter continued:

"Furthermore, in light of all the circumstances, other than normal communication to the medical profession enclosing the Data Sheet and informing them that the vaccine will be available in small quantities in September, our professional information activities with respect to the vaccine will be limited.

We have taken these steps since, having established an excellent relationship over the years with successive Governments, we have no intention of prejudicing it."

5.22. A member of my Private Office staff sent me copies of a minute from Miss Stuart to Mr Venning dated 16 July 1982 [DHSC0001710] and a minute from Mr Collier to Miss Stuart of 12 July 1982 [DHSC0001712], under cover of a handwritten note asking whether I was content with Miss Stuart's advice, set out at paragraph 3 of her minute, that *"no further specific action is called for at the moment"* with regard to the Hepatitis B Vaccine [DHSC0001709].

5.23. I considered the advice from Miss Stuart set out at paragraphs 2 to 4 of her minute of 16 July 1982, which was as follows:

"2. MS(H) also said that he would wish to discourage the use of the vaccine in this country. This would need to involve taking positive steps such as the issuing of a Health Notice to authorities and G.Ps. In view of the much smaller quantity of the vaccine that will now be available here and the low profile MSD seem likely to take this would seem unnecessary – and could provoke a strong

reaction, particularly from health service unions, which would seem best avoided.

"3. If MS(H) agrees, it seems that no further specific action is called for at the moment. Should criticisms arise if and when it is known that an offer of larger supplies of the vaccine was declined or because of lack of advice on use, we will provide suitable briefing. This would be on the lines that Ministers did not feel they should make a general recommendation in favour of using the vaccine in view of its cost in relation to the incidence of the disease even in the higher risk groups; and in light of other demands on NHS resources. But a limited amount of the vaccine is to be available and individual doctors or health authorities will need to decide whether vaccination is warranted in particular cases and in light of any special local factors – e.g. an outbreak of the disease.

4. MS(H) also said that he thought 'the positive policy must be to press on to produce a British product at a more realistic price'. He may like to know that Professor Zuckerman's research has recently suffered a potential set back when British Technology Group withdrew funding at short notice. The Department has agreed to make up the small sums involved - less than £15,000 this year and £30,000 next year - so that the work can continue. There is however no guarantee that the resultant British vaccine would be any cheaper than the MSD one."

5.24. I made the following handwritten comments in response to the question on the covering note:

"Yes. I would like to be involved straight away if there is any sign of press or political interest in this."

5.25. On 22 July 1982, my comments were passed to Miss Stuart by in a minute from Gary Franklin, who enclosed Mr Angel's letter of 13 July 1982 and sought a suitable draft reply [DHSC0001708].

5.26. I was content to follow Miss Stuart's advice to take *"no further specific action"* at that time because I accepted the points made at paragraph 2 of her minute, set out above.

5.27. I am asked by the Inquiry (Q39a) whether I was aware of the setback to the British Hepatitis B vaccine noted in Miss Stuart's minute of 16 July 1982, that the British Technology Group had withdrawn funding at short notice. I was aware of this, having considered that minute. The minute also explained however that this setback had been addressed, by the DHSS agreeing to make up the funding so that the work could continue. This did not therefore alter my thinking in relation to the MSD vaccine.

5.28. I am also asked by the Inquiry (Q39b) why I wished to become involved straight away if there was any sign of press or political interest. My comment must be understood in the context of paragraph 3 of the minute from Miss Stuart of 16 July 1982 which I was responding to, which is set out above. I wished to be to be informed if the possible criticisms outlined by Miss Stuart were raised. I would have wanted to explain the DHSS's position before any public controversy developed.

5.29. On 28 July 1982, a member of my Private Office staff sent me a minute from Miss Stuart dated 27 July 1982, plus enclosures to that minute under cover of a handwritten note [DHSC0001706 and DHSC0001707].

5.30. One of the enclosures was a draft letter of reply to Mr Angel's letter of 13 July 1982. Paragraph 2 of the minute read as follows:

"We are beginning to receive enquiries from practitioners in the field about the availability of the vaccine for particular groups – for example staff in a mental handicap hospital and in Blood Transfusion Centres. We have been considering how best to respond to such enquiries and also whether it would be helpful to provide some general guidance for Regional Medical Officers, GP's and hospital doctors. This could be done by putting a paper to the Regional Medical Officers September meeting and by putting an article in a

publication like the Prescriber's Journal. At 'B' is a draft setting out the line the Department think should be taken. Would M(S)H be content with this please?"

5.31. The second enclosure was the suggested line to be taken in the proposed guidance for Regional Medical Officers, article in the Prescribers' Journal and in dealing with individual queries.

5.32. I can see from handwritten notes between officials dated 30 July 1982 and 2 August 1982 [DHSC0001705] that Lord Trefgarne was asked to send the draft letter of reply to Mr Angel, which he did on 4 August 1982 [DHSC0001704]. It appears from Lord Trefgarne's letter that this step was taken because I was away at the time. The letter responded to Mr Angel's letter of 13 July 1982 in the following terms:

"We recognise that our decision must have been disappointing to you and we are grateful to you for letting us know how the company propose to manage the marketing of a limited supply in the United Kingdom.

As you clearly appreciate, the Government has difficult choices to make in deciding the allocation of limited NHS resources. For our part, we are aware of the interest of the Industry in this field and are appreciative of the approach which you have felt able to take on this occasion."

5.33. I was not involved in considering the draft that would have been provided to Lord Trefgarne and cannot therefore provide any further insight into the position set out in that letter (Q39c). My understanding based on the earlier documents that I did see however, is that Lord Trefgarne was expressing gratitude to MSD for choosing not to adopt an aggressive marketing campaign for its vaccine in the United Kingdom.

5.34. On 20 August 1982, Miss Stuart sent a minute to Mr Hastings, one of my Assistant Private Secretaries, about an article which had appeared in the Nursing Standard about the Hepatitis B vaccine [DHSC0002309_071]. I had been told about the article and wished to have advice on whether a response

could or should be made. Miss Stuart explained that the article was a reasonably accurate one and did not propose responding to it. She did however note that the article emphasised the need for early guidance to Health Authorities. She referred to her minute of 27 July 1982 and asked if I was content with the suggested line attached to that minute. I can see from handwritten annotations I made on the minute that I agreed that the article did not call for a reply. I also commented: *"I must look at the submission at an early stage."* This comment indicated that I was content for guidance to be provided to the Health Authorities but wished to see a submission on this at an early stage.

5.35. My comments on Miss Stuart's minute of 20 August 1982 were conveyed to Miss Stuart in a minute from Mr Hastings dated 23 August 1982 [DHSC0002309_015].

5.36. On 8 October 1982, Dr Ian Field sent a minute to Mr Venning about guidance to the NHS concerning priority groups for receipt of the new Hepatitis B vaccine, due to become available shortly [DHSC0002221_030]. The minute referred to me agreeing, in September, the line then proposed for disseminating guidance from the JCVI to RMOs and individual enquirers on the use of the vaccine. It also referred to the earlier decision that this vaccine was not to be included in the Department's schedule of public policy vaccinations. The minute explained as follows:

"It is clear now that wider distribution of the JCVI guidance, which is based on recommendations from the Advisory Group on Hepatitis, is necessary. The Advisory Group at its meeting this week recommended most strongly that the guidance be circulated within the NHS. With the assistance of the Advisory Group those meriting highest priority have been defined and are set out in the Appendix of the draft CMO/CNO letter. Because of the low incidence of the disease even in the high risk groups, advice is being given that the vaccine should be limited to specific individuals at special risk within these groups. The text has been drafted with a view to avoiding Trade Union criticism, especially

from the ASTMS, that the vaccine will not be liberally available to all their members who might be at risk.

As pressure is mounting for early guidance, we should like to issue the CMO/CNO letter next week. It is not intended that its issue be publicised by the Department."

5.37. My agreement was sought to sending out guidance in the form of the draft letter attached to the minute [DHSC0002221_031], which itself appended a summary of the guidance issued by the JCVI based on recommendations made by the Advisory Group on Hepatitis [DHSC0002221_032], and the proposed timing.

5.38. The guidance was sent as proposed by Dr Field, in a letter from the Chief Medical Officer, Dr Henry Yellowlees, and the Chief Nursing Officer, Mrs Poole, on 15 October 1982 [NHBT0000069_017].

5.39. In relation to the progress of work on a British Hepatitis B vaccine, a minute on this subject was sent by Miss Edwards, a DHSS official, to Mr Alcock, by then my Principal Private Secretary, on 2 December 1983 [DHSC0002237_017 and DHSC0002237_018]. Reference was made to the submission of 26 May 1982 from Dr Geffen and the information contained within it about research in the United Kingdom and elsewhere into producing other Hepatitis B vaccines and the decision made in relation to the MSD product in June of 1982:

"In commenting on the stance to be adopted in regard to the American vaccine, MS(H) said "The positive policy must be to press on to produce a British product at a more realistic price.". Ministers will wish to be aware of the present situation concerning the development of a vaccine against Hepatitis B with British sponsorship."

5.40. Miss Edwards explained that the Department had provided £130,000 in financial support to development work on a new British vaccine, pioneered by Professor Zuckerman at the Public Health Laboratory Service, Porton Down.

The minute summarised the background and the position by that time as follows:

"3. For some years the Department has been supporting research at the London School of Hygiene and Tropical Medicine, under the direction of Professor Zuckerman, on the development of a plasma-'derived hepatitis vaccine. This work has given rise to a technique of presenting a vaccine to the body's immune system known as "micelling". Development of the micelle technology has been money well spent, and the technique is likely to have a valuable and widespread application to a number of vaccine products in the future.

4. The Department had, however, become concerned about the wisdom of continuing to encourage work directed towards the production of a British plasma-derived micelled hepatitis B vaccine and sought the views of an expert group of advisers. The advice given by this Group reflected the view that the work so far on the Zuckerman project in relation to hepatitis plasma-derived vaccine had been overtaken by events. In particular, mention was made of (i) the unwillingness of British manufacturers to be involved with a plasma-derived product (especially due to the emergence of the Acquired Immune Deficiency Syndrome) and (ii) that, simultaneously, developments have occurred in recombinant DNA technology enabling the Hepatitis B surface antigen to be expressed in yeast and other cells. On a realistic forecast of the time necessary to complete the remaining research, development and safety testing of a plasma-derived micelled vaccine (4-5 years), it was clear that in the same period a clinically acceptable and more desirable yeast-derived recombinant DNA vaccine could well become available. There are already British links with companies overseas in developing a synthetic Hepatitis B vaccine and it is now for the British Pharmaceutical Industry to take the initiative. The British Technology Group are funding a collaborative venture between the London School of Hygiene and a Research Institute in Sweden.

5. Officials have concluded that the Department should no longer support the development of a plasma-derived Hepatitis B vaccine for routine use and that

no further encouragement or finances should be directed to this end. Professor Zuckerman's basic research in hepatitis generally and in micelling will continue to be encouraged and considered for further research funding. While no guarantee can be given that there will be a British Hepatitis B vaccine in the foreseeable future, it is a distinct possibility. But the pace of such a development will be governed by the interest of the British Pharmaceutical Industry.

6. If Ministers agree, Professor Zuckerman will be informed of the intention to withdraw funding."

5.41. I can see from the note enclosed with a minute from Miss Edwards dated 13 January 1984, which was copied to Mr Alcock [DHSC0002237_086 and DHSC0002237_087], that I agreed that the Department should discontinue its support for the pre-production development of a plasma-derived Hepatitis B vaccine for routine use being undertaken at Porton Down. As was explained in that note:

"The decision was taken in light of advice from an external group of scientific experts who were unanimous in their view that the project had been overtaken by events, in particular the fact that, simultaneously, developments have occurred in recombinant DNA technology enabling the hepatitis B surface antigen to be expressed in yeast and other cells. Therefore, having made a realistic forecast of the time necessary to complete the remaining research, development and safety testing of the new vaccine, it was clear that in the same period a clinically acceptable and more desirable yeast-derived recombinant DNA vaccine could well become available."

Section 6: Sale of "Left Over" Blood Products

6.1. The Inquiry has drawn to my attention at Q40 to the CBLA having approached DHSS in 1984 for its views on selling blood products to foreign countries. I am referred to a minute dated 17 September 1984 from Mr Williams (HS1A) to Mrs Mixer in the International Relations Division [DHSC0101515]. I have been asked what the DHSS's policy in this regard was and how the issue was resolved.

6.2. As far as I am aware, I had no personal involvement in 1984 with this issue, which appears to have been the subject of correspondence between officials but not Ministers or their Private Office staff. I cannot therefore assist the Inquiry on this matter.

6.3. Whilst I do not think I had any involvement in the question of the sale of blood products to foreign countries in 1984, the principle of the sale of surplus blood products to pharmaceutical companies does appear to have come to my attention in April 1982, shortly after I took office as Minister of State for Health. Whilst I have no recollection of this now, I can see from the documents provided to me that:

a) On 28 April 1982, Robert Oates, one of my Private Office assistant private secretaries at the time, sent me a handwritten note, enclosing a number of documents [WITN0758003], including a letter from a Mr R A Bird, National Officer of the Association of Scientific Technical and Managerial Staffs, dated 26 April 1982 (the letter in fact appears to have been sent on 26 March 1982) about the sale of unprocessed materials from the Laboratory at Elstree to commercial concerns and a draft letter of reply to Mr Bird. Mr Bird had been in communication with Dr Vaughan and proposed further discussion with me as his successor.

b) The documents enclosed with Mr Oates' note included a minute from J Harley to Mr Oates, dated 14 April 1982, which explained that Dr Vaughan had written to Mr Bird on 19 January 1982, fully setting out the

position and promising that the possibility of using surplus material would be taken into account in redeveloping the Blood Products Laboratory. Mr Harley noted that there was nothing yet to be added to the information provided by Dr Vaughan.

c) There was a background note attached to Mr Harley's minute. This explained that the BPL produced a range of therapeutic blood products for the NHS from plasma supplied by Regional Health Authorities, plasma derived from donated blood and that the BPL was the subject of a major development programme (£18 million). The background note continued:

"Surplus Materials

The manufacturing capacity at the Laboratory is fully taken up at present in making products for the NHS; any raw material left over from the production process is incinerated. Negotiations are however taking place, with Ministers' approval, for the sale of some surplus materials to an American pharmaceutical company. Other companies have also expressed interest in purchasing spare materials.

Redevelopment of BPL

When the Laboratory is redeveloped the amount of surplus materials will increase as production is increased. The Director of BPL (Dr Lane) and ASTMS have suggested that the Laboratory should be allowed to produce immunoglobulins beyond the needs of the NHS, for sale to industry and other countries. Our expert advisory committees concerned with the redevelopment of BPL are aware of the position and an undertaking has been given by Ministers, to both Dr Lane and ASTMS, that the possible use of surplus materials will be taken into account in planning the redevelopment.

Legal Position

Powers are available to the Secretary of State under the NHS Act 1977 to over-produce goods of a kind produced or manufactured for NHS purposes, so as to create a surplus for disposal by way of sale, gift or otherwise."

d) Dr Vaughan's letter of 19 January 1982 was also enclosed by Mr Oates. This explained that Mr Finsberg had discussed the possible use of surplus materials with the Director of the Laboratory and that the Joint Management Committee had been asked to take account of it in planning the Laboratory's redevelopment.

e) I wrote to Mr Bird on 13 May 1982 [WITN0758005]. I noted that it was unlikely I would be able to say any more than Dr Vaughan had said in his letter of 19 January, but that I would be very pleased to meet members of the ASTMS's Parliamentary Committee if they would find a discussion helpful. I suggested that Mr Bird rang my office about arrangements for a meeting. It would appear from the handwritten note made by Mr Hastings on Mr Harley's minute of 14 April 1982 [included at WITN0758003] that by 9 December 1982 Mr Bird had not taken me up on this offer. To the best of my knowledge, I did not meet with Mr Bird about this matter and my involvement in this issue was limited to sending the short letter of reply to Mr Bird.

6.4. In addition to the limited involvement set out above, on 8 June 1982, I provided a written answer to a Parliamentary question from Mr Ernie Ross [WITN0758004]. Mr Ross had asked the Secretary of State for Social Services on how many occasions discussion had taken place between the Department and private companies on proposals that the Department sell out of date blood for the manufacture of reagents and blood products. I can see from the documents now provided to me [DHSC0031369, DHSC0023492 and DHSC0023098] that I received a suggested reply from officials, to which I made

minor amendments before confirming with my initial that I was content. The final written answer provided was in the following terms:

"The Department held confidential discussions with one British company which expressed an interest in purchasing outdated red cells surplus to NHS requirements for the manufacture of reagents. The company concerned has since decided not to purchase the cells."

6.5. As noted above, Lord Glenarthur was the Minister with responsibility for blood products at this time, but it is likely that I provided this written answer because he was unable, as a member of the House of Lords, to answer questions in the House of Commons.

Section 7: HIV and Acquired Immune Deficiency Syndrome (AIDS)

7.1. I have been asked a number of detailed questions about my involvement with issues relating to HIV/AIDS and (at Q41 – 43) my knowledge of HIV/AIDS risks. I have explained at paragraph 3.3 above, how I came to be informed about these issues; I took an active interest in these matters. But after the passage of nearly 40 years, the best evidence of what I was informed or advised at any particular point in time that is available is contained in the documentary evidence of the Ministerial submissions that were sent to me via my Private Office at the time, together with any records of meetings that may exist. I have referred to these when available and relevant, below. The documentary record, and my account below, reflects that I had limited involvement with decision-making in this area at the time.

7.2. Q44 – 45 and then Q47 ask for a comprehensive account of the steps taken by the DHSS as a whole, in response to the threat of HIV/AIDS. A comprehensive account would have to be derived by looking at the evidence of many individuals, including other Ministers and officials with more direct involvement than I had in this area. I do not think that I am equipped to offer such a broad perspective; rather, I have tried to explain my own involvement.

7.3. At paragraphs 7.5 to 7.39 and 7.40 to 7.96 below, I have set out a detailed account of my involvement in two areas, the production of a leaflet on AIDS intended for blood donors and the introduction of HTLV-III testing of blood donations.

7.4. I have then made further comments on outstanding Inquiry questions from paragraph 7.97 onwards.

The AIDS Leaflet

7.5. An area of policy in which I was involved was the issue of a leaflet on AIDS to potential blood donors in 1983 and then again in 1984/85, a step taken to

dissuade higher risk donors from giving blood (this issue is raised by the Inquiry at Q46).

7.6. In 1983, discussions took place on the drafting of a leaflet aimed at discouraging high-risk individuals from giving blood. A draft leaflet was sent to Lord Glenarthur and Mr John Patten, but copied to my office (Mr Alcock) with a submission on 1 July 1983 [DHSC0002309_024, DHSC0002309_121 and DHSC0002309_122]. It received approval from both Lord Glenarthur [DHSC0002309_025] and Mr John Patten. I have been shown a copy of a minute from Mr Patten's office, stating:

"Mr Patten has seen Mr Parker's submission of 1 July and has commented:

"In my view, public concern on this issue is mounting, and rapidly.

The earliest possible publication seems desirable, and the Gay Medical Association could take the strain should more fringe-like-gay bodies raise the flag of discrimination." [DHSC0002309_027]

7.7. Plainly this reflects support for the leaflet but also a concern that discouraging homosexuals from donating blood could be seen as discriminatory.

7.8. I understand from the documentary record that some concerns were expressed by Lord Fowler. My recollection is that there was a worry at the time that the AIDS leaflet might lead to further unpleasant homophobic comments in some sections in the press, something we wanted to avoid. Equally, there was the concern that inaccurate or inflammatory reporting ("gay blood") could damage confidence in the blood service or discourage donations. I think that Lord Fowler may have asked me to look at the issue of the leaflet and how it should be handled, as a result of these concerns.

7.9. A meeting was then held on 6 July 1983 to discuss the leaflet; this meeting was attended by both myself and Lord Glenarthur. The minute of the meeting

[DHSC0001511] was copied, amongst others, to the Secretary of State's Private Office and read:

"1. MS(H) had two main concerns - to establish the necessity of a leaflet and to agree how the inevitable publicity surrounding it should be handled.

2. Officials felt that Ministers did not have the option of doing nothing. The main objective of the leaflet was to discourage those who were most at risk from AIDS from giving blood and thereby spreading the infection to patients who needed large amounts of blood, principally haemophiliacs. Similar guidance had been issued by the American Blood Transfusion Service and the Council of Europe had recommended that its Member States should put out a warning. Moreover, one of the Regional Transfusion Directors had let slip to the Press that a leaflet was in the offing and if nothing was now done, speculation would be rife.

3. MS(H) accepted the strength of these arguments. He thought the leaflet, as drafted, read well although he would like it to emphasise more strongly how few cases of AIDS there had been in the UK, perhaps by quoting numbers. It should also emphasise unequivocally that donors would not be questioned about sexual matters when giving blood. It was inevitable that the leaflet would attract wide publicity and a carefully drafted Press Notice and full question and answer briefing would be needed. To minimise the scaremongering, the PN should emphasise how relatively few cases of AIDS had been reported and repeat that there was no question of donors being quizzed about their sexual habits. The main objective was to minimise any damage to the transfusion service. The announcement should be made at the same time as the leaflets were released.

4. Lord Glenarthur would be answering an oral PQ about AIDS from Baroness Dudley on 14 July. If she asked about the Blood Transfusion Service, Lord Glenarthur should emphasise that the risk to haemophiliacs was very small."

7.10. At this stage (6 July 1983), the UK-wide leaflet was being widely circulated amongst Regional Transfusion Directors in what was described as "final form" and that the leaflet was going into print [NHBT0020668 and PRSE0001609].

7.11. There is a further minute about my involvement contained in a note dated 21 July 1983 [PRSE0000646] from Mr Bolitho to Dr Oliver. Mr Bolitho recalls that the MS(H) (i.e. myself) did,

"...not want the leaflet to go out with call up cards. The leaflet is an information leaflet and cannot be seen as a leaflet which you read and then change your mind about giving blood. I am sure that the only way it should be distributed is by having it available when you give blood. If this is distributed with call up cards, it will soon be in the news media and we could have a similar furore to the Gillick case with family planning.

I think MS(H) will be very irritated if we are not able to control distribution the way he wants it. He reacted very unfavourably when this was suggested at the meeting."

7.12. I think that my concerns about the media summarised in this minute related to the concern set out above at paragraph 7.8, namely that we wanted to avoid any unpleasant homophobic comments being published in some sections of the press. It is also apparent from this minute that I had concerns about the impact the leaflet might have on the number of blood donors.

7.13. On 25 July 1983 Dr Oliver sent a response to Mr Bolitho [PRSE0003725], arguing that the leaflets should be distributed with call up cards:

"I am afraid I cannot accept that the leaflet should not be seen 'as a leaflet which you read and then change your mind about giving blood'. To my mind this is precisely what it is intended for although the message has had to be slightly obscured for obvious reasons. Clearly we must bow to Ministers' wishes on the matter of handling the distribution but although I must accept your and [name redacted] *better recollection of our earlier discussions I am not sure that*

Ministers have fully understood the pros and cons. To this end therefore it is essential that the points I raised in my minute to [name redacted] *are brought out in the submission so that Ministers can weigh the possible disadvantage of letting 'risky' blood slip through the net against the advantage of minimising any adverse publicity. 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 adviser whose opinion I respect."*

7.14. On 29 July, a further submission on the leaflet went to my office (Mr Alcock) and the offices of Lord Glenarthur (Mr Joyce) and Mr Patten (Mrs Walden) from Mr Parker, seeking agreement to the leaflets' distribution and arrangements for it [DHSC0002327_016].

7.15. The submission dealt with the issue of distribution and noted that the question of distribution had split the Regional Transfusion Directors, who had been surveyed on the issue. Opinions on the two possible methods (issue with call-up cards and making the leaflet available at donor sessions) were divided. The submission suggested that as the Regional Transfusion Directors were responsible, under the Medicines Act, for the safety of the blood which they issued, due weight should be given to their clinical decisions; furthermore, the two options had differing resource implications. Officials recommended a 6-month trial period during which it would be for the RTDs to decide, at their discretion, the most effective means of distribution in their Regions. Officials would seek feedback.

7.16. As was conveyed in a minute from Mr Alcock dated 2 August [DHSC0002327_119], I approved this suggestion on the basis of the submission and its recommendation:

"A lot of work has obviously gone into this and I am content with it. I am even prepared to allow directors discretion on how to distribute for six months as the arguments are finely balanced. Presumably we will then think again in the light of experience.

I hope that this does not become a 'silly season' story. Handle it in the DHSS through Press Office. Regional Directors should not handle queries themselves. Go ahead with the leaflet as drafted and the press notice."

7.17. Although it is difficult with the passage of time, I do not believe that at the time, I had seen the more forceful views set out in the minute from Dr Oliver, with its reference to advice from an independent consultant.

7.18. Also on 2 August, Mr Patten's comments on Mr Parker's submission were passed to my office [DHSC0002327_118]. Mr Patten queried whether both methods of distribution could be used for the trial period. Approval from Lord Glenarthur followed on 3 August [DHSC0002327_120]. Lord Glenarthur also favoured using both means of distribution. According to Mrs Walden, Lord Glenarthur had added: *"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."*

7.19. Mr Alcock responded to Lord Glenarthur's question on whether he or I should handle press interviews in a minute dated 5 August 1983; I would do so if available [DHSC0002309_033].

7.20. The sensitivity of the topics covered by the leaflet is evident from a minute from Mr Naysmith of my Private Office dated 26 August [WITN0758007]. It appears that there had been some advance press coverage and that it had been alarmist, with headlines such as "Docs Ban Gays' Blood" etc. I can see that I was concerned by the report that similar alarmist action (i.e., presumably, alarmist publicity) caused a shortage of blood in New York. At the time, we were particularly concerned that there might be a crisis within the Blood Transfusion Service caused by a shortage of blood donors, or that people might start refusing life-saving blood transfusions. The issue of distribution was also raised 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. I asked for advice on whether I could insist on one national method.

7.21. After the position had been checked, I agreed that the arrangements based on Regional discretion for a trial period of 6 months could stand (Mr Naysmith's minute to Mr Ghagan on 31 August [DHSC0002309_035]) and made further comments on the arrangements for the launch (Mr Naysmith's minute to Mr Winstanley on 31 August [DHSC0002321_034]).

7.22. On 1 September, Lord Glenarthur suggested a trial period of three rather than six months, which I was content with [DHSC0002309_036].

7.23. The leaflet was published the same day [BPLL0007247]. The leaflet included the following wording:

> *"Since AIDS may be transmitted by transfusion of blood and blood products, the National Blood Transfusion Service wants blood donors to have the facts about the disease."*
>
> And
>
> *"Can AIDS be transmitted by 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. However, in the USA a very small number of patients suffering from haemophilia, an illness in which the blood will not clot, have developed AIDS. Haemophiliacs are more susceptible to AIDS because they need regular injections of a product called Factor VIII. This is made from plasma, obtained from many donors. Should just one of the donors be suffering from AIDS, then the Factor VIII could transmit the disease."*

7.24. The DHSS Press Release [DHSC0006401_006] quoted me as follows:

> *"Announcing publication, Kenneth Clarke, Minister for Health, said:*

"It has been suggested that AIDS may be transmitted in blood or blood products. There is no conclusive proof that this is so. Nevertheless I can well appreciate the concern that this suggestion may cause. We must continue to minimise any possible risk of transmission of the disease by blood donation but it is not possible to test a person's blood for AIDS. The best measure which can be taken at the present time is to ask people who think they may have AIDS or be at risk from it, to refrain from giving blood. That is what this leaflet sets out to do."

7.25. Further notes on the position of Factor VIII products were included, including upon US imports and the special requirements introduced by US Food and Drug Administration to exclude high risk groups from plasma donation. As discussed further below (at paragraph 7.101), the Council of Europe recommendation that all member states should make information on AIDS available to blood donors was also referenced. I have commented on the AIDS leaflet and the press release published on 1 September 1983 further below, at paragraph 7.111.

7.26. The question of the distribution of the leaflets continued to be considered. In late November 1983, I approved the suggestion that they should be distributed in STD clinics [DHSC0002309_037].

The Revised AIDS Leaflet: 1984/85

7.27. The question of revising the leaflet was raised in August 1984, with a submission to Ministers being sent on 10 August [DHSC0002309_044]. The submission noted that the leaflet was now out of date in certain detailed matters and there was a need to strengthen the warning to high-risk groups not to donate. It noted that there had been wide variation in how the original leaflet had been distributed and recommended that the leaflet should now be sent out individually to all registered donors at their next recall by RTCs. Both Lord Glenarthur and I responded positively [DHSC0002309_046]. My approval was conveyed, with an apology for the delay, on 16 October 1984 [PRSE0001914].

7.28. A copy of the revised draft leaflet as it stood in October, can be seen at [CBLA0001970].

7.29. It appears that a further draft of the revised AIDS leaflet was produced on 22 November 1984 and sent under cover of a minute, copied to my office (Ms Bateman) on the same date [DHSC0002323_014]. This was said to have been updated because of the need, in light of recent developments and Ministerial statements, for a much more strongly worded leaflet.

7.30. Mr Patten's comments on the minute of 22 November and the further draft were provided on 30 November [DHSC0002309_056]. He was content if Lord Glenarthur and I were.

7.31. The new leaflet and its intended method of distribution were mentioned by me in a written reply to a question on the spread of AIDS from Sir Raymond Gower MP on 28 November [DHSC0002251_017].

7.32. It appears from a minute of 3 December 1984 [PRSE0000898] that the printing of the AIDS leaflet had been delayed in order to allow the NBTS Working Group on AIDS to discuss the leaflet draft on 27 November. In the event, the Group had only minor comments to make and did not think that it was necessary to adopt a stronger line relating to high risk donors, as had been suggested by the Information Division. The minute stated that if I was content, arrangements could be made for printing the leaflet and its distribution to all donors by the RTCs.

7.33. On 4 December 1984, I gave a written answer to a Parliamentary question from Mrs Renée Short MP [DHSC0002008]. I made reference to the new leaflet, to be given individually to each donor. I have been asked about this answer (Q62). The updates to the AIDS leaflet were recommended by officials, including medical advisors. I have summarised above the information that was provided to me in this respect. I have dealt below with the steps taken to ensure that the leaflet was provided to every blood donor individually, in particular the January

1985 Health Circular sent to all Regional and Special Health Authorities requiring them to ensure that this was done.

7.34. A cluster of minutes evidence the process of securing final clearance for the leaflet in December 1984 – beginning of January 1985:

a) Minute from Mr Ghagan to Miss Bateman on Lord Glenarthur's clearance of the revised AIDS leaflet, 4 December [DHSC0002309_117 and DHSC0002309_118].

b) Minute from M A Harris to Ms Bateman on the need to take the revised AIDS leaflet forward, 14 December [DHSC0002309_060].

c) Minute from Mr Naysmith to Dr Abrams with my comments on the revised AIDS leaflet, 20 December: I commented that I felt that the language suggested by the Information Division in its 22 November draft conveyed the message more effectively and asked for revisions to reflect this [DHSC0002309_062] (this appears to have crossed with a minute of the same date from Mr Williams, providing an update on developments on AIDS and blood donation and seeking my urgent clearance of the revised AIDS leaflet [DHSC0002327_127]).

d) A Minute from R Windsor to Mr Naysmith on the text of AIDS leaflet, attaching a further revised draft leaflet, which was said to retain the general direct style and presentation of the Information Division draft but incorporated some changes which were felt desirable, 21 December [DHSC0002309_063].

e) Minute from Sarah Bateman to Mr Windsor providing my comments on the wording of AIDS leaflet, 31 December [DHSC0002309_064]. I queried whether it was still true to say that there was only a remote chance of getting AIDS from an ordinary blood transfusion, and stated that I was wary of offering to promise blood screening tests and heat treatments and would prefer to see this section removed.

f) Handwritten minute from Mr Williams to Mr Windsor providing a final version of the AIDS leaflet incorporating my comments reported by Ms Bateman, 3 January 1985 [WITN0758008].

7.35. In relation to the submission and comments quoted at (e) above, I have been asked (Q63a) why I was concerned about the statement that there is only a remote chance of anyone getting AIDS from an ordinary blood transfusion. Although it is difficult to remember my thinking at the time now given the passage of time, paragraph 2 of Mr Naysmith's minute of 20 December 1984 [DHSC0002309_062] leads me to believe that I was querying whether assurances such as this could still be justified in light of the two recent cases of AIDS involving blood transfusions. Paragraph 2 of Mr Williams' minute of 3 January 1985 [DHSC0002323_088] contained his assurance that the statement was medically correct and would therefore be left unchanged. I have also been asked (Q63b) why I remained wary of offering to promise blood screening tests and heat treatment. As indicated at paragraph 3 of Mr Williams' minute of 3 January, "the substantive issues on blood screening tests & heat treatment" were "to be considered in the near future", but not quickly enough for conclusions to be put into the leaflet as soon as it was needed. The relevant paragraph was therefore removed from the leaflet. I can see from the documents now provided to me that detailed submissions on these issues had not by this stage been put up to Ministers. It is likely therefore that I required further information on both screening and heat treatment before I was content to commit to their provision in a public leaflet.

7.36. The final revised AIDS leaflet was published in January 1985 [NHBT0096480_022]. It differed from the previous version published in September 1983 in the following ways:

a) All "practising homosexual or bisexual men" were included in the first risk group, as opposed to "homosexual men who have many different partners".

b) The groups listed as being at risk from AIDS were expanded to include the sexual contacts of those in other high risk groups as well as the sexual contacts of people suffering from AIDS.

c) The message to donors who might be at risk of AIDS was strengthened: *"Donors in the risk groups must **not** give blood. Some people in these groups may unknowingly carry the AIDS virus in their bodies."*

7.37. A formal Health Circular was sent by DHSS to Regional and Special Health Authorities when the revised leaflet was issued [DHSC0002159]. At that point, revised distribution arrangements were introduced. The previous discretionary approach was noted, but all RTCs were now directed to send each donors a copy of the leaflet with their call-up notification: "*Ministers have now decided that it is essential that the revised leaflet be brought to the attention of each donor* on an individual basis." Agreement to the revised distribution arrangements and issuance of the Health Circular had been sought from Ministers in advance, by way of a submission dated 3 January [DHSC0002309_065].

7.38. I have been asked (Q66) about a minute dated 2 January 1985 from M A Harris to Mr Williams [DHSC0001694]. Mr Harris suggested that there was a need to ask all RHAs to report back in a month, asking for RHAs to confirm that all donors had been sent a copy of the leaflet. There is a handwritten note: "*Discussed with M.H. – no change to circ[ular] (process of distribution takes up to 6m) – remember to chase RTDs for progress report (excuse [?] is NBTS Advisory Committee*". I think it very unlikely that M.H. here is a reference to me. I was consistently referred to as MS(H) by officials where an abbreviation was used, not M.H. It may be that this handwritten note, whoever it was written by, referred to M A Harris, the author of the original minute. I have no recollection of this issue being raised with me and I think it highly unlikely that it would have been raised with me by an official directly, as opposed to through my Private Office staff.

7.39. A press release announcing the publication of the new leaflet was issued on 1 February 1985 [DHSC0004764_111].

The Introduction of HTLV-III Testing of Blood Donations.

7.40. I am told that the issue of whether donations could be screened so as to detect the risk of AIDS was first raised in the UK in about mid-summer 1984. I have been told that on 25 June 1984, Dr Abrams sent Dr Smithies (copied to Mr Parker) a copy of an article in the journal Nature about the upcoming selection in the US of companies to manufacture a blood test for AIDS [DHSC0000581]. He noted that it raised two questions: *"a. do we foresee doing the test routinely on donor blood, b. if so would we have to buy US kits to do it?"* Mr Abrams asked whether they should discuss the problem with Dr Gunson when they met him.

7.41. Thereafter, discussions were held amongst medical experts, including the Medical Research Council (MRC) Committee on AIDS, and within the NBTS. Initially, it was proposed that a pilot study should go ahead.

7.42. On 31 July 1984, a meeting was held to discuss a paper circulated by Dr Smithies on 27 July 1984 [DHSC0000445]. It was agreed that Ministers should be made aware of the arrangements to screen all blood donors at North West London RTC to start in October. A note "*might also need to deal with the question of publicising the research in such a way as both to take credit for Government support for development of the test and to make it clear that the arrangements at the North West London RTC were experimental, i.e. to forestall pressure on the immediate availability of the test throughout the blood transfusion service and more generally through GPs and STD clinics.*" They discussed the need for a group to advise the DHSS about the development of the test, which was to be mentioned in the note to Ministers.

7.43. A fuller account of the steps taken by officials is set out in a briefing note prepared in collaboration with Dr Smithies, sent to Lord Glenarthur's Private Office (Mr Joyce) on 31 August 1984 [DHSC0000443]. I note that there were

a number of obstacles to be overcome before any test might be used on all donations in the UK. For example, the test was in the stages of development, reagents to carry out the tests were in short supply and the UK had to seek US Assistant Health Secretary's permission to use Dr Gallo's isolate (which was not forthcoming), as well as working on obtaining the UK's own isolate of HTLV III from which the test could be developed (this was eventually the solution that 'came through').

7.44. I have been asked (Q59) whether this submission came to my attention at the time. As far as I am now aware, it did not. The names on the copyee list on the covering note for the submission do not include names of any of my Private Office staff.

7.45. From the documents now provided to me, it would appear that some limited written information on a screening test had come to my Private Office on 19 November 1984, but this consisted of one paragraph included in a note on recent developments on AIDS, which was sent to the Secretary of State and copied to my Private Office [DHSC0002309_053]. The paragraph relating to a screening test, paragraph 6, read as follows:

"A screening test for evidence of infection with the causative virus has been developed at the Chester Beatty Institute and the Middlesex Hospital. This has enabled studies of AIDS patients, haemophiliacs and blood donors on a research basis to be undertaken. It is hoped that this test can be extended to screen more blood donors as the reagent becomes available. Until more is known about the AIDS agent such a test is the best that can be used to ensure safe blood and plasma supplies. Tests are being developed in the USA and are expected to be available commercially early in 1985."

7.46. I cannot say whether I saw this paragraph at the time (a lot of correspondence was copied to my Private Office, but staff there made judgments on what I needed to see). But I can see that the matter had been discussed at a meeting about central funding commitments on 13 November 1984 (see paragraph 7.51 below). By 23 November 1984, some further discussion had taken place, since

a minute summarising my initial views was sent by Dr Abrams to Dr Smithies [DHSC0000435]. It appears that the question of screening had been covered in a briefing session provided to me the night before ahead of an interview with ITV. Dr Abrams explained in his minute that I felt that to spend around £2 million on this was not cost effective when there were so few AIDS cases and the money could be better spent elsewhere.

7.47. I have been asked (Q64(g)(ii)) why I took this view. At this stage, I had been provided with very little information about a screening test. As far as I am aware, it had not yet been the subject of a Ministerial submission. My initial view was just that, an initial view. Part of the job of being Minister of State for Health was to challenge proposals that were being considered by the DHSS and to require explanations, where I felt there were still questions to be answered. However, once I received a fully reasoned submission on the matter (see further below at paragraphs 7.55 to 7.70), I was persuaded of the merits of the case for screening and gave my approval accordingly.

7.48. Also on 23 November 1984, Charles Kennedy MP put a Parliamentary question to the Secretary of State, in which he asked whether he would make the necessary money available to enable all blood donors to be screened for AIDS. I provided a written answer, stating that the possible test was still in the development stage so that the cost of introducing routine screening for HTLV III could not "yet" be predicted [CBLA0000042_057] (draft reply at [DHSC0000347]).

7.49. In response to the Inquiry's Q64(g)(i), the fact that costings were considered to be provisional only at the time can be seen from Mr Williams' minute of 26 November 1984 [DHSC0000436]. Mr Williams noted that it was *"not yet possible to forecast accurately the costs of such testing, which would depend amongst other things on the extent to which it is applied".*

7.50. I have already explained that my initial reaction to the issue of screening was given before I had been provided with a fully reasoned case for the need for screening. It is also important to note that I was not blankly refusing to agree

to the principle of introducing screening; I was expressing the view that central funds should not be earmarked for this purpose. Mr Williams' minute, which was sent to provide an update requested by PS(L) (i.e., Lord Glenarthur) explained that *"MS(H) has decided that allocation from Central Reserves would be inappropriate; funding would therefore have to come from Regional Health Authorities existing budgets)".*

7.51. I am asked (Q64(g)(iv)) about my reasoning for considering that central funding was inappropriate. A general impression of how the "ear-marking" of central funding worked can be seen from an earlier minute of 31 October 1984 [WITN0758011] which set out an account of the demands on the central revenue programme and central capital programme for 1985/1986. As it stated, only "A small proportion of the revenue and capital available for health authorities is retained centrally." I was present at a meeting held on 13 November 1984, at which the bids for the following year were considered [DHSC0002309_052]. AIDS testing was rejected as "*Hypothetical. Additionally, should be expenditure for regions, not Central Pre-emption.*" There were many worthwhile projects that were funded regionally rather than centrally. Central funding was limited and it was often considered more appropriate for Regional Health Authorities to budget locally for such projects; this was by no means a departure from the norm. Ultimately, this division was maintained, with the central government providing substantial funding for the contribution of the PHLS, but the Regions continuing to fund the contribution of the Blood Transfusion Centres.

7.52. I am also asked (Q64(g)(vi)) whether I believed that screening "could have been achieved by the use of existing RHA budgets". The answer is that I did; and furthermore, as far as I am aware, this is exactly what happened in due course, with the central government of course funding the additional PHLS costs.

7.53. I am referred (Q64(g)(v)) to (a) terms of reference and membership of the Advisory Committee on the National Blood Transfusion Service Working Group on AIDS, the agenda for a meeting of that Group on 27 November 1984 and a summary of that meeting [WITN0758009 and DHSC0002251_011] and (b) a

draft position paper on AIDS sent by Dr Smithies to Dr Sibellas on 31 December 1984 [DHSC0001693]. I would not have seen these papers at the time; they appear to be papers that were circulating amongst the medical advisors.[7] I have tried to explain in this statement which papers would have been sent to Ministers as submissions, and which would not.

7.54. I have been referred (Q65) to a copy of a minute from Dr Smithies dated 2 January 1985 (PRSE0003287). I do not think that this is a minute that I saw at the time or that I am in a position to comment further on this area of policy.

7.55. On 11 January 1985, Dr Smithies sent a minute to Dr Alderslade, for the CMO's attention, which detailed the proposed introduction of a screening test for AIDS, awaiting approval [DHSC0000562]. She noted that the UK test was being used at the Middlesex Hospital and at the Central Public Health Laboratory, Colindale to detect antibody carriers amongst patients thought to have AIDS or the AIDS related complex, haemophiliacs and male homosexuals attending STD clinics. She explained that scale up of production of the reagent was necessary before the test could be used more widely.

7.56. Dr Smithies enclosed a draft submission for Ministers titled "AIDS and Blood Transfusion - Introduction of HTLV III Antibody Screening Test for all Blood Donations", which the CMO had wished to consider, and also an extract from Hansard containing a response from myself as Minister for Health to a Parliamentary question about Departmental guidance on AIDS. The submission described the public health problem that the spread of AIDS presented and the need to reduce transmission through blood and blood products. It set out the action taken in the UK in relation to the spread of AIDS and stated that "the campaign to dissuade high risk groups from donating blood" was "not enough". The submission described the screening test and its financial implications (estimated to cost between 75p to £2.00 for each donation). It was noted that the tests for AIDS antibodies would not guarantee

[7] I note that Dr Abrams' summary of the meeting was copied to Mr Oates. Whilst Mr Oates had been a member of my Private Office staff, he had moved to the CMO's Private Office by this point.

the purity of donated blood as there was a time lapse between infection and development of a detectable antibody. However, there was "*no doubt that despite these problems the balance of advantage lays clearly with the introduction of a routine test of donations as soon as possible.*" Approval of the following was sought from Ministers:

"Ministers are asked to agree in principle to the introduction of a test for AIDS antibody for all blood donations and to an announcement made to this effect at the appropriate moment indicating that the development of a test is being backed by the Department."

7.57. It appears from my minute of 22 January (see below) that a final version of the submission was sent to Ministers on 15 January.

7.58. On 21 January I provided a written answer to a Parliamentary question about steps being taken to check the growth rates of AIDS [PRSE0002058]. Among other steps being taken, I explained that consideration was being given to the need to screen blood donations for the HTLV III antibody.

7.59. Q67 asks about this answer, and further asks:

a) What steps had been taken by this stage to reduce the risk of the spread of AIDS though blood transfusion and the use of blood products. I have set out my knowledge of the matters with which I was concerned at the time in this Statement;

b) What I meant by the statement that "we are also considering the need to screen blood donations for the HTLV III antibody". The statement that the matter of screening was under consideration was a reference to the fact that no final decision on this policy had been made at the time, as is apparent from the chronology I have outlined.

c) The arguments in favour of the policy are set out in the minutes from officials and the submission sent to Ministers on 15 January 1985 that I

have referred to above. The policy was accepted and adopted a few days later, by the end of January 1985 – which was still well in advance of the tests actually being able to be deployed.

d) The factors being considered at the time are apparent from the above.

7.60. The next day (22 January), I sent Dr Acheson a minute in response to the Ministerial submission of 15 January (see above at paragraph 7.56 for a summary of the final or near final draft of this submission) [DHSC0002482_012]. The minute read as follows:

"Thank you for your submission of 15 January. This looks inevitable, I suppose. Could I have drafts please of the proposed public announcement of both points. Could I also have a draft of a letter to go to all Chairmen of RHAs explaining our proposals.

How did Wellcome corner this market and why did they bring CAMR in?

Will the cost be met from the income now going to the blood transfusion service from the charges introduced for the handling of blood to private hospitals? I never did understand what else that money was to be spent on.

Before we all panic further, it is presumably the case that the ending of the collection of blood from homosexuals greatly reduces the risk from blood collected in this country? Also, as only haemophiliacs have died and they may have had Factor VIII from American blood, is it the case that we have not had one AIDS fatality from blood donated in this country yet?

Do we need this <u>and</u> heat treatment of the blood?"

7.61. As can be seen from the first three lines of the minute, I agreed, as Ministers were asked to in the submission sent on 15 January 1985, to the principle of the introduction of screening, and sought drafts of the proposed public

announcement and letter to Chairmen of the RHAs explaining the Department's proposals on this issue.

7.62. I have been asked (Q64(g)(iii)) whether I considered the introduction of screening to be a matter of "credibility and reputation". This wording is taken from a minute from Mr Williams to Mr Staniforth dated 26 October 1984 [DHSC0101679], to which I am referred at Q64(b). I would not have seen this minute at the time as it was not sent to me or my Private Office staff. To put the reference to "credibility and reputation" in context, Mr Williams expressed the following view in his minute:

"It is anticipated that Ministers, to secure the credibility and reputation of the NBTS, and BPL's blood products, will wish to instruct RHA's Regional Transfusion Centres to adopt the new test."

7.63. It appears that Mr Williams was referring to public confidence in the Blood Transfusion Service. The importance of patient confidence in the blood provided for transfusions was one of the factors stressed in support of the need for a screening test in the submission of 15 January 1985 (at paragraph 4): "*Prolonged hospitalisation, increased morbidity and mortality will be the consequences of patients refusing transfusion.*" Public confidence in the Blood Transfusion Service was a main factor when I gave my approval to the principle of the introduction of screening.

7.64. I did have some questions for the CMO about the policy, which I set out in my minute on 22 January 1985, and the CMO sent a response to these questions on 31 January 1985 [DHSC0002311_050, DHSC0002311_051, DHSC0002311_052 and DHSC0002311_053], as well as a further note dated 1 February 1985 [DHSC0002327_028].

7.65. I have been asked (Q68) to comment on:

a) The question in my minute beginning "Before we all panic further ...".

b) The question in my minute beginning "Also, as only haemophiliacs have died ...".

c) What the Inquiry describes as my "apparent reluctance" to take "measures additional to heat treatment".

7.66. When I referred to panic, I did so with the desire not to feed public alarm and concern very much in mind. I was asking for clarification on the effectiveness of the steps that were being taken in relation to high-risk donors, as my understanding was that these would greatly reduce the risk from blood donated in this country. As to (b), my question about AIDS fatalities from blood donated in this country has previously been taken out of context. It was most emphatically not a statement disparaging haemophiliacs or devaluing the importance of haemophiliac fatalities. What I was querying was the risk of transmission of AIDS via blood donations from British donors. I was asking whether, if it was true that those who had died had received imported American Factor VIII, this imported product was the source of the infection and not blood donated in this country. This is quite clear from the question read as a whole.

7.67. My question was clearly understood in the way it was intended by the CMO, who advised in reply on 31 January 1985 that:

"As far as is known there are no causes of the actual disease AIDS in the UK which have arisen following blood transfusion and the three haemophiliac patients with AIDS had received imported Factor VIII. However, there are three further patients to whom the infection has been transmitted by blood donated in the UK who may yet develop the disease." [DHSC0002311_051].

7.68. The question "Do we need this and heat treatment of the blood?" reflected the fact that I was questioning what the risk of infection from donated blood was. The CMO commented in response that it could not be guaranteed that all risk groups would stop giving blood. See further the Memo dated 1 February 1985 from Sir Donald [DHSC0002327_028], which records that I was asking for clarification of the need for heat treatment as well as an antibody test. It seems

that at the time, I was concerned to understand the impact of the different measures, how they interrelated, and the case for each one.

7.69. I was not reluctant to take measures additional to heat treatment. I simply had questions for the CMO about the actions it was proposed should be taken in relation to AIDS. Seeking further information on important issues and questioning the case being presented to me was part of my role as Minister of State for Health. It also reflected the fact that I would frequently be asked to provide interviews or statements in which I would be asked to explain or defend policies. Furthermore, it should be recognised that in this minute (i.e., that of 22 January 1985) I accepted the case for introducing HTLV III blood screening.

7.70. I have been asked (Q70(c)(i)) whether this the CMO's note of 31 January 1985 changed my opinion about the need to introduce a screening test for blood donations. But as I have explained above, I had already agreed that screening should go ahead, on 22 January.

7.71. Q69 refers to a written answer given by me to a question from Mr McCrindle MP on 24 January 1985, in which I referred to the development of tests to screen blood donations for the HTLV III antibody [BNOR0000036]. I have been asked how much money the Government provided for research to advance the current medical knowledge on AIDS, including in relation to tests for screening blood donations. The only information about funding for AIDS research that I would have been provided with whilst I was Minister for Health would have been that provided in briefings and draft answers for Parliamentary questions or in relevant Ministerial submissions or briefings. Mr McCrindle's question did not ask about funding for AIDS research. I certainly cannot assist with the overall amount of money the Government provided for AIDS research (either during my time as Minister for Health or more broadly). I did however provide a written answer to a question from Mr Brown MP about funding for the development of an effective screening test on 4 December 1984, in which I explained that Government financial support for AIDS research had been provided through the MRC, for which the Secretary of State for Education and Science was responsible [DHSC0002008]. As was usual, I was provided with a draft answer

to this question by officials [DHSC0002009]. I note as well that some information about funding provided by the MRC and the DHSS was provided at paragraph 12 of a briefing note for the Secretary of State sent by Dr Smithies on 19 November 1984 [DHSC0002309_053]. I cannot say now whether I had sight of this at the time, although it was copied to my Private Office (Ms Bateman). I provided further information about Government financing of AIDS research through the MRC in a written answer to a Parliamentary question from Dr McDonald MP on 12 March 1985 [DHSC0001602] and in a letter to Mr Thomas MP on 27 March 1985 [MACK0002649_018]. I would have been provided with drafts of both of these responses for my consideration before final replies were provided.

7.72. I have been referred (Q70(c)) to the minutes of a meeting of the Expert Advisory Group on AIDS (EAGA) dated 29 January 1985 and asked (Q70(c)(ii)) what steps the Department took to speed up the introduction of a screening test after the EAGA had endorsed the proposal that that blood donations should be screened for the AIDS antibody as soon as reliable testing facilities were available. I would not have seen these minutes at the time and I cannot comment on the detail of the practical arrangements that were being put in place to implement the introduction of screening once reliable testing facilities became available, which would have been a matter for the medical advisors and the relevant expert advisory groups.

7.73. On 20 February 1985, I provided a written answer to a question from Dr Mawhinney MP, which set out in some detail the steps that were being taken to control the risk of AIDS [DHSC0002261_043]. I referred to the fact that the Department was coordinating the evaluation work needed to ensure that a test could be introduced routinely in the NBTS as soon as possible. I explained that RHAs had that day been asked to set aside funds in 1985/86 for the introduction of this screening test in their RTCs. The circular requesting this is at [DHSC0002261_031]. A press release of the same date set out the same level of detail about the steps being taken to control the risk of AIDS [DHSC0101892].

7.74. Information relating to screening was also provided to the House of Commons on 22 February, in a written answer I gave to a question from Mr Bendall [DHSC0002261_080]. I noted that screening tests were available for research purposes only at the present time, but it was hoped that they would be released for general use "later this year". Much the same was repeated on 25 February 1985 [PRSE0003350] when I again referred to the hope that tests would be available "later this year" and that they would be thoroughly evaluated to see which would be most suitable for use in the NHS. I answered a further question from Mr Austin Mitchell MP on 26 February 1985, when I noted the importance of assessing the reliability of tests in terms of false positives and false negatives [DHSC0002261_065]. I also noted the importance of the AIDS leaflet in meeting the policy objective of ensuring that high risk donors did not give blood.

7.75. I would like to stress that my initial reaction to the question of screening blood donations for the HTLV III antibody came before I had been presented with a fully reasoned Ministerial submission on the issue. Once I had considered the first submission on this issue, sent to me on 15 January 1985, I approved the proposed policy of introducing a screening test in my minute of 22 January 1985. I did have some questions for the CMO about the policy and about other steps being taken to combat AIDS, and their interrelationship. Sir Donald answered my questions satisfactorily and I was grateful for the information. But I asked these questions having already requested drafts of the press release announcing the introduction of screening and the circular that was to be sent to RHAs informing them of the Department's proposals. To suggest that I was, at this stage, in some way rejecting the proposed policy is simply incorrect. Further, as I understood matters at the time and understand them now, a screening test was not yet available in January 1985; it was this and then the question of identifying *reliable* tests that affected the speed with which routine screening of blood donations for the HTLV III antibody could be introduced, and not any delay in the policy being approved.

Further Progress on the Introduction of Testing in 1985

7.76. I have been referred (Q74) to an oral answer given by Mr Patten on 16 April 1985 to a question from Mr Key MP about whether the HTLV III test was "still on target" [DHSC0002267_034]. It is suggested, on the basis of Mr Patten's answer, that there was a delay in the introduction of screening blood donations for the HTLV III from a planned date of April 1985 to the date that routine screening of blood donations in fact commenced, in October 1985. There was no such delay. Whilst this was not my answer and I would have had no involvement in its provision, it is apparent from the documentary record that Mr Patten made a mistake when answering this question, which it appears was corrected at the time.

7.77. Before I turn to the relevant documents, I note that in a question posed by Mr Dubs MP, immediately before Mr Key's question, concern was being raised in the House about "*people's reluctance to go to blood transfusion centres for fear of being refused the chance to donate blood because of HIV*". This was consistent with the concern felt by Ministers when the AIDS leaflet was first being discussed in 1983, in relation to a potential reduction in blood donors.

7.78. Mr Patten referred in his answer on 16 April to the "hope" that a screening test would be available "within a few weeks". I cannot comment on the basis for this statement as I would not have seen any briefing notes provided to Mr Patten in preparation for dealing with oral questions on that day. I have, however, been shown an official's corrective note to Mr Patten's Private Office (Ms McKessack), which reads as follows:

"In reply to a supplementary question from Mr Robert Key, PS(H) said "we hope to have a screening test within a few weeks"... It would be more accurate to say that we hope to begin evaluating screening tests within a few weeks. The work is due to start on 13 May, and full evaluation is likely to take several months. Realistically a screening test for HTLVIII antibody is unlikely to be introduced routinely into the National Blood Transfusion Service until the latter half of 1985.

PS(H) may feel it appropriate to write to Mr Key and place a copy in the House of Commons Library, A draft is attached ..." [WITN0758010]

7.79. The draft letter which was enclosed [DHSC0000420] also refers to a statement from Lord Glenarthur in the Lords, which set out the position on the start of the evaluation work within the next three weeks.

7.80. There was never, therefore, an expectation of being able to introduce routine screening of blood donations for the HTLV III antibody in April 1985. I note that Mr Key made reference in his question to the HTLV III test having been "promised for July". I do not know where Mr Key got this date from. My own written answers to the House provided in February 1985 (see paragraph 7.74 above) referred to the hope that screening tests would be available for general use (as opposed to research use) "later this year" and that these would then be thoroughly evaluated to see which would be most suitable for use in the NHS.

7.81. In relation to my own involvement, I note that in a letter dated 5 June 1985 to Sir Philip de Zulueta (Abbott Laboratories) [DHSC0001569], I stressed the importance of ensuring that a reliable test was identified and said that it was not yet possible to say when the evaluation process would be completed. There is a little more background to the reply in a minute supplied to my Private Office by M A Harris on 30 May 1985 [DHSC0002311_016]. I wrote again to Sir Philip, in a similar vein, on 1 August 1985 [DHSC0000220].

7.82. I have been asked (Q76) whether I agree with Sir Philip that there was "slow progress" in the introduction of the HTLV III antibody test, and whether one should have been introduced earlier. It should be apparent from this Statement, including the excerpts from the CMO's advice below, that the process of the introduction of screening tests was a topic which closely concerned the medical advisors. In particular, the CMO advised Mr Patten on the strategy for evaluation of the tests, and his advice was accepted. I was not then and am not now in any position to 'second-guess' that advice.

7.83. On 7 June 1985, a paper setting out the strategy for introducing a screening test for blood donations, as previously agreed by Ministers, was sent to Mr Patten's Private Office (Ms McKessack) and copied to my Private Office (Ms Bateman) and Baroness Trumpington's Private Office (Mr Joyce), among other copy recipients [DHSC0002311_019]. The paper explained the policy behind the requirement for evaluation of the available tests, and stressed the importance of a reliable test. The recommendation was to require both early evaluation by PHLS and further field trials within the BTS; the test should be selected from the first 2 or 3 which had been subject to this double evaluation, but testing of other candidates would continue. This recommended option was expected to take 5 months to implement. The paper proposed that £500,000 of the £742,000 required by the PHLS for its input in 1985/86 could be provided from centrally financed services, "provided that Ministers agree that this has priority over competing bids". The remaining £242,000 would have to come from as yet unidentified savings. Since this paper was copied to my Private Office, I may have seen at the time. I have seen no documents to suggest that I provided any comment on it, however, and Mr Patten was leading on this policy.

7.84. I am asked (Q75(a)) whether I had sight of an earlier draft of this paper sent by M A Harris to other officials and medical advisors on 5 June 1985 [DHSC0002311_018], which included a decision tree that does not appear to have been attached to the final paper, or a minute from Dr Smithies dated 31 December 1984 [DHSC0001693], also sent only to medical advisors and officials. I would not have seen these documents. I cannot assist with the questions at Q75(c) and (d) as the answers are not apparent from the paper of 7 June. I am asked (Q75(e)) what attempts were made to secure the necessary resources for the PHLS for the proposed strategy. I can only assume that the resources were found in the way proposed in the paper of 7 June, since, as outlined below, my understanding is that Mr Patten agreed to the proposals.

7.85. The CMO recommended agreement of the strategy to Mr Patten by a minute dated 10 June 1985 [the first page of PRSE0000105]. He noted that it was likely that support for a different view would appear in the medical press

(attaching by way of example a letter from Professor Bloom). It can be seen that Sir Donald disagreed with that view, and set out the risks and consequences of rolling out an ineffective test. Again, whilst the CMO's minute was copied to Ms Bateman, I do not think that I played an active part in the decision-making on the proposed strategy, Mr Patten being the Minister leading on this.

7.86. That the strategy proposed in the paper of 7 June 1985 was agreed can be seen from a minute dated 27 June 1985 sent by Mr Williams to Ms Bateman and Dr Hunt (the CMO's Private Office) ahead of my announcement of the evaluation of the available screening tests by way of an answer to an inspired Parliamentary question [DHSC0003828_186, DHSC0003828_187, DHSC0003828_188, DHSC0003828_189, DHSC0003828_190 and DHSC0003828_191]. The minute enclosed a draft reply to the question and a draft press release for my consideration and a draft letter from the CMO to editors of medical journals dealing with Professor Bloom's recent letter suggesting that introduction of a test should not await evaluation of the tests, for the CMO's consideration.

7.87. On 27 June 1985, I duly provided a written answer to the House, which announced that a test would be introduced within the next few months (it was hoped, within four to five months) to screen all blood given by blood donors for antibodies to the virus causing AIDS [HSOC0018679_003]. I explained that whilst I understood and shared the concern to get the test in use as soon as possible, it was important that tests were accurate and could be trusted - a number of test kits were available and in use abroad but reports from those countries suggested that the tests were not entirely reliable. No test should be introduced in the UK until its reliability had been established. An evaluation programme was being undertaken by the PHLS and the NBTS as a matter of urgency.

7.88. The DHSS issued a press release about the announcement the same day [DHSC0001184, CMO's background note at DHSC0001501].

7.89. I have been asked (Q77) a series of questions about the written answer I gave on 27 June. The basis of the information given, and the information given to me, is apparent from the background papers that I have referred to.

7.90. I gave a further written answer dated 5 July 1985 to a question that asked about funding for the BTS for these tests [DHSC0002271_019]. I referred back to the letter that had been sent to RHAs on 20 February 1985, asking authorities for set money aside for 1985/86: "*We would expect regional health authorities to find the money needed from within the £9,505 million made available for the hospital and community health services in 1985-86*". As is apparent from the references to the submission of June 1985, this was a reference to the costs for the BTS. There were also increased central costs for the PHLS: these were funded centrally.

7.91. The results of the screening test kit evaluation by the PHLS (i.e., the first stage) were available by the end of July 1985 [DHSC0002273_034] and were publicly announced on 1 August [DHSC0000513]. I can see that the Department also wrote to RHAs and SHAs to update them about the evaluation on 1 August [BART0000778].

7.92. I have been referred (Q78) to a Memo from M A Harris to Ms Bateman "AIDS Screening Test: Abbott Laboratories" dated 2 August 1985 [DHSC0002116]. It is apparent that Abbott (which was not one of the preferred test manufacturers) was disappointed with the results of the trials and lobbied hard to get it reversed. The minute from M A Harris explained the background and asked if I was content with the recommended approach. On 8 August, I confirmed that I was [DHSC0002327_036]. I do not think that I can add to this documentary record, now. Equally, Q81 asks me why the Abbott test "failed" in the UK; but that question would need to be directed at those at PHLS and others who devised the research protocol and applied it.

7.93. The Inquiry has referred me (Q79) to an article in the New Scientist which accused Ministers of delaying the introduction of a blood test for antibodies to the AIDS virus until a UK test was available [DHSC0000509]. I do not accept

this allegation, which is not supported by any of the documents that I have seen. I can see from documents provided that Mr Patten asked for a briefing in response to the article; see the minute of 16 August 1985 from Dr Smithies in response, which was not copied to me or my Private Office [DHSC0000501]. It is apparent that it was felt that there was no justification for the allegations made, and also that Abbott specifically wrote to retract the suggestion that the DHSS had delayed official approval.

7.94. Also relevant is the "trenchant response" to the article by Dr Napier (Chairman of the Western Regional Transfusion Director Division), who wrote in response to this article (see Dr Smithies' minute of 2 September 1985 [DHSC0002277_075 and PRSE0002548]). He noted, amongst other things, that "simple calculations" of the number of false positives suggested that some 3,000 – 6,000 donors would be falsely identified as positive, all of whom would need interviews, repeats tests and counselling. He also noted that "for many of these, disruption family and social life will be unavoidable". He stressed the need for the care of donors as well as patients.

7.95. The Inquiry has also referred me to a letter from Mr Williams to Dr Darnborough dated 23 August 1985 (Q80) [NHBT0004235]. As far as I can recall, I was not involved in nor aware of these arrangements at the time.

7.96. As I set out at the outset of this Statement, I left the DHSS at the beginning of September 1985, so had no further involvement in the introduction of screening tests after that point.

HIV and AIDS in 1983

7.97. Having set out my involvement the AIDS leaflet (from 1983 – 1985) and the introduction of routine screening of blood donations for HTLV III in full, I have returned to the Inquiry's questions at Q48 onwards (HIV and AIDS in 1983).

7.98. Q48 asks about the impact of FDA Regulations in March 1983. It is, presumably, linked to the documents considered under Q49. I can see that at

times there was reference to the FDA Regulations, in documents that I had some involvement with. For example, the DHSS press release announcing the publication of the AIDS leaflet on 1 September 1983 [DHSC0006401_006] included notes on the position of Factor VIII products, including upon US imports and the special requirements introduced by US Food and Drug Administration to exclude high risk groups from plasma donation. This is not an area in which I had any involvement in decision-making. It is possible that at the time, I took comfort from the fact America was obviously taking steps to ensure the safety of blood supplies, and that the DHSS's own policies took account of these measures.

7.99. Q49 asks about a minute from Dr Oliver to Mr Parker dated 17 May 1983 [DHSC0001395]. It is linked to:

a) A minute from Dr Walford dated 16 May 1983, which Dr Oliver's minute enclosed; and

b) A minute from Dr Fowler to Dr Walford dated 25 May 1983 [B/41/151-153 DHSC0002229_006], responding to Dr Walford's questions in her minute of 16 May.

7.100. I do not think that I can add materially to the contents of these documents circulating between officials. In particular, whilst I have been asked about my own knowledge of the risks from "unsafe" sources of Factor VIII at this time (May 1983), I had no clinical expertise in relation to this and any knowledge I did have would have derived from my involvement in relevant issues as set out above, discussions with colleagues in the DHSS or my own general knowledge gleaned from relevant media coverage I saw at the time. In general terms,

a) I knew from my involvement in the redevelopment of the BPL that it was important to ensure self-sufficiency in blood products, at least in part because they were considered to be safer than imported products.

b) I can see that by about this time, there were press articles on the topic; see for example the article in the Daily Mail published on 18 May 1983: "US Gay Blood Plague Kills Three in Britain" [PRSE0000589]. The article claimed that UK doctors were blaming the US blood transfusion system, which exported blood to the UK, as it was based on paid contributions which encouraged "gays, junkies and other 'less fit' people to give blood for money". Whilst I cannot remember whether I would have seen this particular article, I had a daily press cuttings service and it is likely that I would have seen articles like this at the time.

c) I have already explained my involvement in the AIDS leaflet; the submission of 1 July 1983 [DHSC0002309_024] (copied to my office) drew attention to the risks which the leaflet was designed to address (see paragraph 7.6 above). I have commented on the links to the FDA's policies above.

7.101. Q50 asks about Recommendation R(83) 8 of the Council of Europe's Committee of Ministers, adopted on 23 June 1983. I do not have any recollection of briefings on this matter, which would probably have been a matter for those with more direct involvement in blood policy. I can see that a minute was sent by Mr Cumming to Mr Patten's office (Mrs Walden) on 2 July 1983, enclosing the Recommendation in question. It appears that a copy of the minute was sent to my office (Mr Alcock) and Lord Glenarthur's office (Mr Joyce), although it is unclear whether the enclosure was included with the copy minute [DHSC0002309_086 and MACK0000307]. The documentary record shows that Lord Glenarthur replied positively about the Recommendation [DHSC0002309_029]. He noted that there might be merit in referring to the "European" advice when announcing the publication of the AIDS leaflet for blood donors; I was asked whether I agreed. Mr Alcock replied on my behalf on 26 July 1983, saying that I did [DHSC0002309_031]. It appears from Mr Alcock's minute that I had been provided with a copy of Mr Cumming's minute of 2 July 1983 by Lord Glenarthur's office. I cannot now recall whether I had sight of the Recommendation itself. I was being asked to consider it in the fairly narrow context of my announcement of the publication of the AIDS leaflet. The

DHSS press release announcing the publication of the AIDS leaflet on 1 September 1983 included reference to the recommendation that all member states should make information on AIDS available to all blood donors [DHSC0006401_006].

7.102. The Inquiry has asked me (at Q51) about contact with the World Federation of Hemophilia. I did not have any involvement with this group.

7.103. I have been asked (Q52) whether "the decision of the Biological Sub-Committee of the Committee on the Safety of Medicines", taken on 13 July 1983, was brought to my attention. I have been shown, in particular, a summary of the main points considered at this meeting [DHSC0001208], which shows detailed consideration of and decisions on a range of issues. I cannot remember involvement in decision-making on this issue, but I may have been aware from conversations with others in the DHSS, possibly the CMO, that such issues were being considered by the experts. This would have been a general understanding however and I do not think I was aware at the time that this particular group of experts were considering these matters.

7.104. Q53 asks about my knowledge of the risks from blood collected from prisoners within the UK, and DHSS policy on the same in 1983. I do not have any recollection of involvement in this issue at the time. The documents referred to by the Inquiry [PRSE0004345; PRSE0004729] suggest that the subject was regarded by officials (at least in July/August 1983) as a matter for individual Regional Transfusion Directors, and noted that Directors were due to discuss the matter in their meeting in September 1983, in the light of AIDS risks in particular.

Public Discussion of Risks

7.105. At Q54 the Inquiry refers me to the announcement made at the time when the leaflet "AIDS and how it concerns Blood Donors" was published, on 1 September 1983. I have set out the DHSS press release [DHSC0006401_006] above at paragraph 7.24, but to repeat it:

"Announcing publication, Kenneth Clarke, Minister for Health, said:

> *"It has been suggested that AIDS may be transmitted in blood or blood products. There is no conclusive proof that this is so. Nevertheless I can well appreciate the concern that this suggestion may cause. We must continue to minimise any possible risk of transmission of the disease by blood donation but it is not possible to test a person's blood for AIDS. The best measure which can be taken at the present time is to ask people who think they may have AIDS or be at risk from it, to refrain from giving blood. That is what this leaflet sets out to do."*

7.106. Further notes on the position of Factor VIII products were included, including upon US imports and the special requirements introduced by US Food and Drug Administration to exclude high risk groups from plasma donation.

7.107. I have been asked what the basis for the statement was, and what information was provided to me in order to make it. In general terms, as is evidenced by the documents summarised elsewhere in this Statement, draft press statements would have drafted by officials, usually with input from those involved in the policy area in question and sent to me for approval before their use. The particular statement that there was no conclusive proof that AIDS may be transmitted in blood or blood products would have been based on the medical advice of the medical officers within the Department.

7.108. There is a submission, sent to me and to Lord Glenarthur and dated 29 July 1983, which sought approval for the publicity arrangements for the leaflet, and purported to enclose, along with a draft revised leaflet and a question and answer brief, a draft statement for the press release [DHSC0002327_016]. It appears from a minute from Mr Naysmith of my office dated 26 August [DHSC0002309_034 at p. 1] and that I in fact saw the draft statement for the press release and the Q and A brief [DHSC0002309_034 at pp. 2 - 7], after I saw the submission.

7.109. I note that the Q & A brief I considered alongside the draft statement contained the following question and answer:

"21. Why issue a leaflet at all?
While there is no conclusive evidence that AIDS is transmitted through blood or blood products we believe that it is right that blood donors should be fully informed about AIDS and we have produced an information leaflet for blood donors which asks those who think they may either have AIDS or be at risk from it not to donate blood."

7.110. The statement was approved by Lord Glenarthur on 3 August [DHSC0002327_120] and by myself, subject to some minor amendments, on 31 August 1983 [DHSC0002321_034]. These minor amendments did not alter the text of the draft statement as it related to the first two lines of my statement set out above, which remained unchanged from the draft.

7.111. Looking at it now, I can see that there is a tension between the statement that "*There is no conclusive proof*" of transmission by blood or blood products, and the statement in the leaflet itself [BPLL0007247], that AIDS was "*almost certainly*" carried by blood. I cannot now recall whether I recognised this at the time. However, the statement that there was "no conclusive proof" of transmission was based on the preferred form of words provided to me by the medical advisors reporting to the CMO. I had no reason to challenge this, nor the expertise to do so. In addition, the statement made was balanced by a recognition of concerns about the topic, and information about all that was being done to minimise risks. So there was a clear recognition of the risks, which (in addition) had been widely reported in the press by that time. I have already explained the sensitivities of the leaflet, both in terms of possible accusations that it discriminated against high-risk groups but also the worry that people might be deterred from accepting blood transfusions, which might have had yet more devastating consequences. It is apparent from a minute dated 2 August [DHSC0002321_031], not sent to Ministers, that the draft statement was designed to be *"low key"*, to put the *"problem of AIDS into perspective"* and to

"justify" the leaflet initiative. It may be that it was felt at the time that the message to blood donors in the leaflet needed to be stronger than the message being given to the wider public in the press.

7.112. The Inquiry's questions at Q54 have been repeated with regards to the written answer to a Parliamentary question given on 14 November 1983 [PRSE0000886]. Since this answer is further addressed at Q57, I return to these below at the appropriate point in the chronology.

7.113. I have been asked (Q55) about how a memo from Ms Sibellas to Dr Field relating to known AIDS cases as of 9 September 1983 [DHSC0001666], which included the information that two patients were haemophiliacs who had received American Factor VIII, aligns with the press statement made a week or so earlier. To the best of my knowledge, I would not have seen this or similar tables at the time. However, from memory, it was not clear at the time that the very few haemophiliacs that were being reported to have contracted AIDS at this stage had contracted it from their treatment for haemophilia, as opposed to by other means, as other AIDS patients had, for example through sexual activity. It was only when reports of haemophiliacs being infected in much higher numbers came to light that the position became clearer. Furthermore, my understanding is that the Department was working to minimise the risk of transmission, on the assumption that transmission via blood or blood products **was** possible – the leaflet was one of the steps being taken in relation to this.

7.114. Q56, about a departmental memorandum that I do not believe I would have seen at the time, raises exactly the same issues.

7.115. I have had my attention directed (by Q54 and Q57) to a written answer to a Parliamentary question dated 14 November 1983, which reads as follows:

"*Blood Products (Imports)*

Mrs Currie asked the Secretary of State for Social Services what advice has been given to hospitals concerning the use of imported factor VIII in the light of

recent concern about its possible contamination with the causative agent of acquired immune deficiency syndrome.

Mr Kenneth Clarke: There is no conclusive evidence that acquired immune deficiency syndrome (AIDS) is transmitted by blood products. The use of factor VIII concentrates is confined almost exclusively to designated haemophilia centres whose directors and staff are expert in this field. Professional advice has been made available to all such centres in relation to the possible risks of AIDS from this material." [PRSE0000886]

7.116. At the present time, I have not been provided with the draft answer or short explanatory brief I would have been sent before I approved this written answer. It is difficult therefore to be precise about the information I was given at the time. The statement that there was "no conclusive evidence" that AIDS was transmitted by blood products was, as I have already explained, based on the preferred form of words provided to me by the medical advisors. The continued use of this statement in November 1983 would have been on the same basis. I have been shown a briefing for the CMO from Peter Lister of the Scientific Services Division (MED SEB) on 4 November 1983 [DHSC0003823_173, DHSC0002235_064 and DHSC0002235_065]. Whilst I would not have seen this document at the time, it appears to provide a good summary of the Department's understanding of the aetiology of AIDS at that stage:

"There is intensive research activity in the USA and elsewhere directed both at searching for the causative agent and at the basic immunology of the syndrome. The question of whether the pre-existing immune dysfunction allows infection by an AIDS virus or whether the agent itself causes the immune defect remains unknown. Although there is a fairly general acceptance of a viral aetiology the possibility of bacterial or fungal infection has not been dismissed..."

7.117. I am asked (Q57(b)) what the "professional advice" was that was made available to the designated Haemophilia Centres in relation to the possible risks of AIDS from this Factor VIII concentrates. In the absence of having seen the

explanatory brief which would have accompanied a draft of this answer, I cannot say what information about this was provided to me at the time. However, I understand that on 24 June 1983, the Chairman and Secretary of the UK Haemophilia Centre Directors Organisation, Professor Bloom and Dr Rizza, wrote to all Haemophilia Centre Directors summarising the discussions at a meeting of the UK Haemophilia Reference Centre Directors on 13 May 1983. In view of the risk of AIDS, recommendations for treatment for haemophiliacs had been agreed; these were set out. I am further informed that this advice continued to be discussed and kept under review by the UK Haemophilia Reference Centre Directors.

7.118. I am also asked when, and on what basis "no conclusive evidence" ceased to be "the DHSS's line to take" (Q57(c)). I do not recall when the advice of the medical advisors on the aetiology of AIDS changed. I can only assume that the medical advice followed the available medical evidence. From the documents, I do not think that I gave any answers to the House including the "no conclusive evidence" statement after the answer of 14 November 1983, but I cannot speak for other Ministers in relation to their answers to Parliamentary questions or correspondence.

7.119. I have been informed (Q58) that Edwina Currie MP stated in July 1990 that "whoever wrote the ["no conclusive evidence"] answer for Kenneth Clarke needs his head examined." I have been asked for my comments on this statement. Edwina Currie had the advantage of the benefit of hindsight when she expressed this opinion in July 1990. At the relevant time, I trusted the advice that I was receiving from the CMO and his team of medical advisors which, as I have already observed, I had no reason to challenge.

HIV and AIDS in 1984

7.120. I have been asked a number of questions about events in 1984. To the extent that they relate to the introduction of HTLV-III screening, I have answered them to the best of my ability above, 7.40 to 7.96. The topic of the AIDS leaflet is covered at paragraphs 7.5 to 7.39.

7.121. Plasma supplies and the introduction of heat treatment were discussed by me in an ITV interview I gave on 22 November 1984, which is drawn to my attention at Q60. In relation to the first issue, I said in the interview that the Department had been taking the issue of plasma supplies up with the Regional Health Authorities and that we were getting assurances from them that they would be delivering sufficient plasma. I agreed that this was an important issue. As regards heat treatment, I referred to an announcement made by the Board that ran "this service" that Factor VIII ought to be heat treated and said that the Department was taking advice on whether heat treatment would be "a proper protection against AIDS" or whether some other method would be more effective. I explained that the Department was "as anxious as everyone else" to see whether heat treatment was effective and to look at the practicality of doing this. The type of information that may have been provided to me before this interview can be seen from a briefing note for the Secretary of State dated 19 November 1984 from Dr Smithies [DHSC0002309_053], which was copied to my Private Office (Ms Bateman), although I cannot be sure now whether I saw this at the time. The documents also show that there was a briefing session with officials before the interview (see [DHSC0000435]). However, I have not been shown any documentary record of that briefing session, and so I cannot comment further on what information was given to me during it.

7.122. I have been asked (Q60(a)) to provide details of the assurances that were received from the RHAs about plasma supplies. Whilst I cannot be sure, in the absence of any documentary record of the briefing I was given prior to the interview, I think it is very unlikely that I would have been aware of the details of these assurances at the time. I also cannot assist the Inquiry with how the RHAs' commitments to meeting plasma targets were monitored (Q60(b)) or what action was taken if an RHA fell behind its target (Q60(c)). My understanding is that the DHSS officials with involvement in seeking assurances from the RHAs are more likely to be able to assist with this than I am. I have further been asked (Q60(d)) about the expert advice received by the DHSS at the time. Documents such as [DHSC0002249_034], which is a minute from Dr Smithies dated 20 November 1984 that I would not have seen

at the time, show that the view that was being taken of heat treatment by DHSS medical advisors at the time, but also that topic was being discussed by the Expert Advisory Group on AIDS. I am asked (Q60(e)) about the Board I referred to in the interview. It is apparent from the briefing note for the Secretary of State from Dr Smithies that the CBLA announced, on 19 November 1984, that they intended to heat treat all Factor VIII manufactured there from April 1985. It seems clear that the CBLA was the Board that I referred to in the interview, although I have not been shown a copy of their press release now. I understand that others have or will give detailed accounts of its genesis, membership and remit.

7.123. Q61 refers to the written answer which I gave to a question from Mr Nicholas Brown MP in Parliament on 4 December 1984 [DHSC0002008], in which I explained that we were strengthening our efforts to dissuade people from donating blood if they were a high risk of transmitting the AIDS virus. At the time:

a) The leaflet for blood donors aimed at discouraging high-risk groups from giving blood was being revised; and

b) There were more general education efforts being supported, to educate high risk groups (see, for example, paragraph 11 of the 19 November 1984 briefing note for the Secretary of State from Dr Smithies [DHSC0002309_053]).

7.124. I have covered the subject of the revision of the AIDS leaflet in more detail above.

HIV and AIDS in 1985

7.125. I have been asked (Q65) to comment on Dr Smithies' paper circulated on 2 January 1985 [PRSE0003287], which references an application for funding from Dr Tedder. I think it would be more informative if those questions were directed at those who were directly involved in this issue, as I would not have

seen this paper at the time, nor would I have apprised of the detail of applications for funding or the scientific steps being taken in development of a screening test.

7.126. I have been asked (Q71) why the Expert Advisory Group on AIDS (the EAGA) was "only" set up in January 1985. The question of what medical advisory groups would be most useful was predominantly a matter for the CMO, and Sir Donald Acheson was heavily involved in the creation of the EAGA. Whilst I was aware of its establishment, having provided written answers Parliamentary questions on 21 January and 20 February 1985 referring to this as part of the action taken to control the spread of AIDS [PRSE0002058 and DHSC0002261_043], I cannot now assist the Inquiry with why it was established **at this point**. I can see that the day before I gave my written answer of 20 February 1985 I was provided, through my Private Office (Mr Naysmith), with a Q&A briefing on the blood transfusion aspects of AIDS [DHSC0001598]. This did not however provide any background to the establishment of the EAGA.

7.127. Q72 asks me about the availability of heat-treated products, and the product licence application process, referring me to a written answer I provided to Mr Butterfill MP on 4 February 1985 [DHSC0006401_012]. Q73 asks questions about yields of heat-treated Factor VIII and DHSS's reaction to the need for heat-treatment of Factor VIII. Whilst I provided an answer to Mr Butterfill's question (a draft of which would have been provided to me), I do not believe that I had any personal involvement with this aspect of blood products policy, and I do not believe that I am able to help the IBI with these questions, some of which are technical. The type of information that I was being provided with about heat treatment for the purpose of answering Parliamentary questions (I have already explained that the Ministers with responsibility for blood products would not have been able to provide answers in the House of Commons, being members of the House of Lords) can be seen in the Q&A briefing provided to me through Mr Naysmith on 19 February 1985 [DHSC0001598], which I have referred to above. The response to question 7 explained as follows:

"Product licences are required by pharmaceutical firms wishing to market blood products in the UK, and the Department's Medicines Division are considering urgently a number of abridged applications for licences to cover heat-treated Factor VIII preparations.

However imported heat-treated Factor VIII is available now for prescription by clinicians on a "named-patient" basis. It is hoped that by April this year all the Factor VIII made by the Blood Products Laboratory Elstree will be heat-treated; limited supplies are available at present for clinical trials."

7.128. It appears that, in general terms, I would have been kept abreast of the progress of the introduction of heat treatment of blood products in the United Kingdom. I have been shown a copy of an update from the CMO to the Secretary of State, dated 30 July 1985, about the progress with regards to this [DHSC0000514]. The CMO was updating the Secretary of State. He advised that it was extremely unlikely that any patients with haemophilia treated in the United Kingdom would in future be infected with the HTLV III virus, but that "sadly a very high proportion of the haemophiliac population already are infected due to previous use of un heat treated Factor VIII". Although the minute is addressed to the Secretary of State, there is a note at the top, "MS(H) to note", which suggests that it was brought to my attention.

Section 8: General or Other Issues

8.1. I have been asked (Q82) what consideration, if any, was given by the DHSS during my tenure as Minister for Health to issuing (either directly or via the CMO) guidance, advice or instruction to clinicians and health bodies about the risks of infection from blood or blood products, the information to be provided to patients regarding such risks or the circumstances in which patients should or should not receive treatment with blood or blood products. This was not an area in which I had personal involvement and I am not in a position to provide an account of the consideration that others within the DHSS gave to it.

8.2. I am aware from the documents now provided to me that on 15 May 1985, the CMO sent out information for all doctors in England about AIDS [DHSC0105232]. It contained a paper from the Department's Expert Advisory Group on AIDS and a paper from the PHLS Communicable Disease Surveillance Centre with a detailed account of the epidemiology of the condition. This was sent out at a time when, according to Sir Donald, there had been only 159 cases of AIDS reported, but it was anticipated that it would become substantially more frequent. Sir Donald explained in his covering letter that he was sending the information he did because AIDS was a new disease about which information was not yet in text books but which had been widely discussed in the media often in an inaccurate and misleading way. I note that the papers enclosed by Sir Donald covered risk factors for AIDS, including the risk of infection as a result of blood transfusion and from blood products, and discussion of heat-treatment in relation to the latter [at pages 4, 9 and 14].

8.3. A press release was issued on 15 May 1985 about the provision of this information [DHSC0002269_049], which contained the following comments from Sir Donald:

"This latest initiative is part of a series of public health measures aimed at health professionals and people at risk. I hope it will provide doctors with information

which they will find helpful in the diagnosis and treatment of the disease and in counselling those who have worries about it."

8.4. I also note that the latest information about the availability of heat-treated Factor VIII concentrate was sent by Dr Harris, DCMO, to all Haemophilia Centre Directors on 15 August 1985, after concern had been raised by some Haemophilia Centre Directors in the British Medical Journal that some Haemophilia Centres were still using non heat-treated products [DHSC0002489_110].

8.5. Whether and what information was provided to clinicians and health bodies would have been entirely a matter for the CMO, who would not have sought my views on this. It seems to me that the CMO would have been reliant on expert advice from specialist doctors when it came to information or guidance about haemophilia care or the use of blood products. Moreover, it would not have been appropriate for the CMO to provide "instruction" to clinicians about the treatment of their patients. The Department did not then and does not now supervise how patients are treated and clinical freedom was and remains an important and respected principle.

8.6. I have next been asked (Q83) to provide a chronological list of all Parliamentary contributions made during my tenure as Minister of State 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, as well as the exhibit number where I have exhibited an answer I provided to the House to this Statement. It is complete to the best of my understanding, but it is of course dependent on the accuracy of the searches for documents that have been made on my behalf and the completeness of the Hansard online records.

8.7. I have been asked to state whether I consider that the government responded to the risks posed by infected blood and blood products in a timely manner (Q84). As to this, first, any answer that I can give must be limited to my period as Minister of State for Health, and not a more general and undefined period of

time. Equally, I have made it clear that I was involved in only a part of the government's response, and cannot speak to the detail of other parts. However, I did not at the time, nor do I now, consider that the Department omitted to act where it should have done. Had I thought from my relatively limited involvement in relevant matters that the Department was not handling these issues properly or in a timely manner, I would not have kept silent; I would have intervened, first by speaking to Lord Fowler, as Head of the Department.

8.8. Finally, I have been asked if there are any other issues arising during my time as Minister for Health that may be of relevance to the Inquiry. Only two issues have been identified that are not already covered in this Statement, which are as follows:

a) It appears that there was a concern in September 1982 that blood for use in patients in Scotland was being imported from Southern Ireland, raised in a minute from Dr Edmund Harris to Dr Griffin and Mr Williams of 16 September 1982 [DHSC0004047_434]. This minute referred to Ministers holding very strong views on this matter and suggested that I had recently stated to a meeting with the Private Sector Liaison Committee that the Department would not tolerate the importation of blood. I cannot remember any further details about the issue.

b) On 6 August 1985, Mr Patten announced that the Government had asked health authorities to draw up plans for a nationwide AIDS counselling service and had funded St Mary's Hospital, Paddington to set up a new training course for AIDS counsellors, the first of its kind in the UK [BMAL0000010_018]. I do not think I was involved in action taken in this area but I draw it to the Inquiry's attention nonetheless.

Statement of Truth

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

Signed GRO-C

Dated 1/7/2021

Annex A – List of Parliamentary Contributions

Date	Hansard Ref	Event	Topic	Link	Exhibit number where applicable
16 March 1982	HC Deb 16 March 1982 vol 20 c93W	Written Answers, Commons	BPL	https://api.parliament.uk/historic-hansard/written-answers/1982/mar/16/blood-laboratory-elstree#S6CV0020P0_19820316_CWA_311	
22 March 1982	HC Deb 22 March 1982 vol 20 cc256-7W	Written Answers, Commons	Blood supplies	https://api.parliament.uk/historic-hansard/written-answers/1982/mar/22/blood-supplies-private-health-care#S6CV0020P0_19820322_CWA_210	
06 April 1982	HC Deb 06 April 1982 vol 21 c295W	Written Answers, Commons	Blood donations	https://api.parliament.uk/historic-hansard/written-answers/1982/apr/06/blood-donations#S6CV0021P0_19820406_CWA_203	
06 April 1982	HC Deb 06 April 1982 vol 21 c300W	Written Answers, Commons	Blood transfusions	https://api.parliament.uk/historic-hansard/written-answers/1982/apr/06/blood-transfusions#S6CV0021P0_19820406_CWA_245	
11 May 1982	HC Deb 11 May 1982 vol 23 c226W	Written Answers, Commons	Blood supplies	https://api.parliament.uk/historic-hansard/written-answers/1982/may/11/blood-	

				supplies#S6CV0023P0_19820511_CWA_141	
24 May 1982	HC Deb 24 May 1982 vol 24 cc237-8W	Written Answers, Commons	National Blood Transfusion Service	https://api.parliament.uk/historic-hansard/written-answers/1982/may/24/national-blood-transfusion-service#S6CV0024P0_19820524_CWA_149	
08 June 1982	HC Deb 08 June 1982 vol 25 c61W	Written Answers, Commons	Blood Products (Imports)	https://api.parliament.uk/historic-hansard/written-answers/1982/jun/08/blood-products-imports#S6CV0025P0_19820608_CWA_440	
08 June 1982	HC Deb 08 June 1982 vol 25 c61W	Written Answers, Commons	Blood Supplies	https://api.parliament.uk/historic-hansard/written-answers/1982/jun/08/blood-supplies#S6CV0025P0_19820608_CWA_442	
08 June 1982	HC Deb 08 June 1982 vol 25 cc61-2W	Written Answers, Commons	Blood Sales	https://api.parliament.uk/historic-hansard/written-answers/1982/jun/08/blood-sales#S6CV0025P0_19820608_CWA_444	WITN0758004
21 June 1982	HC Deb 21 June 1982 vol 26 c30W	Written Answers, Commons	Blood Transfusion Service	https://api.parliament.uk/historic-hansard/written-answers/1982/jun/21/blood-transfusion-service#S6CV0026P0_19820621_CWA_205	

07 July 1982	HC Deb 07 July 1982 vol 27 c141W	Written Answers, Commons	Blood Transfusion Service	https://api.parliament.uk/historic-hansard/written-answers/1982/jul/07/blood-transfusion-service#S6CV0027P0_19820707_CWA_213	
19 July 1982	HC Deb 19 July 1982 vol 28 cc52-3W	Written Answers, Commons	Blood Supplies	https://api.parliament.uk/historic-hansard/written-answers/1982/jul/19/blood-supplies#S6CV0028P0_19820719_CWA_332	
25 Oct 1982	HC Deb 25 October 1982 vol 29 c310W	Written Answers, Commons	Blood Supplies	https://api.parliament.uk/historic-hansard/written-answers/1982/oct/25/blood-supplies#S6CV0029P0_19821025_CWA_379	
16 Nov 1982	HC Deb 16 November 1982 vol 32 cc136-7W	Written Answers, Commons	Blood Transfusion Service	https://api.parliament.uk/historic-hansard/written-answers/1982/nov/16/blood-transfusion-service#S6CV0032P0_19821116_CWA_390	
14 March 1983	HC Deb 14 March 1983 vol 39 c59W	Written Answers, Commons	Blood Supplies	https://api.parliament.uk/historic-hansard/written-answers/1983/mar/14/blood-supplies#S6CV0039P0_19830314_CWA_372	
5 July 1983	HC Deb 05 July 1983 vol 45 cc51-2W	Written Answers, Commons	Factor VIII	Question here: https://api.parliament.uk/historic-hansard/written-	WITN0758002

	HC Deb 05 July 1983 vol 45 cc52-3W			answers/1983/jul/05/factor-viii Answer wrongly filed here: https://api.parliament.uk/historic-hansard/written-answers/1983/jul/05/pensions	
5 July 1983	HC Deb 05 July 1983 vol 45 c53W	Written Answers, Commons	Blood Products Laboratory	https://api.parliament.uk/historic-hansard/written-answers/1983/jul/05/blood-products-laboratory	
11 July 1983	HC Deb 11 July 1983 vol 45 c275W	Written Answers, Commons	Blood Supplies	https://api.parliament.uk/historic-hansard/written-answers/1983/jul/11/blood-supplies#S6CV0045P0_19830711_CWA_486	DHSC0006401_005
27 July 1983	HC Deb 27 July 1983 vol 46 cc500-2W	Written Answers, Commons	Blood Supplies	https://api.parliament.uk/historic-hansard/written-answers/1983/jul/27/blood-supplies-2#S6CV0046P0_19830727_CWA_435	
24 Oct 1983	HC Deb 24 October 1983 vol 47 c55W	Written Answers, Commons	NHS Blood (Charges)	https://api.parliament.uk/historic-hansard/written-answers/1983/oct/24/nhs-blood-charges#S6CV0047P0_19831024_CWA_393	
04 Nov 1983	HC Deb 04 November 1983 vol	Written Answers, Commons	Blood Supplies (Private Hospitals)	https://api.parliament.uk/historic-hansard/written-answers/1983/nov/04/blood-supplies-private-	

	47 cc486-7W			hospitals#S6CV0047P0_19831104_CWA_149	
8 Nov 1983		Written Answers, Commons	Blood Supplies (Handling Charges)	https://api.parliament.uk/historic-hansard/written-answers/1983/nov/08/blood-supplies-handling-charges	
14 Nov 1983	HC Deb 14 November 1983 vol 48 cc327-8W	Written Answers, Commons	Blood Products (Imports)	https://api.parliament.uk/historic-hansard/written-answers/1983/nov/14/blood-products-imports#S6CV0048P0_19831114_CWA_350	PRSE0000886
16 Nov 1983	HC Deb 16 November 1983 vol 48 c490W	Written Answers, Commons	Blood Donors	https://api.parliament.uk/historic-hansard/written-answers/1983/nov/16/blood-donors#S6CV0048P0_19831116_CWA_305	
16 Nov 1983	HC Deb 16 November 1983 vol 48 c497W	Written Answers, Commons	Blood (Handling Charge)	https://api.parliament.uk/historic-hansard/written-answers/1983/nov/16/blood-handling-charge#S6CV0048P0_19831116_CWA_359 (N.B. Written Answer of 8 Nov referred to was an answer provided by the Secretary of State announcing the detail of the handling charges)	

22 Nov 1983	HC Deb 22 November 1983 vol 49 c110W	Written Answers, Commons	Hepatitis B vaccine	https://api.parliament.uk/historic-hansard/written-answers/1983/nov/22/hepatitis-b-vaccine#S6CV0049P0_19831122_CWA_288	
17 Jan 1984	HC Deb 17 January 1984 vol 71 cc222-3W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1984/jan/17/aids#S6CV0071P0_19840117_CWA_331	
11 April 1984	HC Deb 11 April 1984 vol 58 c278W	Written Answers, Commons	Blood and Blood Products	https://api.parliament.uk/historic-hansard/written-answers/1984/apr/11/blood-and-blood-products#S6CV0058P0_19840411_CWA_434	
14 May 1984	HC Deb 14 May 1984 vol 60 c74W	Written Answers, Commons	Acquired Immune Deficiency Syndrome	https://api.parliament.uk/historic-hansard/written-answers/1984/may/14/acquired-immune-deficiency-syndrome#S6CV0060P0_19840514_CWA_552	
12 July 1984	HC Deb 12 July 1984 vol 63 c660W	Written Answers, Commons	Blood (Sale)	https://api.parliament.uk/historic-hansard/written-answers/1984/jul/12/blood-sale#S6CV0063P0_19840712_CWA_458	
16 July 1984	HC Deb 16 July 1984 vol 64 c78W	Written Answers, Commons	Blood and Blood Products	https://api.parliament.uk/historic-hansard/written-answers/1984/jul/16/blood-and-blood-	

				products#S6CV0064P0_19840716_CWA_496	
23 Nov 1984	HC Deb 23 November 1984 vol 68 cc325-6W	Written Answers, Commons	Raw Blood Plasma	https://api.parliament.uk/historic-hansard/written-answers/1984/nov/23/raw-blood-plasma#S6CV0068P0_19841123_CWA_268	CBLA0000042_057
23 Nov 1984	HC Deb 23 November 1984 vol 68 c326W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1984/nov/23/aids#S6CV0068P0_19841123_CWA_270	CBLA0000042_057
28 Nov 1984	HC Deb 28 November 1984 vol 68 c521W	Written Answers, Commons	Blood Products	https://api.parliament.uk/historic-hansard/written-answers/1984/nov/28/blood-products#S6CV0068P0_19841128_CWA_347	DHSC0002251_014
28 Nov 1984	HC Deb 28 November 1984 vol 68 c531W	Written Answers, Commons	AIDS (Blood Donors)	https://api.parliament.uk/historic-hansard/written-answers/1984/nov/28/aids-blood-donors#S6CV0068P0_19841128_CWA_389	DHSC0002251_017
03 Dec 1984	HC Deb 03 December 1984 vol 69 cc71-2W	Written Answers, Commons	Blood Donations (Screening Tests)	https://api.parliament.uk/historic-hansard/written-answers/1984/dec/03/blood-donations-screening-tests#S6CV0069P0_19841203_CWA_553	

04 Dec 1984	HC Deb 04 December 1984 vol 69 cc160-1W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1984/dec/04/aids#S6CV0069P0_19841204_CWA_365	DHSC0002008
11 Dec 1984	HC Deb 11 December 1984 vol 69 cc470-1W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1984/dec/11/aids#S6CV0069P0_19841211_CWA_538	
10 Jan 1985	HC Deb 10 January 1985 vol 70 c543W	Written Answers, Commons	AIDS (Blood Donors)	https://api.parliament.uk/historic-hansard/written-answers/1985/jan/10/aids-blood-donors#S6CV0070P0_19850110_CWA_135	
17 Jan 1985	Unknown	Written Answers, Commons	AIDS	Does not appear to be available on Hansard online	DHSC0002257_030
21 Jan 1985	HC Deb 21 January 1985 vol 71 cc346-7W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/jan/21/aids#S6CV0071P0_19850121_CWA_466	PRSE0002058
22 Jan 1985	HC Deb 22 January 1985 vol 71 c414W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/jan/22/aids#S6CV0071P0_19850122_CWA_383	
23 Jan 1985	HC Deb 23 January	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/jan/23/aids#	

	1985 vol 71 c464W			S6CV0071P0_19850123_CWA_301	
24 Jan 1985	HC Deb 24 January 1985 vol 71 cc523-4W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/jan/24/aids#S6CV0071P0_19850124_CWA_358	BNOR0000036
01 Feb 1985	HC Deb 01 February 1985 vol 72 c363W	Written Answers, Commons	AIDS (Nurses)	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/01/aids-nurses#S6CV0072P0_19850201_CWA_242	
04 Feb 1985	HC Deb 04 February 1985 vol 72 cc450-1W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/04/aids#S6CV0072P0_19850204_CWA_479	DHSC0006401_012
04 Feb 1985	HC Deb 04 February 1985 vol 72 c451W	Written Answers, Commons	Blood Products	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/04/blood-products#S6CV0072P0_19850204_CWA_483	DHSC0006401_012
04 Feb 1985	HC Deb 04 February 1985 vol 72 c451W	Written Answers, Commons	Blood Donors	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/04/blood-donors#S6CV0072P0_19850204_CWA_485	DHSC0006401_012
04 Feb 1985	HC Deb 04 February 1985 vol 72 c464W	Written Answers, Commons	AIDS (Nurses)	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/04/aids-	

				nurses#S6CV0072P0_19850204_CWA_554	
05 Feb 1985	HC Deb 05 February 1985 vol 72 c525W	Written Answers, Commons	Heat-treated Factor IX	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/05/heat-treated-factor-ix#S6CV0072P0_19850205_CWA_421	
05 Feb 1985	HC Deb 05 February 1985 vol 72 cc525-6W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/05/aids-1#S6CV0072P0_19850205_CWA_423	
05 Feb 1985	HC Deb 05 February 1985 vol 72 c527W	Written Answers, Commons	Blood Products	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/05/blood-products-1#S6CV0072P0_19850205_CWA_433	CBLA0002020
07 Feb 1985	HC Deb 07 February 1985 vol 72 cc681-2W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/07/aids#S6CV0072P0_19850207_CWA_312	
08 Feb 1985	HC Deb 08 February 1985 vol 72 c730W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/08/aids#S6CV0072P0_19850208_CWA_236	
11 Feb 1985	HC Deb 11 February 1985 vol 73 c71W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/11/aids-	

				2#S6CV0073P0_19850211_CWA_488	
12 Feb 1985	HC Deb 12 February 1985 vol 73 c160W	Written Answers, Commons	AIDS (Blood Donors)	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/12/aids-blood-donors#S6CV0073P0_19850212_CWA_485	
14 Feb 1985	HC Deb 14 February 1985 vol 73 c279W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/14/aids#S6CV0073P0_19850214_CWA_401	
15 Feb 1985	HC Deb 15 February 1985 vol 73 c320W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/15/aids#S6CV0073P0_19850215_CWA_198	
18 Feb 1985	HC Deb 18 February 1985 vol 73 c388W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/18/aids#S6CV0073P0_19850218_CWA_411	
19 Feb 1985	HC Deb 19 February 1985 vol 73 c446W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/19/aids#S6CV0073P0_19850219_CWA_323	
19 Feb 1985	HC Deb 19 February 1985 vol 73 cc446-7W	Written Answers, Commons	Factor VIII	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/19/factor-	MACK0000067_007

				viii#S6CV0073P0_19850219_CWA_325	
20 Feb 1985	HC Deb 20 February 1985 vol 73 cc498-500W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/20/aids#S6CV0073P0_19850220_CWA_363	DHSC0002261_043
21 Feb 1985	HC Deb 21 February 1985 vol 73 cc585-6W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/21/aids#S6CV0073P0_19850221_CWA_486	
22 Feb 1985	HC Deb 22 February 1985 vol 73 c600W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/22/aids#S6CV0073P0_19850222_CWA_23	DHSC0002261_080
25 Feb 1985	HC Deb 25 February 1985 vol 74 cc65-6W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/25/aids-2#S6CV0074P0_19850225_CWA_385	PRSE0003350
26 Feb 1985	HC Deb 26 February 1985 vol 74 c139W	Written Answers, Commons	Blood Products	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/26/blood-products#S6CV0074P0_19850226_CWA_264	
26 Feb 1985	HC Deb 26 February 1985 vol 74 cc139-40W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/26/aids#S6CV0074P0_19850226_CWA_266	DHSC0002261_065

27 Feb 1985	HC Deb 27 February 1985 vol 74 cc213-4W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/feb/27/aids-1#S6CV0074P0_19850227_CWA_327	
05 March 1985	HC Deb 05 March 1985 vol 74 c500W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/mar/05/aids#S6CV0074P0_19850305_CWA_515	
07 March 1985	HC Deb 07 March 1985 vol 74 c598W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/mar/07/aids#S6CV0074P0_19850307_CWA_518	
07 March 1985	HC Deb 07 March 1985 vol 74 cc600-1W	Written Answers, Commons	Factor VIII	https://api.parliament.uk/historic-hansard/written-answers/1985/mar/07/factor-viii#S6CV0074P0_19850307_CWA_536	
07 March 1985	HC Deb 07 March 1985 vol 74 c601W	Written Answers, Commons	Haemophilia Society	https://api.parliament.uk/historic-hansard/written-answers/1985/mar/07/haemophilia-society#S6CV0074P0_19850307_CWA_540	
12 March 1985	HC Deb 12 March 1985 vol 75 cc140-1	Commons Sitting	AIDS	https://api.parliament.uk/historic-hansard/commons/1985/mar/12/aids#S6CV0075P0_19850312_HOC_111	

12 March 1985	HC Deb 12 March 1985 vol 75 c117W	Written Answers, Commons	Factor VIII	https://api.parliament.uk/historic-hansard/written-answers/1985/mar/12/factor-viii#S6CV0075P0_19850312_CWA_263	DHSC0001602
12 March 1985	HC Deb 12 March 1985 vol 75 c117W	Written Answers, Commons	Haemophilia Society	https://api.parliament.uk/historic-hansard/written-answers/1985/mar/12/haemophilia-society#S6CV0075P0_19850312_CWA_267	
12 March 1985	HC Deb 12 March 1985 vol 75 cc117-8W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/mar/12/aids#S6CV0075P0_19850312_CWA_269	
15 March 1985	HC Deb 15 March 1985 vol 75 cc322-3W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/mar/15/aids#S6CV0075P0_19850315_CWA_230	
21 March 1985	HC Deb 21 March 1985 vol 75 c591W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/mar/21/aids#S6CV0075P0_19850321_CWA_342	
25 March 1985	HC Deb 25 March 1985 vol 76 c87W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/mar/25/aids#S6CV0076P0_19850325_CWA_449	

20 May 1985	HC Deb 20 May 1985 vol 79 c330W	Written Answers, Commons	Blood Donors	https://api.parliament.uk/historic-hansard/written-answers/1985/may/20/blood-donors#S6CV0079P0_19850520_CWA_312	
24 June 1985	HC Deb 24 June 1985 vol 81 cc328-9W	Written Answers, Commons	Blood	https://api.parliament.uk/historic-hansard/written-answers/1985/jun/24/blood#S6CV0081P0_19850624_CWA_473	
27 June 1985	HC Deb 27 June 1985 vol 81 cc473-4W	Written Answers, Commons	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1985/jun/27/aids#S6CV0081P0_19850627_CWA_224	HSOC0018679_003
01 July 1985	HC Deb 01 July 1985 vol 82 c65W	Written Answers, Commons	NHS (Blood Supplies)	https://api.parliament.uk/historic-hansard/written-answers/1985/jul/01/nhs-blood-supplies#S6CV0082P0_19850701_CWA_352	
05 July 1985	HC Deb 05 July 1985 vol 82 c303W	Written Answers, Commons	Blood Transfusion Service	https://api.parliament.uk/historic-hansard/written-answers/1985/jul/05/blood-transfusion-service#S6CV0082P0_19850705_CWA_156	DHSC0002271_019