Witness Name: John Patten
Statement No: WITN5297001
Exhibits: None
Dated: 5 April 2022

INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF JOHN PATTEN

I, John Haggitt Charles Patten will say as follows: -

CONTENTS TABLE FOR STATEMENT

Section 0: OPENING COMMENTS

0.1. I was the Parliamentary Under-Secretary of State for Health between 14 June 1983 and 2 September 1985. I make this statement to assist the Inquiry in response to a Rule 9 request for a statement dated 17 December 2021. I have followed the general ordering of the Inquiry's request.

0.2. I wish to express my profound personal sympathy for all those affected by the infected blood issues. I am very conscious that such statements may seem formulaic to some, but it is truly felt and meant.

0.3. On a personal level I would wish to add this: I support this Inquiry and its aims. There are some who may question an inquiry which in part is looking back 40 or more years ago. I am not one of them. In a very different context, later on as a Home Office Minister, I opposed in parliament attempts to time limit war crimes investigations. For this Inquiry, I accept that there is significant value in looking at the events of the 1970s and 1980s. I declare a limited interest in that, going back over very many years, Teresa May was an undergraduate pupil of mine and remains a colleague and friend (though I have not discussed these events with her, nor indeed with my fellow Ministers from the time). I fully support her decision to hold this Inquiry and I approach my evidence in that spirit, recognising the importance of the Inquiry's aims. The passage of time does however make it *exceptionally* difficult for me to answer many of the questions the Inquiry has raised, though I have done as much as I can to do so. On many aspects, the Inquiry has requested (in quite some forensic detail) my opinions and recollection on matters about which I have no memory now; where I was not the Minister principally dealing with the subject at the time; and on which I can only attempt a rationalisation or reconstruction of my likely thinking based on the available documents, which very unfortunately are not in the event always complete. Against that background, I fear I can make no apology for repeating a number of times in this statement the limitations of my memory and role. I have nevertheless tried to give full answers and offer my views in the spirit of support for the Inquiry to which I have referred.

0.4. I am the first to admit that I am, by disposition, forgetful. This is something I have recognised since my own school days. Before reviewing the various documents now made available to me, I had virtually no independent memory of the matters being considered by this Inquiry. I had some limited recollection of my visit to the United States (New York and Washington) in the summer of 1985 which I have addressed in Section 5 of this statement.

0.5. While people sometimes speak of having 'refreshed their memory' from documents, I find that having reviewed all the documents made available to me, they have not in fact triggered any actual recollection of meetings or discussions, although some of the names certainly are familiar. I remain, therefore, entirely dependent on the written records.

Section 1: INTRODUCTION

1.1. The Inquiry asks me to set out my background, qualifications and a brief overview of my career. I am 76 years old and my date of birth is known to the Inquiry and my address is House of Lords, SW1A 0PW.

1.2. I read geography at Cambridge, and went on to complete a PhD there in historical geography. I was a Fellow and Tutor at Hertford College, Oxford from 1972 – 1994 and University lecturer from 1969 – 1979, lecturing in geography. I do not therefore have a medical or scientific background.

1.3. In terms of public service, I was an Oxford City Councillor from 1973 – 1976. I entered Parliament as the Conservative member for the City of Oxford in the 1979 election, and was an MP until the 1997 election (City of Oxford 1979-1983; then, following boundary changes, Oxford West and Abingdon between 1983 -1997). I stood down at the 1997 election.

1.4. During that time, I had the following roles:

(1) 1980 – 5 January 1981: Parliamentary Private Secretary to the Ministers of State at the Home Office;

(2) 5 January 1981 - 13 June 1983: Parliamentary Under-Secretary of State (Northern Ireland Office);

(3) 14 June 1983 - 2 September 1985: Parliamentary Under-Secretary for Health (Department of Health and Social Security);

(4) 2 September 1985 - 12 June 1987: Minister of State (Department of Environment) (Housing and Urban Affairs);

(5) 13 June 1987 - 9 April 1992: Minister of State (Home Office)

(6) 10 April 1992 - 20 July 1994: Secretary of State for Education and Science.

1.5. I was created a Life Peer on 17 June 1997.

1.6. Since 2001, I have been Senior Advisor to Charterhouse Capital Partners LLP a long established private equity firm (formerly Charterhouse Development Capital Ltd) and prior to that I was an Adviser and non-executive Deputy Chairman of Charterhouse PLC. Between 1997 and 2016, I also held various positions with the Lockheed Martin Group. I am Honorary Fellow of Harris Manchester College, Oxford.

1.7. Save in respect of the Ministerial roles set out above, I have not had a role (such as committee or society membership or office) on issues directly relevant to the Inquiry's terms of reference.

1.8. I have not given evidence to other inquiries, investigations or litigation relevant to the subject matter of this Inquiry.

Section 2: DECISION MAKING STRUCTURES (DHSS)

Structure and organisation of the Department of Health and Social Security 1983 - 1985

2.1. The Inquiry asks me to explain what responsibility I had had for matters relating to blood and blood products as Parliamentary Under-Secretary of State for Health.

2.2. Throughout the period that I held the post, the Secretary of State for Health and Social Security was Norman Fowler and the Minister of State for Health was Kenneth Clarke (both of whom were already in post when I joined the Department). There was a joint Parliamentary Under-Secretary of State in the Lords. Lord Glenarthur took up that role at the same time I joined the Department in June 1983, and Baroness Trumpington succeeded him in late March 1985.

2.3. Blood and blood products fell within the portfolio of responsibilities of the Parliamentary Under-Secretary in the Lords and – to the best of my knowledge – would have been subject to escalation to the Minister of State and Secretary of State as deemed necessary.

2.4. The documents made available to me and the detailed questions raised of me by the Inquiry show that I was copied into – and at times contributed to – submissions and consideration of issues in the area, even though this was not a subject within my specific list of responsibilities. This was not unusual because:

(1) Lord Glenarthur was a Minister in the Lords and so Kenneth Clarke and I would need to be able to cover the issues when raised in the Commons;

(2) Decision making was to some extent collegiate in any event and it was not unusual for the Private Office of other Ministers to be copied into submission principally addressed to other Ministers. We had what I think were weekly meetings of Ministers, with the Permanent Secretary in attendance, where current issues would be discussed. Inevitably there were other informal discussions within the Ministerial team.

(3) As the documents make clear, early on – in June 1983 – I had expressed an interest in AIDS policy and on that basis I think officials would have been more inclined to include me in the copy list for submissions. We did not work in silos.

(4) There was a general preference not to put the Minister in the Lords up for media interviews since it was generally considered more appropriate for the elected Ministers from the Commons to fulfil media commitments.

2.5. The first of these points is one I would like to emphasise and expand on in part because of the nature of some of the Inquiry's questions which seek information on what I personally did as result of submissions. This was Lord Glenarthur's area with the Minister of State often getting involved. In the nicest possible way, Lord Glenarthur would not have appreciated me attempting to make the decisions in his area. It is not altogether easy to explain the interplay between what were termed PS(L) and PS(H). In a sense, on Lord Glenarthur's policy areas, I had to act as a sort of 'understudy' or 'shadow' to him for when matters might be raised in the Commons. And the same worked in reverse with Lord Glenarthur having to be 'understudy' for my areas (such as Special Hospitals) when they were raised in the Lords. We could and would contribute a view if we had one and generally help each other. And the process meant that we were, to an extent, informed about each other's policy areas, which was necessary and a positive. But it did not mean that the lines of responsibility were blurred. Nor did it mean that I would go on to get involved in (or be responsible for) follow-up actions in his areas of responsibility. I emphasise this so that the relatively frequent copying-in of my Private Office in submissions is not misinterpreted in any way.

2.6. In Section 5 of this statement, I have addressed questions from the Inquiry about the introduction of the screening test of blood donations for HIV. The submission was addressed to me via my Private Secretary rather than being addressed to Baroness Trumpington. As I have addressed in Section 5 of this statement, the available records do not explain why this particular submission came directly to me for a decision, despite being in Baroness Trumpington's area of responsibility. I can only really speculate that it is possible that:

(1) Baroness Trumpington was away at the time or there was some similar issue of practicality or convenience that meant that officials came to me;

(2) As I had seen the earlier submissions in 1984/early 1985 and statements, and/or because I had recently been in general discussion with the CMO, it was felt more appropriate for this submission to be addressed to me;

(3) It was directed to me in error.

In any event, there is some suggestion in the papers that it may have been Baroness Trumpington and Mr Clarke who made the decision, or at least that they were involved in it. I return to the detail of this in Section 5.

2.7. Most ministerial decisions would be taken following a written submission to the relevant minister, such submissions being sent to the Private Office of the minister expected to take the decision, and sometimes copied to the Private Office of other ministers, and to senior officials in the relevant and associated areas (this might include the Chief Medical Officer and / or Permanent Secretary who also had Private Offices). To expand on the general process, I would say that:

(1) In some cases, the minister would ask for (or be offered) a meeting / verbal briefing on the issue in addition to the written submission;

(2) If the submission was going to one of the Parliamentary Under-Secretaries of State (for health this was Lord Glenarthur and me), we could escalate the issues to the Minster of State or Secretary of State if

we felt it necessary. Further and in any event, we would have Ministerial meetings at which current issues for decision would be discussed and we would also naturally have less formal discussions with each other as Ministers in the same Department.

(3) Submissions directed to the Private Office for decision by that Minister would naturally normally be seen by that Minister. There could be exceptions to this, however. For example if the Private Secretary on reviewing the submission did not feel that there was sufficient information or if the Private Secretary knew that it was a decision which ought to be taken by a different Minister for whatever reason. Normally, however, the Minister to whom the submission was addressed would see that submission.

(4) Submissions which were merely copied to the Private Office of a Minister were somewhat different in that the Private Office would exercise discretion as to whether the Minister actually needed to see that particular submission and, if so, when. Current workload, and where the Minister physically was (e.g. away on ministerial business, on holiday *etc.*) would be a relevant consideration.

2.8. The relevant policy and medical civil servants had to exercise judgement on when to come to Ministers whether for a decision or to update them. There are some categories where Ministerial submissions were obviously required: a change of policy or significant new spending commitments being obvious examples. Submissions would often be written by the Principal or Senior Principal working in the policy area (or by the equivalent rank of medical officer), but the submission would be checked and cleared at a higher level such as Assistant Secretary level who might forward the submission with their own comment or observation. So for example the submission on the revision of the blood donor leaflet in August 1984 was prepared by Mr Williams but sent to Ministers by Mr Parker with his own brief comments [DHSC0002309_044].

2.9. The Inquiry asks how effective the process was in my experience in ensuring that ministers were suitably informed of key issues. To an extent, that is an impossible question because by nature you are not aware of the matters not drawn to your attention. I was impressed by, and had a high regard for, the vast majority of the civil servants working in the Department. My general recollection is that certainly I did not want for information. The reality in a huge and busy Department like the DHSS was that there was an unrelenting flow of correspondence, submissions, and briefings which the Private Office had to try to control and keep within manageable bounds. Inevitably, there would be occasions when you would think 'I should have been told about that' or perhaps 'told about that sooner' but these were the exception rather than the rule.

2.10. Reviewing the papers provided to me in preparation of this statement, I regret that after so long I do not recall many of the officials who were involved and the submissions themselves (and the senior officials to whom they were copied) are the best guide to the key persons involved. I do recall the following:

(1) The Permanent Secretary, Sir Ken Stowe. He was highly experienced and impressive.

(2) Donald Acheson the Chief Medical Officer from late 1984 onwards. My recollection is that he gave excellent help. I cannot remember his predecessor Sir Henry Yellowlees at all, nor ever having any meetings with him.

(3) From the other names I have seen on the papers, I very vaguely recalled Dr Walford, to the extent that I remember that she was a strong-minded and impressive medical officer.

Relationship with relevant departments concerning Scotland, Wales and Northern Ireland

2.11. As Parliamentary Under-Secretary of State for Health in the DHSS, I did not have responsibility for health matters in Scotland, Wales and Northern Ireland which (pre-devolution) were the responsibilities of the respective territorial

Departments. However on some matters, UK-wide policy was in reality led by England by virtue of greater population / resource.

2.12. As a junior health minister, to the best of my recollection, I did not have much direct contact with the junior ministers in the territorial Departments. Most liaison was done at the level of officials; submissions could be copied to civil servants in the Scottish, Welsh and Northern Ireland Office or there could be separate correspondence and discussions with them. Where there were serious issues that needed resolving, they tended to be dealt with at Secretary of State level because the respective Secretaries of State were each Cabinet Ministers. I cannot recall having direct contact with the health-related bodies in Scotland, Wales and Northern Ireland, as opposed to the Ministers of those Departments.

Section 3: KNOWLEDGE OF AND RESPONSE TO RISK OF INFECTION ASSOCIATED WITH BLOOD AND BLOOD PRODUCTS - AIDS

Initial briefings and knowledge

3.1. The Inquiry asks what I can recall from memory and from the available documents about the early information that came to me about the risk of HIV transmission through blood products. Beyond the documents made available to me, I do not have any active memory about what I learnt on this and from whom so the written records are the best guide to what I was told, though I appreciate that they may not be complete.

3.2. On 28 June 1983, P Winstanley minuted my Private Secretary noting that I had:

> *"... expressed interest in AIDS and, although Ministerial responsibility for the National Blood Transfusion Service now rests with Lord Glenarthur, has asked for some information." [DHSC0002309_022]*

Mr Winstanley then attached an earlier briefing for Lord Glenarthur which had been sent to him on 22 June 1983 and had been drafted by Dr Walford [DHSC0002309_121] and [DHSC0002309_124]. Mr Winstanley went on to note that,

> *"Mr Patten may be interested to know that we shall also be putting a submission to Lord Glenarthur shortly to approve the issue of the AIDS leaflet mentioned in the brief, and within the next month hopefully a note detailing the progress made in those areas where action is being taken or contemplated to prevent the spread of AIDS together with recommendations."*

3.3. So far as I can now remember, I had expressed an interest in AIDS policy to officials because it was a subject of growing parliamentary and media interest. As I have explained, I was not responsible for signing things off in this area but I anticipated there would be questions about it in the Commons and more widely in the media, as indeed proved to be the case.

3.4. Having expressed an interest in AIDS policy and been sent Dr Walford's briefing paper for Lord Glenarthur on the subject, I expect that I would have read it at the time. I think this paper from Dr Walford is probably the most reliable guide to the information I was provided with in the early weeks at the Department. I would have read it with an interested-eye rather than an area where I would be making direct decisions. I do not believe that I had any meetings or further verbal briefings on this from Dr Walford at the time.

3.5. The Inquiry asks what I understood from the section of Dr Walford's paper which stated,

> *"As a secondary method of spread, contaminated needles used by drug addicts and the transfusion of blood and plasma taken from donors carrying the AIDS agent, account for the occurrence of AIDS in intravenous drug abusers, haemophiliacs and recipients of blood transfusion. Haemophiliacs seem at greatest risk of acquiring AIDS in this way, since the clotting factor which they need (Factor VIII) is prepared from the pooled plasma of many thousands of donations. It is interesting however, that although the numbers of AIDS cases reported in homosexuals appears to be increasing at a rate of 4-5 new cases daily, the numbers of haemophiliacs with AIDS (10 out of an estimated 12,000 haemophiliacs requiring treatment in the USA) does not seem to have altered over the past several months."*

I have no recollection of what I actually thought or understood from this at the time, or whether I particularly alighted on this passage. Reading it now, it suggests that needles, and blood and transfusion of blood and plasma were a likely route of infection for drug abusers and haemophiliacs/blood transfusion recipients respectively. I note now that, later in the briefing, Dr Walford stated that the cause of AIDS was unknown but the evidence was suggestive that it may be a virus and that it also seemed likely that some additional pre-disposing factors may determine an individual's susceptibility.

3.6. I am asked how my knowledge of the risk of transmission of AIDS by way of blood or blood products evolved over my time as Parliamentary Under-Secretary for Health. It is really exceptionally difficult, so long after the events, to give a timeline of how my knowledge evolved. I have to rely on the

documents, though they do not capture any discussions I may have had, for example with ministerial colleagues.

3.7. The Inquiry asks what role I had in respect of policy in relation to AIDS generally at this time and to the risk of transmission of AIDS through blood and blood products specifically. As the documents make clear, this fell under Lord Glenarthur's area of delegated responsibilities. My involvement came from the fact that I had expressed an interest in the subject, probably linked with the fact that I would need to be kept informed because of the likelihood of questions arising in the Commons. Looking at it now, my early expression of interest in late June 1983, was probably why officials began fairly routinely copying me in, including in relation to the blood donor leaflet consideration from early July (see further below).

3.8. The Inquiry asks if I had any concerns about the blurring of the lines of ministerial responsibility. As I have already mentioned, I do not think that the lines of responsibility were blurred in any way. Mr Winstanley was clear that this was Lord Glenarthur's area. Being pro-active and identifying areas of developing policy was very much part of a junior minister's role in health and did not entail any encroachment upon Lord Glenarthur's policy responsibility. This did not mean that I had "oversight" of Lord Glenarthur's subject area. But – as was the case with the blood donor leaflet – it meant that policy officials and the other Private Offices would tend to copy my Private Office in so that I could – if I felt it appropriate – express my own views and would be, broadly speaking, kept informed.

3.9. The Inquiry asks if the responsibilities changed later on. I do not think that they did, but I address my more direct involvement in HIV screening of blood donations in Section 5 of this statement below.

3.10. The Inquiry also asks who was responsible for the National Blood Transfusion Service prior to Lord Glenarthur's appointment. Lord Glenarthur and I were appointed at the same time following the June 1983 election. I do not now have any knowledge of how the ministerial responsibilities were allocated prior to our appointment.

The September 1983 donor leaflet

3.11. The Inquiry refers me to the following documents:

(1) Covering minute dated 1 July 1983, sent by Mr Parker to Mr Joyce, Lord Glenarthur's Private Secretary [DHSC0002309_024];

(2) the submission attached to that minute [DHSC0002309_121] and the appended draft leaflet [DHSC0002309_122];

(3) a minute dated 4 July 1983 from Mr Joyce indicating Lord Glenarthur's approval of the submission relating to the leaflet [DHSC0002309_025];

(4) a further minute dated 4 July 1983 from Mr Parker concerning a public announcement of the leaflet [DHSC0002309_026];

(5) a meeting note dated 6 July 1983, the meeting having been attended that day by Mr Clarke, Lord Glenarthur, Mr Parker, Dr Oliver and Mr Bolitho, regarding the leaflet and surrounding publicity [DHSC0001511]. The meeting note was copied to my Private Secretary amongst others;

(6) my response to the 1 July submission, sent by my Private Secretary (Mrs Walden) to Mr Clarke and copied to Lord Glenarthur's Private Secretary amongst others on 6 July 1983 [DHSC0002309_027];

(7) I note from the available papers that, in addition to the above, on 8 July 1983 my Private Secretary was informed that Mr Clarke had noted my views of 6 July without comment upon them [DHSC0001660].

3.12. The Inquiry asks what involvement I had in the discussions that took place about this leaflet in or around July 1983. Again, I feel that I should make clear

that I do not have any independent recollection now of the exchanges around this leaflet so I am entirely dependent on the available documents.

3.13. Looking now at the documents, I expect that I would have been included in the discussions on the leaflet where practicable. However the note of the meeting on 6 July 1983 records each attendee and I was not amongst them [DHSC0001511]. It is impossible for me to comment particularly meaningfully now on why I was not at that specific meeting and whether I would have expected to have been. The minute of 4 July 1983 from Mr Parker to Mr Joyce, Lord Glenarthur's Private Secretary, suggests that Lord Glenarthur was already content with the information leaflet enclosed with the submission [DHSC0002309_026]. So it may have been Ken Clarke as Minister of State who called for the meeting on 6 July. It may be that I was simply not available that day and that Lord Glenarthur's attendance (as the Parliamentary Under-Secretary with the delegated responsibility for the subject) was far more important than mine.

3.14. What I was able to do – and did do– was contribute my own brief views on the 1 July submission, in that my Private Secretary passed on my view to the Minister of State that,

> *"In my view, public concern on this issue is mounting, and rightly.*
>
> *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]*

I think that response speaks for itself. My own view was that we should publish the leaflet as soon as possible. I could see that there was the potential for discrimination arguments to be raised, a point of concern raised as a sensitive issue in the 1 July submission. But I was supportive of the line taken in the submission that the Gay Medical Association had already been approached by the NBTS Directors and could properly be used to dispel concerns amongst the homosexual community that the action was discriminatory. It is difficult now to put oneself back in time and comment (as the Inquiry asks me to do) on what timeframe for publication I had in mind. I do not feel that I can put a specific

timeframe on it; I can only say that my inclination was that we should just get on with it.

3.15. The Inquiry asks what impact the concerns about discrimination had. I do not now particularly recall this concern about discrimination being raised but it is apparent that it was something that had to be taken into account in the handling of the blood donor leaflet. Mr Parker's submission of 1 July 1983 had been copied to the Home Office and the available records include a response to Mr Parker, dated 8 July 1983, on the discrimination point [DHSC0002229_072]. From the available records, it does not seem to me that the discrimination concern impacted on the timescale for publication but it was a factor that had to be considered.

3.16. The Inquiry asks if I had any concerns about the way the leaflet had been drafted or its content. My main focus would probably have been on the policy issue raised which was whether we were prepared to fund and publish the leaflet despite the sensitivities, as this was in the best interests of public health. My own response of 6 July was a firm affirmative to that, although it may be implicit in what I said that I had no particular concerns about the actual content of the leaflet as drafted.

3.17. The Inquiry refers me to a Scottish Home and Health Department minute from Dr Albert Bell [PRSE0000049]. I would not have seen this at the time. The Inquiry notes that paragraph 2 of the minute records that, "…we *are informed that Mr Fowler's first reaction is that the terms of this leaflet are too strong, and that DHSS may therefore make further amendments.*" The Inquiry asks if I have any recollection of Mr Fowler expressing views about the terms of the leaflet and if so whether I agreed with his position. I have no memory of this at all.

3.18. The Inquiry refers me to:

(1) an exchange of minutes between Mr Parker, Dr Oliver, and Mr Bolitho[1] dated between 19 and 25 July 1983 in which the method of distribution of the leaflet was debated, including what these officials had understood Mr Clarke's and Lord Glenarthur's views on this issue to have been. My Private Office was not a copy recipient of these minutes. Within these minutes, the view was attributed to Mr Clarke that the leaflet operation should be kept low key and that he was against distribution of the leaflet with the call-up cards. This was against the background of needing to ensure that we did not spread unnecessary alarm and despondence amongst donors. Mr Bolitho, in his minute of 21 July 1983 suggested that, "*The leaflet is an information leaflet and cannot be seen as a leaflet which you read and then change your mind about giving blood*". [DHSC0002321_028];

(2) The submission from Mr Parker to Mr Clarke's Private Office dated 29 July 1983, was copied to Lord Glenarthur's Private Office and mine [DHSC0002327_016] and [DHSC0002327_117]. In this submission, officials recommended that Regional Transfusion Directors should be given the discretion to decide between distributing the leaflet with call-up cards and making it available at donor sessions, for a six month trial period.

(3) The Ministerial responses to this submission, namely:

(a) The response from my Private Office, dated 2 August 1983 giving my views:

> *"1. I think that printing and distribution arrangements should go ahead as soon as possible, with low key publicity as suggested.*
>
> *2. We need to do something, and for it to be known that we have done something, in case the worst does happen. Can it be done by end August?*
>
> *3. Is there any reason why Directors could not follow both methods of distribution for the trial period?" (original emphasis)[DHSC0002327_118]*

[1] Mr Parker to Dr Oliver, 19 July 1983 [DHSC0002321_026]; Dr Oliver to Mr Parker, 20 July 1983 [DHSC0002321_027]; Mr Bolitho to Dr Oliver, 21 July 1983 [DHSC0002321_028]; Dr Oliver to Mr Bolitho, 25 July 1983 [DHSC0002321_029].

(b) The response from the Minister of State's Private Office also dated 2 August 1983

"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." (original emphasis) [DHSC0002327_119]

(c) The response from Lord Glenarthur's Private Office, dated 3 August 1983

"(i) He approves the text of the leaflet and statement.

(ii) He has asked if we have a publication date in view;

(iii) He has asked whether he or MS(H) should deal with any TV/radio interest;

(iv) He favours using both methods of distribution and feels that the risk of embarrassment to potential donors is outweighed by the need to achieve wide distribution.

… He has 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." [DHSC0002327_120]

(d) The further minute from the Minister of State's Private Office dated 5 August 1983: [DHSC0002309_033]

"Thank you for a sight of Lord Glenarthur's comments. My own view is that MS(H) would want to handle any press interviews if he were available at the time.

I understand that it will take about 3 weeks for the leaflet to be printed at which time MS(H) will be in Birmingham and could handle interviews from there or Nottingham. I suggest we take a rain check when we know that the leaflet has been printed."

3.19. The Inquiry asks a number of questions about the above documents which I think are to some extent interrelated.

3.20. Looking at the documents now, it is plain that there were factors pulling in different directions:

(1) On the one hand there was the important point that this was a public health protection measure and there was a strong case for getting the leaflet printed and distributed quickly, and distributed as widely as possible.

(2) On the other hand, there was the concern – specifically referenced in the meeting note of 6 July - about scaremongering and wishing to avoid damage to the transfusion service. Looking at the documents now, I think the concern here was that adverse publicity might cause a degree of panic and put donors (and possibly donor recipients) off completely. That is why there was such concern to stress that donors were not going to be questioned about sexual matters. And, looking at the available documents again now, I think that is why the submission of 29 July 1983 referred to Ministers being anxious to avoid misinformed Press publicity which could '....*blow up the problem out of all proportion".* There was also a concern about perceived discrimination against the homosexual community but that does not seem to me to have been as significant a factor as the concern about inducing a sense of panic in the transfusion service.

3.21. It was in the context of the latter concern that there was emphasis given to dealing with the leaflet with low key media handing. I would surmise that this is also why some had concerns about the leaflet being sent out with call-up cards, although it seems from the documents that I personally saw no difficulty with that option.

3.22. I think it is fair to say that, in my responses, I saw the former concerns as largely outweighing the latter concerns. I was certainly very clear that the leaflet was necessary. But I note that while I pressed for early distribution of the leaflet and suggested that both forms of distribution should be used, I was in favour of the low key approach to publicity. In addition,

(1) The Inquiry asks what I meant by "low key publicity" and what this would have entailed. From the available documents, what was initially envisaged was explained in Mr Parker's minute of 4 July 1983 (the leaflet being sent to selected journalists). However by the time of the 29 July submission, officials were recommending a low-key public statement.

(2) The Inquiry also asks about my statement that, "*We need to do something, and for it to be known that we have done something, in case the worst does happen.*" I think I was here averting to the risk that AIDS could be transmitted through donated blood and that if that did transpire, questions would obviously be raised about what was done and when in response to the risk.

(3) As to the nature of the risk, I would have been guided by the advice being given by officials; the submission of 1 July 1983 had said that there was "*… increasing evidence that AIDS may be transmitted by the transfusion of blood which is taken from a person who is either suffering from AIDS or who is in the incubation period of the disease*", though we would also have noted that the case numbers (at this stage) were small, albeit in relation to a disease with a lengthy incubation period.

(4) I would not have seen it at the time but the Inquiry asks me about Mr Bolitho's minute. I do not think I would have agreed with Mr Bolitho's suggestion that "*The leaflet is an information leaflet and cannot be seen as a leaflet which you read and then change your mind about giving blood*". One of the leaflet's aims was to deter the high risk groups from donating blood.

3.23. While I cannot speak for Lord Glenarthur, from the documents, his views appear to have been broadly similar to mine.

3.24. Similarly I cannot speak for Mr Clarke, but from the documents he would appear to have been particularly concerned about the risk that the media could end up inducing a panic-type reaction which could itself be harmful.

3.25. The Inquiry refers me to the relevant records for late August and early September 1983:

(1) Minute of 26 August 1983 from Mr Naysmith (Mr Clarke's Private Office) to Mr Winstanley [DHSC0002309_034]. My Private Office was a copy recipient. This minute recorded that Mr Clarke has seen the Q&A briefing and proposed press statement as well as Information Division information on recent alarmist press coverage, and that Mr Clarke had commented,

> *"The publicity is annoying, partly because it is what I feared and what we do not want."Docs Ban Gays' Blood" etc. I am concerned by the report that similar alarmist action caused a shortage of blood in New York.*
>
> *The range of views from Directors is also alarming. Have we agreed on one method of using the leaflet. There could well be a fuss and a scare if different steps are taken in different parts of the country. What authority do I have to insist on one national method and what are the options?"*

(2) Minute from Mr Naysmith (Mr Clarke's Private Office) to Mr Ghaghan (Lord Glenarthur's Private Office) dated 31 August 1983 [DHSC0002309_035]. My Private Office was a copy recipient. This minute recorded that the two Ministers had met the previous day. The printing and distribution of the leaflets had been completed and the RTD were awaiting the go-ahead. Mr Naysmith said,

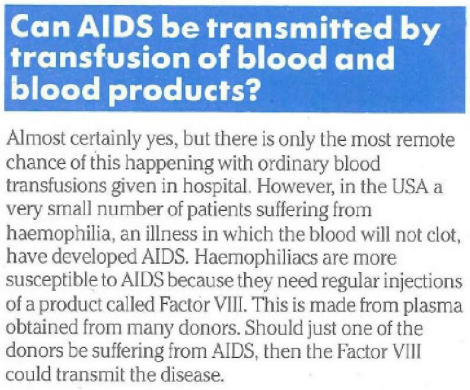
> *"2 … Mr Winstanley drew my attention to Stephen Alcock's minute of 2 August, which contained MS(H)'s comments on the question of how best to distribute the leaflet. At that time MS(H) was not aware of the wide divergence of opinion between the Regional Transfusion Directors but was content to allow them discretion to use the leaflet.as they saw fit, for a six month trial period.*
>
> *3. MS(H) has been reviewing his earlier decision and in the light of the information supplied by Mr Winstanley has confirmed that he is content to allow the distribution to proceed on the basis outlined above, subject to any last minute views which Lord Glenarthur may have.*
>
> *4. I will be minuting Mr Winstanley with the full text of MS(H)'s comments in due course. In the meantime could I ask you to bring PS(L) up to date on the current situation and obtain his comments on the six-month trial proposal, as soon as possible please."*

(3) The available records also include a further minute from Mr Naysmith to Mr Winstanley on the same day, 31 August 1983, which gave Mr Clarke's views and was also copied to Lord Glenarthur's Private Office and my own [DHSC0002321_034]

(4) Minute from Mr Ghagan (Lord Glenarthur's Private Office) to Mr Naysmith (Mr Clarke's Private Office) dated 1 September 1983 [DHSC0002309_036]. My Private Office was a copy recipient. The minute conveyed that,

> *"Lord Glenarthur has seen your minute of 31 August and has suggested that the trial period should last 3 months instead of 6 months. I understand that MS(H) is content with this and the leaflet can now go ahead.*
>
> *Lord Glenarthur would like copies of the Director's responses and copies of the briefing you have requested from Miss Edwards when this arrives."*

(5) The leaflet as published on 1 September 1983 [BPLL0007247]. This included the following passage:



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.

(6) The associated Press Release on 1 September 1983 [DHSC0006401_006]. The Inquiry suggests in its request that in this statement Mr Clarke, *"… stated that there was "no conclusive proof" that AIDS may be transmitted in blood or blood products"*. Citing from the press announcement a little more fully, I note that it contained the following wording,

> *"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 the presence of 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. This is what this leaflet sets out to do"

3.26. The Inquiry raise a number of issues related to the above.

3.27. First, I am asked about the length of time that it took for the leaflet to be published (so far as Ministerial involvement was concerned, this was the two months from 1 July 1983 to 1 September 1983). Three weeks of this period appear to be accounted for by the time required to print the leaflet during the month of August. As to the remainder of the time, there appears to have been:

(1) the period 1 July – 6 July 1983 when the ministerial team considered the 1 July submission with views expressed in writing and the meeting of Lord Glenarthur and Mr Clarke on 6 July;

(2) the period between 6 July and 29 July 1983 when officials made minor changes to the wording of the leaflet and debated the means of distribution issue. From the available papers, I note that within this period there was also an exchange of minutes between Lord Glenarthur's Private Office and Mr Clarke's Private Office, 22 July 1983 [DHSC0002309_029] and 26 July 1983 [DHSC0002309_031] concerning reference to the Council of Europe Recommendation (see further paragraph 3.42 *ff* below)

(3) 29 July – 3 or 5 August 1983, when the leaflet was cleared;

(4) 26 August – 1 September 1983 when it seems the issue of the nature of the distribution was briefly revisited by Mr Clarke with a response by Lord Glenarthur.

3.28. Looking at these timescales now, my observations would be that

- Judged by today's standards of digital publication, the three weeks for printing the leaflets of course appears too long. But in 1983 that period was difficult to avoid.
- Matters could perhaps have been pushed through more quickly in July than they were, though the issues being considered were rightly to be debated.

3.29. Second, I am asked if I was involved in the discussion at the end of August when the distribution method was looked at further or in the terms of the press release. I am afraid that I simply cannot now recall. Based on the documents alone, it looks as if the final distribution method (agreeing to the discretion but for a short trial period of three months) was decided upon by Mr Clarke and Lord Glenarthur, and similarly the clearance of the press release. I would not consider that to have been inappropriate given that this was Lord Glenarthur's policy area and that Mr Clarke was giving input at Minister of State level. I would not have expected to have been involved in the mechanism for reporting back the result of the trial period. That sort of aspect would normally be handled by officials and at Ministerial level they would, in the first instance at least, normally report to the junior minister within whose portfolio the subject matter fell. I had earlier mooted the possibility of both methods of distribution being trialled. However, given the reported difference of view between Regional Transfusion Directors, it was perhaps better to press on with the compromise of the discretion by-way-of trial approach than delay distribution beyond 1 September.

3.30. Looking at the matter now with the knowledge of the large numbers of those infected, it is of course the case that one can say that the leaflet could have been published sooner; that the distribution could have been more forthright (circulated both with call-up cards and at donor sessions) and the terms of the leaflet could have been stronger. You have to deal with the situation as it presents itself, including such matters as the (reported) difference of view between Regional Transfusion Directors on the best method of distribution.

Nevertheless, I think my only other comment would be that at the time, I was impressing the need for the earliest possible publication.

Meeting on 15 September 1983

3.31. I am referred by the Inquiry to Lord Glenarthur's witness statement and specifically §6.8 in which he said as follows,

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

3.32. I have no recollection of this meeting at all, and Lord Glenarthur's statement has not helped to jog any memory of it. If Lord Glenarthur recalls me being there and his personal diary records I was due to attend, I have no reason to doubt that is correct. But I cannot speak to what was discussed. The Inquiry asks why I was invited to this meeting and not previous meetings with Lord Glenarthur and Mr Clarke. We all had very busy diaries and I find nothing unusual in the fact that there were some meetings between Lord Glenarthur and Mr Clarke which I did not attend, and one or more others that I did attend. I would go back to the fact that it was Lord Glenarthur's area of responsibility and Mr Clarke was involved at Minister of State level. I had expressed an interest in AIDS policy

and contributed where I could or was asked. But my attendance at such discussions would not have been essential and did not involve me in taking of any policy decisions.

'No conclusive proof'

3.33. The Inquiry refers to a number of occasions in which ministers publicly stated that there was "no conclusive proof" that AIDS was transmitted by blood or blood products or phrases to similar effect. The examples to which the Inquiry refers me are as follows (though I have given slightly fuller citations of the use of the phrase for context):

(1) **Lord Glenarthur, Oral Questions in the Lords'. 14 July 1983:**

> ***Baroness Dudley**: ...To ask Her Majesty's Government how widespread is the disease AIDS in the United Kingdom and Europe, and what steps are being taken to prevent it spreading in the community.*
>
> ***The Parliamentary Under-Secretary of State, Department of Health and Social Security (Lord Glenarthur):** My Lords, 14 confirmed cases of AIDS have been reported to the Communicable Disease Surveillance Centre at Colindale, and a further two cases are under investigation. On the basis of the information available to us there are some 60 cases within other member states of the Council of Europe.*
>
> *The Medical Research Council has established a working party and co-ordinate research into the disease. The Communicable Disease Surveillance Centre is operating a national surveillance system, which includes making available a summary of information for doctors about the incidence, identification and methods of control of the disease. Although there is no conclusive evidence that AIDS is transmitted by blood or blood products, the department is considering the publication of a leaflet indicating the circumstances in which blood donations should be avoided." [DHSC0002229_085]*

(2) **A letter from Lord Glenarthur to Clive Jenkins dated 26 August 1983 [DHSC0002231_036]**:

> *"I think that I should emphasise, firstly, that there is no conclusive evidence that AIDS is transmitted through blood products. Nevertheless we are taking all practicable measures to reduce any possible risks to recipients of blood and blood products. Our scope*

for action in this is limited, as there is no means of testing for the presence of AIDS in blood donors or in blood products.

With regard to blood donation in the UK a leaflet is in the course of preparation which will be circulated through the 'National Blood Transfusion Service seeking to discourage potential donors in high-risk groups from giving blood until more is known about what causes AIDS."

(3) **A letter from Lord Glenarthur to Baroness Masham dated 30 August 1983 [DHSC0002231_037]**:

"There is, in fact, no conclusive proof that AIDS can be transmitted by blood, cryoprecipitate or Factor VIII concentrates. While no cryoprecipitate for therapeutic use is imported into this country, we are at present dependent on imports from the USA for about half our requirements of Factor VIII for the treatment of haemophilia. In March this year the US Food and Drug Administration initiated new Regulations for the collection of plasma, designed to exclude donors from high-risk groups. Although future supplies of Factor VIII both for export and for use in America will be manufactured from plasma collected in accordance with these Regulations, there is still a quantity of stock, some already in the UK and more in America awaiting shipment here, which has been made from "pre-March" plasma. The FDA has recently decided not to ban the use of similar stocks intended for the USA market because to do so would cause a crisis of supply.

The same considerations apply to the UK supply position. My officials have been in close touch with the Haemophilia Society about the AIDS problem and we are all very grateful to them for the constructive and responsible attitude they have taken. Naturally this is a matter of great concern to them; but they did not support the cries from some quarters to ban the import of Factor VIII because they accepted that the possible risks of infection from AIDS must be balanced against the obvious risk of not having enough Factor VIII. You will, however, be interested to know that I have arranged to meet the Society on 8 September to hear, at first hand, some of the problems they are facing. One of the topics I am sure they will wish to discuss is progress on the new Blood Products Laboratory at Elstree which, when completed in three years' time at a cost of £21 million, will be capable of making this country self-sufficient in blood products."

(4) **The Press Release accompanying the 1 September 1983 blood donor leaflet as set out at paragraph 3.25(6) above**;

(5) **A letter from Lord Glenarthur to John Maples MP dated 16 December 1983 [ARCH0000679]**:

> *"I can well appreciate the anxiety, particularly amongst haemophiliacs and their families which recent press reports on AIDS may have caused and would first of all like to put matters into perspective: the cause is as yet unknown and there is no conclusive proof that the disease has been transmitted by American blood products. Nevertheless, I would like to assure your constituent that the Government is committed to making this country self-sufficient in blood products. Over £2m has already been spent on improving the production facilities of the Blood Products Laboratory at Elstree, Herts and a major redevelopment programme is under way. When this is complete the Central Blood Laboratories Authority will have a new Laboratory of a size capable of meeting the demands of England and Wales for blood products. Meanwhile, in the absence of a satisfactory alternative, we shall be [dependent] upon imports from the USA for an adequate supply of Factor VIII. While there is as yet no test for AIDS, such imports, prepared from plasma collected after March this year, will be subject to new regulations initiated by the US Food and Drug Administration, designed to exclude donors from high risk groups, (eg persons with symptoms and signs suggestive of AIDS; sexually active homosexual or bisexual men with multiple partners: intravenous drug abusers). Although future supplies of Factor VIII both for export and for use in America will be manufactured from plasma collected in accordance with these Regulations, there is still a quantity of stock which has been made from pre-March plasma. The FDA has recently decided not to ban the use of such stocks because to do so would cause a crisis of supply. The same considerations apply here.*
>
> *We are of course anxious to minimise the possible risk of the transmission of AIDS by blood donation in this country. My Department, in conjunction with Regional Transfusion Directors, has issued a leaflet "AIDS and how it concerns blood donors" which asks people from high risk groups to refrain from giving blood. A copy is enclosed."*

3.34. While none of these examples is of documents originating from me, I think I may have been aware at the time that the line to take involving 'no conclusive proof' was being used.

3.35. I understand that this line to take was developed and in use before I had taken up post and so I do not know who first formulated it nor the evidence considered when it was drawn up.

3.36. In terms of my own understanding of the degree of risk of transmission of AIDS by blood or blood products, as I have indicated, I would have been guided by the advice of officials contained in documents such as Dr Walford's paper of 22 June 1983, and the submission of 1 July 1983.

3.37. The Inquiry asks whether at the time, or now, I considered that there was a tension, "*between the unqualified statement that there is "no conclusive evidence that AIDS is transmitted by blood or blood products""* and various of the examples set out above. Had this been spotted *at the time* as a tension then I have no reason to doubt that I and others would have raised it. Looking at it now, I accept that there is a degree of tension and that a better balance could have been struck in the wording. However, the Inquiry is, I believe, wrong to assert that the statements were unqualified. In the fuller citations of the documents set out above there is, in each case, contextual reference to the steps that the Department was taking to deal with the risk and/or overt reference to the possible risks. The Inquiry's request notes the difference between the press statement accompanying the blood donor leaflet and the content of the donor leaflet itself. However,

(1) The press statement did also contain the reference, "*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 the presence of AIDS*";

(2) A copy of the donor leaflet (containing the wording that AIDS could 'almost certainly' be transmitted by transfusion of blood and blood products) was attached to Lord Glenarthur's letter to Mr Maples.

I accept, therefore, that there is clear force in the Inquiry's identification of a tension in the wording used, but nor should the 'no conclusive proof' line be quoted out of the context in which it appeared. Read as a whole, the documents do indicate that there was a risk of transmission and that the government was taking action accordingly.

3.38. The Inquiry refers me to a 26 March 1984 handwritten note by a DHSS official, who stated, "*We dropped 'there is no conclusive proof that AIDS is transmitted through blood or blood products' from our standard line some time ago*" [DHSC0002239_089]. I do not know the circumstances in which the line to take using the words "no conclusive proof" came to be dropped or who decided upon this. The documents available to me do not assist on the point.

3.39. The Inquiry invites me to reflect on the use of the phrase and the fact that its use was maintained until December 1983. As I have already indicated, a better balance could have been struck in the wording and I think it also right that the wording should have been amended sooner. The Inquiry also asks if the phrase assisted or hampered the public's or patients' understanding. The phrase itself was – I as understand it – accurate. But my reflection now is that it required more balance if it was to be used. I think it would be wrong for me to speculate on what actual impact this had on public understanding, as I have no idea nor data. An analysis of that question should look at the government and NHS communications as a whole, rather than taking a single clause without the context in which it was used.

The approach to the importation and use of plasma products

3.40. The Inquiry invites me to consider a letter of 9 May 1983 with the attached paper sent by Dr Nichol Spence Galbraith, Director of the Communicable Disease Surveillance Centre, Public Health Laboratory Service to Dr Ian Field of the Department [CBLA0000043_040]. This letter was sent before I joined the Department as a Minister so obviously I would not have seen it at the time. I have no memory now of seeing it once I was within the Department and, unless there is a record of it being copied to my Private Office at a later stage, I think it extremely unlikely that I was shown it.

3.41. The Inquiry asks if I think this should have been drawn to my attention and notes Dr Galbraith's view that all blood products made from blood donated in the USA after 1978 should be withdrawn from use in the UK until the risk of AIDS transmission had been clarified. However the Inquiry also draws to my attention the contrary views of Dr Walford as expressed in her minute of 13 May 1983 [DHSC0002227_047]. Both these pre-dated my arrival in the Department. The Inquiry's later questions to me include questions about the consideration that was given to the continuing use of imported Factor VIII by the Biologicals Sub-Committee of the Committee on the Safety of Medicines. In general terms, if a balancing of risk involved clinical expertise and was within the domain of an expert body like the Committee on the Safety of Medicines, then I would expect that body to give independent scrutiny to the range of credible views and the evidence base. However, if there were dissenting views on an important matter of patient safety when considered by the expert body then the machinery ought to have enabled matters to be escalated to the CMO and Ministers if appropriate. And there would be some cases where it would be useful for Ministers to be specifically alerted to the decision of the expert body.

Council of Europe Recommendation R(83)8

3.42. The Inquiry refers me to the following:

(1) The Council of Europe Recommendation R (83) 8 of 23 June 1983, "on preventing the possible transmission of Acquired Immune Deficiency Syndrome (AIDS) from affected blood donors to patients receiving blood or blood products" [MACK0000307];

(2) An undated minute of July 1983 from Mr Cumming to Mr Lupton and my Private Secretary Mrs Walden, also copied to the Secretary of State's Private Office and then copied on to the Private Offices of Lord Glenarthur and Mr Clarke [DHSC0002309_086]. This minute referred to the CoE recommendation and advised,

"3. The subject of the Recommendation is the prevention of transmission of acquired immune deficiency syndrome (AIDS) from affected blood donors to patients receiving blood or blood products.

On the basis of present knowledge it is assumed that AIDS is transmissible by blood and the recommendation aims to ensure that appropriate precautions are taken in the preparation of certain blood products and that specific groups of recipients such as haemophiliacs are accordingly reassured.

4. An information leaflet for blood donors used by the American Red Cross is appended to the Recommendation for the convenience of National Blood Transfusion Services wishing to draw up their own leaflet.

5. The Recommendation does not prevent the United Kingdom from continuing to import factor VIII concentrate from the USA on whom we currently rely for about 50% of our supply."

(3) A minute from Mr Joyce (Private Secretary to Lord Glenarthur) to Mr Clarke's Private Secretary, dated 22 July 1983, recording that Lord Glenarthur was in favour of accepting the Recommendation and *"[feels] there might be merit in referring to the 'European' advice when MS(H) announces the publication of our own leaflet to potential blood donors*" [DHSC0002309_029].

(4) The minute in reply dated 26 July 1983 from Mr Clarke's Private Office to Lord Glenarthur's noting that Mr Clarke was in agreement that the leaflet should refer to the European advice [DHSC0002309_031].

3.43. I am unable to say with confidence whether or not Mr Cumming's undated minute was specifically drawn to my attention [DHSC0002309_086]. It was addressed to my Private Office for reasons I cannot now understand. The handwritten annotations show that it was forwarded to Lord Glenarthur and Mr Clarke's Private Offices. Minutes addressed directly to my Private Office for my attention ordinarily would be shown to me but in some circumstances they might not be, including if my Private Office felt that the matter should be redirected to another Minister. This may have been one such occasion.

3.44. In general terms I would have expected officials to ensure that the UK action in response to the AIDS risk in blood was in conformity with recommendations of this kind, unless there was a necessary reason to depart from it. However I am

not able to describe, from my personal knowledge, what assessment was in fact done. As I have explained, while I expressed an interest in AIDS policy and was therefore copied into some submissions and contributed views, this was not my policy area. There may have been discussions at the time but if so, I cannot recall the detail so long after the event. The Inquiry asks more generally, how significant recommendations from the Council of Europe were on policy formulation but I cannot say as I cannot now remember how they were viewed. In terms of action taken in response to this particular recommendation, I have no actual recollection. My view looking at the documents now is that:

(1) The decision making on modes of treatment (avoiding the use of large pool plasma products 'wherever possible') and information given to individual treating physicians / patients would have been led by the clinicians and their representative bodies whose responsibility it was. But I cannot from my personal knowledge say what liaison there may have been between officials and bodies such as the United Kingdom Haemophilia Centre Directors.

(2) In terms of information to blood donors, the leaflet was going to give information to donors to discourage the risk groups from donating. The exchange of minutes between the Private Offices of Lord Glenarthur and Mr Clarke show that they considered it appropriate to refer to the advice in what was published when the leaflet was finalised. I note that the press release of 1 September 1983 did refer to the Council of Europe recommendation [DHSC0006401_006].

3.45. The Inquiry draws my attention to the specific phrase used by Mr Cummings that, "*On the basis of present knowledge it is assumed that AIDS is transmissible by blood*" [DHSC0002309_086]. I have addressed my understanding of the risks of transmission at paragraph 3.36, above; I think the reason why action was being taken was that we were acting on the assumption that AIDS could be transmitted by blood.

3.46. The Inquiry asks what steps were taken by myself or within the DHSS to find an alternative method of gaining access to Factor VIII supplies. I think that my understanding at the time was that until the new BPL facility at Elstree came online, we would not have sufficient capacity to produce enough domestic (NHS) Factor VIII and were therefore dependent upon imports where Factor VIII remained the advisable treatment and there was insufficient domestic product. I have addressed the redevelopment of the BPL facility in Section 6 of this statement.

World Federation of Hemophilia

3.47. The Inquiry refers me to the Resolutions by the World Federation of Hemophilia General Assembly regards AIDS, of 29 June 1983 [PRSE0001351]. The two recommendations of the Medical Board were as follows:

> *"1) There is insufficient evidence to recommend at the present, any change in treatment; therefore present treatment, of hemophilia should continue with whatever blood products are available, according to the judgement of the individual physician.*
>
> *2) Longitudinal studies are urgently needed on the questions already mentioned, as well as better definition of the relative risk/benefit ratios of various treatment regimens."*

These were followed by a list of actions being undertaken by the World Federation.

3.48. I cannot recall being aware of these Resolutions at the time and I expect that they would have been considered by officials in the Department.

3.49. The Inquiry refers me to the written answer I gave to Gwyneth Dunwoody MP on 11 July 1983,

> *"Mrs. Dunwoody asked the Secretary of State for Social Services how many people have died from acquired immune deficiency syndrome in the United Kingdom; and how many of these people were haemophiliacs.*
>
> *Mr. John Patten: The communicable disease surveillance centre, in collaboration with microbiologists, clinicians and the Office of Population Censuses and surveys, has been undertaking surveillance of acquired*

immune deficiency syndrome since September 1982. Up to 7 July 1983, five male deaths had been reported, none of which were haemophiliacs." [DHSC0006401_005]

The Inquiry asks how I would be kept updated about the latest developments in relation to blood / blood products and AIDS. For a PQ such as this, officials would produce a draft answer normally with a background note which the Minister answering the question would be asked to approve. Where, as here, the question related to a policy area covered by the Minister in the Lords, I would expect the suggested answer to also be copied to that Minister. Where the PQ asked for up-to-date figures, officials would be expected to supply the most recently available reliable data for the proposed answer. In terms of updates on developments more generally, Ministers were kept informed by submissions and verbal briefings as I have set out in the process I have sought to describe in Section 2 of this statement.

The meeting of the Biologicals Sub-Committee of the Committee on the Safety of Medicines, 13 July 1983

3.50. The Inquiry refers me to the meeting of the Biologicals Sub-Committee on the Safety of Medicines on 13 July 1983, and specifically:

(1) A record of the conclusions of the meeting [DHSC0001208];

(2) Minutes of the meeting [ARCH0001710];

(3) Minute H Morgan to various DHSS officials referring to the CSM(B) meeting of 13 July and attaching the Chair's working paper and a paper by Dr Fowler [DHSC0003618_147];

(4) The Chairman's working paper / suggested agenda for discussion on AIDS at the meeting [DHSC0001209];

(5) Paper on AIDS by Dr L K Fowler (DHSS) [DHSC0002229_059].

3.51. In answer to one of the Inquiry's questions, I can say with confidence that I was not involved in "influencing or shaping" the views of the Sub-Committee. I say

that because it was not the role of Ministers to influence the outcome of these kinds of expert committees who would be expected to apply their independent expertise to the issues under consideration.

3.52. So long after the events, it is much more difficult to address the Inquiry's questions as to whether I was aware of the CSM(B)'s deliberations and conclusions. The available papers do not suggest that they were drawn to the attention of my Private Office at the time by way, for example, of being copied into a submission directed to Lord Glenarthur / Mr Clarke. I am unable to say whether they may have been raised in meetings and verbal briefings.

3.53. Looking at things now in the round, given the importance and profile of this issue, I think that it would have been appropriate for the CSM(B) consideration / decision to have been the subject of a submission to Ministers, which in this case ought to have been to Lord Glenarthur.

3.54. Beyond the specific conclusions of the CSM(B), the Inquiry asks me more widely about whether I received briefings or submissions on:

(1) Whether blood products made from pooled plasma should be withdrawn from NHS use, and whether patients should be treated with cryoprecipitate instead.

(2) Whether blood products made from pooled plasma by companies outside the UK should be excluded from the UK.

(3) Whether I was aware of the American Food and Drug Administration ("FDA") recommendations introduced in March 1983.

(4) Whether blood products manufactured in the United States using plasma collected before the FDA introduced new regulations in March 1983 should be excluded from the UK.

(5) The steps that could be taken to reduce the risk of infected donors giving blood within the UK.

(6) Any other steps that could be taken to reduce the risk of patients becoming infected with AIDS through the use of blood and blood products.

3.55. In respect of (5), above, I have already addressed the contributions which I made to the discussions on the introduction of the blood donor leaflet issued from 1 September 1983. If submissions on the other areas were going to go to Ministers, I would have expected them to go to Lord Glenarthur in the first instance but I might be copied in. However, from the available records, these issues do not appear to have been the subject of specific submissions to Ministers. I think I would have been aware, in general terms, that imported Factor VIII had not been banned but I do not believe that I was involved in the formulation of the policy that this should continue (or in a specific decision not to ban such imports). I would have been aware at the time of the FDA Regulations because these were referred to in Dr Walford's briefing to Lord Glenarthur. I note further that Lord Glenarthur's reply to Baroness Masham referred to the US FDA regulations and that the UK (like the US) was not banning pre-FDA regulation stocks because of the risk of a crisis of supply. I find it hard to say now whether I would have been aware of that detail at the time but as Lord Glenarthur was corresponding about it, it may have come up in Ministerial discussions, but given the passage of time, I cannot be more specific than that. It was clearly correct for the relevant expert committee to consider the ongoing licensing of imported Factor VIII products. But looking at it now, as I have said above, I think this should appropriately have been raised at Ministerial level to Lord Glenarthur.

Section 4: REVISION OF AIDS LEAFLET 1984/5

4.1. In this section of its R9 request, the Inquiry asks about two further leaflets, a leaflet designed towards warning the homosexual community about the dangers of promiscuous sex, and the revised blood donor leaflet.

Consideration given to a leaflet warning the homosexual community of the dangers of promiscuous sex

4.2. The Inquiry refers me to a number of documents which concerned a leaflet which it was envisaged might be published by the Health Education Council and be geared towards warning the homosexual community of the dangers of promiscuous sex:

(1) A minute from Mr Fanning to Dr Sibellas dated 28 March 1984, and the draft submission to Mr Clarke attached to it [DHSC0002309_039].

(2) A submission sent to my Private Office dated 17 April 1984 concerning the Medical Research Council's Working Party on Aids, which was also copied to Lord Glenarthur's Private Office [DHSC0002321_044]. This submission was primarily concerned with the MRC's Working party on AIDS press conference due to take place that afternoon. However, paragraph 5 discussed the proposed HEC leaflet on AIDS aimed at the homosexual community.

(3) My response to the submission dated 18 April 1984 conveyed by my Private Secretary [DHSC0002309_040]. In this I noted the sensitivity of the proposed HEC leaflet and expressed some doubts:

> *"Any leaflets on prevention by the HEC as described in paragraph 5 must be handled very sensitively, and I think that MS (H) should be aware of this. I am doubtful."*

(4) Lord Glenarthur's response to the above submission, dated 25 April 1984 [DHSC0002309_041]. Lord Glenarthur's Private Secretary said that PS(L),

> *"… takes a somewhat different view to PS(H) - Miss McKessack's minute of 18 April - in that he favours a further leaflet, directed particularly at promiscuous gays. Lord Glenarthur's view is based*

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

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

(5) A minute from Dr Smithies to M Cunningham dated 26 April 1984 [DHSC0002321_045] in which Dr Smithies said that she was uncertain about the current state of play about the HEC AIDS leaflet but nevertheless made some comments on the draft Ministerial submission.

(6) Mr Alcock's minute of 4 June 1984, conveying Mr Clarke's views [DHSC0002309_042]. Mr Clarke appears essentially to have been against the HEC leaflet, commenting, "*I think that this is best left to the Gay Medical Association!*" In the margins, a comment to Mr Arthur reads, "*Somewhere you will find the previous papers where CHC proposed that HEC should produce a leaflet on Aids, aimed to advise homosexuals to change their practices. It appears to have had Ministerial thumbs down. It does not affect our revision of the NBTS Aids leaflet to go to RTDs for comment*" (original emphasis).

(7) The submission on the Health Education Council ("HEC") leaflet sent by Mr Cunningham on 9 August 1984 to Lord Glenarthur, through Dr Oliver [DHSC0002309_043].

(8) The response from Lord Glenarthur's Private Office giving his approval for preparations for the HEC leaflet to continue [HSC0002309_045].

4.3. I do not have any independent recollection now of the consideration of the health education leaflet aimed at the homosexual community. The substantive submission on the leaflet was originally being drafted to go to Mr Clarke (see the draft attached to Mr Fanning's minute of 28 March 1984) but eventually went to Lord Glenarthur on 9 August 1984. The caution I noted about the leaflet (and my advice to ensure the Minister of State was aware) would – I think – have been because I would have known about Mr Clarke's concern as to how the media could react in this area from our consideration of the earlier blood

donor leaflet. I can only surmise that my doubts may have been because, as the submission later made clear, there were difficulties with such a leaflet. The advice in such a leaflet would need to be practical if it was to have any effect, but there were concerns both about the efficacy of advice on sexual behaviour coming from a public body, and the potential for a backlash by those opposed to homosexuality as the Government seeming to condone homosexual practices. In the very different times of 1983, the question was whether advice effectively on safer sex for homosexuals was too sensitive for any public body It is in that context that there was an argument (as initially expressed by Mr Clarke) that it might be best for the advice to come other than from Government. Rather than advice coming from the Department of Health itself, the use of the Health Education Council (who already wished to publish such a leaflet) was in effect a compromise approach. And, in the end, we did approve the HEC leaflet.

4.4. This leaflet was different to the blood donor leaflet because its principal aim was to warn about personal sexual behaviours that now carried greater risk. I have set out Lord Glenarthur's view as expressed in the minute of 25 April 1984 fully at paragraph 4.2(4) above, which in context appeared to be referring to some who were critical of the Government not doing enough concerning the risk of AIDS to promiscuous gay men. My only comment would be that the eventual decision taken, to tackle this by agreeing to the publication of the HEC leaflet, was probably the right course, although there was of course later a much larger scale public health campaign.

4.5. As the notes in the margins of the minute of 4 June 1984 stated at the time, this issue was separate from the revised blood donor leaflet, to which I now turn.

Revision of the Blood Donor Leaflet Concerning AIDS

4.6. A revised blood donor leaflet was published on 1 February 1985. The Inquiry further refers me to the following series of documents illustrating the background to the publication of the revised leaflet.

(1) A minute dated 14 February 1984 from Dr Smithies to Mr Williams, [DHSC0002239_015].

(2) The submission sent to my Private Office dated 17 April 1984 concerning the Medical Research Council's Working Party on Aids, which was also copied to Lord Glenarthur's Private Office [DHSC0002321_044]. I have referred to this in the previous section of this statement but it included the comment that,

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

(3) Lord Glenarthur's response to the above submission, dated 25 April 1984 [DHSC0002309_041].

(4) The ministerial submission from Mr Parker to Lord Glenarthur's Private Office dated 10 August 1984; the Minister of State's Private Office and mine were copy recipients [DHSC0002309_044].

(5) Response from Lord Glenarthur's Private Office[2], dated 21 August 1984, supporting the publication of the revised leaflet with strengthened distribution arrangements [DHSC0002309_046].

(6) Response from Mr Clarke's Private Office dated 16 October 1984 giving his agreement [DHSC0002309_050].

(7) Briefing note to the Secretary of State, which referred to the original leaflet and the fact that it had been revised, 19 November 1984 [DHSC0002309_053]. I do not now specifically recall reading this submission though I strongly expect I would have done so at the time.

(8) DHSS press release: AIDS and Blood Products press release dated 18 November 1984 with a statement given by me [PRSE0003367].

[2] Contrary to the suggestion in the Inquiry's R9 request, this was not a minute from me / my Private Office; Mr Ghagan was a member of Lord Glenarthur's Private Office.

(9) DHSS press release: 'Britain to be self -sufficient in blood products by late 1986; and more health education and research on AIDS', dated 19 November 1984 also containing a statement from me [PRSE0002251].

(10) Minute from Janet Hewlett-Davies to Mr Cashman, attaching a revised version of the updated leaflet, 22 November 1984 [DHSC0002323_014]. This minute was copied to Ministers' Private Offices including mine, and stated that:

> *"I endorse your view that the first revise had to be looked at again in the light of recent developments and ministerial statements. The need is for a much more strongly worded leaflet and for urgent approval, production and distribution. I think our draft meets the first need, and should be grateful for your support in getting the quickest possible clearance."*

(11) Minute from Dr Abrams to Dr Smithies concerning a briefing session with the Minister of State, 23 November 1984 [DHSC0000435]. This noted that Mr Clarke was happy with the revised donor leaflet but was content to hold it up until after a meeting of the Working Group on AIDS.

(12) Minute from my Private Secretary to the Private Offices of Mr Clarke and Lord Glenarthur, dated 30 November 1984. [DHSC0002309_056]. This made clear, following Ms Hewlett-Davies minute of 22 November 1984, that I was content with the revised leaflet if Mr Clarke and Lord Glenarthur were.

(13) Minute from Dr Abrams to Mr Clarke's Private Office, dated 3 December 1984, seeking approval of the revision of the leaflet following consideration by the Working Group on AIDS on 27 November 1984 [DHSC0002309_058].

(14) Minute from Lord Glenarthur's Private Office giving his agreement, 4 December 1984 [DHSC0002309_059].

(15) Minute from Mr Williams to Mr Clarke's Private Office regarding (among other matters) pressing for approval for the revised leaflet, 20 December 1984 [DHSC0002327_127].

(16) Minute from Mr Clarke's Private Office to Dr Abrams regarding the revised leaflet, 20 December 1984 [DHSC0002309_062]. This stated,

> *"2. MS (H) has now seen your revised version of the leaflet "AIDS and how it concerns blood donors", together with the Information Division version. His initial reaction to both was that we may need to look at some of the assurances again in the light of the publicity surrounding the two cases involving blood transfusions.*
>
> *3. On presentation, MS(H) saw nothing wrong with your revised text, but felt that the language of the ID version conveyed the message more effectively. I should be grateful therefore if you and your medical policy division colleagues would co-operate with Information Division in producing a third (and hopefully final) version of the leaflet based upon the ID text to take account of any recent significant developments, and amended as necessary to ensure medical accuracy.*
>
> *4. I appreciate the need to produce the revised leaflet as soon as possible, however, I understand that the forthcoming Christmas break will inevitably delay printing until the New Year. That being so, I should be grateful if you could ensure that MS (H) has an opportunity to comment of the agreed version before printing and distribution goes ahead."*

(17) A minute and revised leaflet as sent to Mr Clarke by Mr Windsor of the Information Division which incorporated some changes, 21 December 1984 [DHSC0002309_063].

(18) Minute from Mr Clarke's Private Office to Mr Windsor, 31 December 1984 [DHSC0002309_064]. This stated

> *"MS(H) has seen your submission of 21 [December] and has commented:*
>
> *"Is it still true to say that there is only a remote chance of anyone getting AIDS from an ordinary blood transfusion, as it says at the top of page 2?*
>
> *I remain wary of offering to promise blood screening tests and heat treatments. I would therefore like to leave out the paragraph at the bottom of page 3 "What is being done" etc. Otherwise OK."*

(19) Submission from Mr Williams to Lord Glenarthur's Private Office seeking clearance for the final revised version, 3 January 1985 [DHSC0002309_065].

(20) Health Circular HC 85 (3), dated January 1985, concerning the revised leaflet and directing that unused copies of the original leaflet should be destroyed [DHSC0002159].

(21) Draft press release and letter to Regional Health Authorities concerning (among other matters) the revised leaflet, 1 February 1985 [DHSC0002311_053] and [DHSC0002311_088].

(22) The final revised leaflet [NHBT0096480_022].

(23) The press release of 1 February 1985 [DHSC0004764_111].

4.7. I note that in addition to the documents raised by the inquiry the available documents also include:

(19a) The reply to Mr Williams' submission of 3 January 1985 giving Lord Glenarthur's approval [DHSC0002482_010];

(19b) A further note from Lord Glenarthur's Private Secretary also dated 3 January 1985 and stating:

"This is to confirm my telephone message that Lord Glenarthur and PS(H) are content with the draft as "finally" revised accompanying your minute of 3 January and that PS(H) is content to revert to the wording "serious" rather than "killer" disease." [DHSC0002482_011]

4.8. Following the publication of the first leaflet on 1 September 1983, I have not seen any submissions that were copied to my Private Office mentioning the outcome of the trial period for the first leaflet until that of 17 April 1984 [DHSC0002321_044]. I have not seen any Ministerial submissions which would suggest that Dr Smithies's concerns in February 1984 were drawn to my attention. This remained Lord Glenarthur's policy area and I cannot speak for what information came to him. However the Inquiry has provided me with a copy of Lord Glenarthur's published statement and I note:

(1) That his statement provided a note summarising the actions of officials with regards to the leaflet;

(2) That on 25 April 1984 he requested a fuller note on the NBTS trial of the first leaflet [DHSC0002309_041] but has not seen a response to that request;

(3) That he agrees that the second blood donor leaflet should have been achieved more quickly.

4.9. I have not seen a reply from my Private Office to the submission of 10 August 1984 addressed to Lord Glenarthur and therefore I cannot say whether or not this was drawn to my attention by my Private Office to whom it was copied. However I expect that I would have seen this. I am sure that I would have agreed with the strengthened distribution methods suggested because I had been in favour of using both distribution methods when the first blood donor leaflet arrangements were being considered. I would also have agreed the publication of the revised version should be accorded priority (it was noted that it would cost £15,000 and would impact on more routine NBTS publicity but that officials considered this prioritisation appropriate) and that we would be open to criticism if we failed to take all reasonable practicable measures to dissuade high-risk donors from giving blood, which was the reason given in the submission from Mr Williams for extending the distribution, to distribution with call – up cards, in all cases.

4.10. My Private Office responded to the 22 November 1984 submission indicating that I was content with the revised wording. I infer from that that at the time I was satisfied that the firmer wording in the revised version served the purpose of conveying the desired stronger message. The high risk groups were more widely defined and the wording was much stronger in the entreaty that they must not give blood which was emboldened and repeated in the leaflet. The 3 January 1985 minute indicates that I did not oppose a decision to revert from "killer disease" back to "serious disease" [DHSC0002482_011].

4.11. The Inquiry asks what my role was in the discussions on the revised leaflet. While I have no independent recollection now, based on the documentary records, it seems that Lord Glenarthur and Mr Clarke were again leading on this version of leaflet but I was offered the opportunity to comment.

4.12. The Inquiry asks whether I had concerns at the time taken for the revised leaflet to be published. I think it is clear from my contributions to the 1983 version of the leaflet that I was a strong advocate for pressing on with the publication and distribution arrangements and I have no reason to think that my approach would have been any different for the revised leaflet. I do not now have a specific recollection of being concerned at the time about how long it was taking so I cannot definitively say what my thinking was at the time. Looking at it now, it seems there was certainly an avoidable delay in the revision of the leaflet. One facet of this appears to be that because the leaflet did not get clearance sufficiently quickly after the 10 August 1984 submission, it ended up then getting further delayed because of a perceived need to re-consider the leaflet in light of: (i) the views of the Working Party on AIDS and (ii) further strengthening following the developments reported on in the submission to the Secretary of State of 19 November 1984. There followed a round of further considerations of different versions.

Section 5: SCREENING TEST FOR HTLV-III / HIV FOR BLOOD DONORS

Developments Prior to June 1985

5.1. The Inquiry asks me about my role in decisions concerning the introduction of a screening test for HTLV-III/HIV for blood donors in the United Kingdom. For ease of reference, I will use HIV virus throughout this section of my statement rather than HTLV-III.

5.2. As I have referred to in the previous section of my statement, on 10 August 1984 Mr Parker minuted Lord Glenarthur's Private Office attaching a submission to Ministers concerning the revision of the AIDS leaflet, [DHSC0002309_044]. It was copied to my Private Office and that of Mr Clarke. Paragraph 7 of the submission stated,

> *"Ministers will be pleased to learn that a test for the suspected AIDS agent in blood donation is currently being developed by the Middlesex Hospital, based on viral material recently isolated in the United States. Work in developing this test is still at the research stage, but it is hoped that trials will start at one or two Transfusion Centres in October. However, it will be some time before the significance of the test results can be assessed; the leaflet meets the continuing need to dissuade high-risk group volunteers from donating their blood until the test has been evaluated and can be used to screen donors in all Centres."*

5.3. Since this minute and submission were provided to my Private Office I believe I probably would have seen them, although I cannot be absolutely sure (see paragraph 4.9, above). Assuming that I did see this submission, I would have been aware that a test for HIV was in the development stage.

5.4. The Inquiry also refers me to a briefing note by Dr Smithies and colleagues dated 31 August 1984. It was sent with a minute from Mr Arthur to Mr Cashman and to Lord Glenarthur's Private Office [DHSC0000443]. On the face of it, it seems unlikely that I would have seen the minute or briefing note because they were not copied to my Private Office, although again, I cannot be sure. I can

see that the briefing note dealt with a scientific article that was to be published in The Lancet the following day 1 September 1984 [NHBT0000068_015] and an item on the same topic in the Guardian on 31 August 1984. The briefing note set out that the test being developed detected an antibody in the blood, indicating whether someone had contracted HIV. Even if I was not aware of the specific matters contained in the briefing note, I think I would probably have been aware at this time, and in general terms, that a test was being worked on.

5.5. The Inquiry refers me to a number of documents in relation to the introduction of a screening test for HIV and how this would be funded. These are:

(1) Minute from Dr Abrams to Dr Smithies dated 10 July 1984 that recommended the introduction of a screening test "...as quickly as possible" and that the Department "...should give whatever help is needed to move this along" [DHSC0001574]. This does not appear to have been copied to Ministers.

(2) Minute from Mr Williams to Mr Staniforth dated 26 October 1984 indicating that the Department had put in a bid of £2m for HIV testing in 1985-86. He commented that the relative imprecision of the bid should not be confused with the high priority which they attached to the need for such a test. He assumed that Ministers would want to instruct RHA's and RTCs to adopt the new test and advised that presentationally this would be better done with offers of funding assistance rather than imposing a Ministerial priority and the RHAs having to pay from their own allocations [DHSC0101679]. This does not appear to have been copied to my Private Office.

(3) Submission from Mrs Banks of 31 October 1984 discussed in a meeting of 13 November 1984, described below [DHSC0002309_051]. This submission was addressed to the Minister of State's Private Office but was copied to other Ministerial Private Offices including mine. The AIDS test was referred to in paragraph 8: "*HS Division have advised that the proposed central funding of Aids Tests (when a testing technique is*

developed - before 1985-86) will be politically difficult to resist, though the cost estimate of £2 million is provisional only".

(4) Note of a meeting to discuss HCHS (Hospital and Community Healthcare Services) Central Reserves on 13 November 1984. Attendees were Mr Clarke as Minister of State, Mr Hart, Mr Lillywhite and Mr Staniforth [DHSC0002309_052]. Paragraph 4v recorded, "*Aids Tests - Hypothetical. Additionally, should be expenditure for regions not Central Pre-emption*". A manuscript note suggests that the note of the meeting was copied to my Private Office, though I was not at the meeting itself.

(5) Minute from Dr Abrams to Dr Smithies dated 23 November 1984 indicating Mr Clarke felt *"...that to spend around £2m was not cost effective when there were so few AIDS cases and that the money could be better spent elsewhere*" [DHSC0000435]. This does not appear to have been copied to my Private Office.

(6) Minute from Mr Williams to Lord Glenarthur's Private Office and copied to the Minister of State's Private Office and mine, dated 26 November 1984. Mr Williams provided an update on the AIDS screening test and noted that Mr Clarke felt it inappropriate for funding to come from Central Reserves [DHSC0000436].

(7) Minute from Dr Abrams to Dr Harris dated 27 November 1984 which summarised the meeting of the NBTS working group on AIDS and stated that there was a "unanimous strong view that the anti-body test for HTLV III must be used for all NBTS donors as soon as possible" (original emphasis). Regarding the heat treatment of factor VIII the minutes stated that "this should be in addition to a screening test when this is available" (original emphasis) [DHSC0002251_011].

(8) Minute from Mr Arthur to Mr Harris dated 14 December 1984 which referenced the fact that Mr Clarke had refused the £2m bid [DHSC0002331_044].

(9) Minute from Dr Smithies to Dr Sibellas dated 31 December 1984 containing the draft position paper for the CMO, "AIDS and its prevention in the United Kingdom". The minute stated that at a meeting of the NBTS

Working Group on AIDS held on 27 November 1984 "It was agreed there that a screening test for HTLV III antibody should be introduced to all RTCs as soon as possible" [DHSC0001693, CBLA0001934_001 and CBLA0001934_002].

5.6. The Inquiry asks me to comment on which of these documents I would have seen.

5.7. I do not believe I would have seen the minute from Dr Abrams to Dr Smithies of 10 July 1984 [DHSC0001574] as this was a minute between staff in the medical division and it was not copied to my Private Office or that of any other minister. Similarly I do not believe I would have seen the 26 October 1984 minute from Mr Williams to Mr Staniforth [DHSC0101679].

5.8. The submission from Mrs Banks of 31 October 1984 [DHSC0002309_051] was copied to my Private Office and it may have been drawn to my attention by my staff as it concerned HCHS reserves for the following financial year 1985-86. As the submission explained, a small proportion of revenue and capital available for health authorities was held centrally and was available for "a variety of initiatives of an experimental or pump-priming nature". New bids on the reserve for 1985-85 were set out at paragraph 8 and at Annex 3 and funding for "AIDS Tests" was one of the new initiatives to be considered for funding. I believe it is likely (although I cannot be sure) that the reason my private office was copied into this submission was because some of the bids - not those concerned with AIDS – may have been in my area of responsibility.

5.9. I did not attend the meeting on 13 November 1984 which, amongst other things, considered the funding of the HIV test. As can be seen from [DHSC0002309_052], Mr Clarke as Minister of State attended with three civil servants. Mr Clarke was the focal point for financial decision-making.

5.10. The minutes record that the decision taken was that the central reserve would not fund the HIV test and Mr Clarke had decided that expenditure should come from the Regional Health Authorities.

5.11. I most probably would not have seen the minute from Dr Abrams to Dr Smithies of 23 November 1984 [DHSC0000435]. The minute of 26 November 1984 from Mr Williams setting our Mr Clarke's decision was copied to my Private Office but I am unable to say whether its content was drawn specifically to my attention. I do not recall when I first became aware of the decision that funding should come from RHAs and not from central funds. I could not say whether it first came to my notice when that minute was received or whether previously Mr Clarke or someone else may have informed me.

5.12. I do not believe I or my Private Office would have seen the minute from Dr Abrams to Dr Harris of 27 November 1984 [DHSC0002251_011], the Minute from Mr Arthur to Dr Harris of 14 December 1984 [DHSC0002331_044] or the minute from Dr Smithies to Dr Sibellas of 31 December 1984 [DHSC0001693]. The position at this point was that the test for HIV antibodies was being developed and it was agreed that it should be introduced as soon as possible. I understand that funding for the development of the test had been provided by the Medical Research Council. Once it was available, RHAs would fund the testing of blood donors.

5.13. The Inquiry asks about my views on the source of the funding for the screening test. As to this:

(1) The papers suggest that it was Mr Clarke who took the decision that central HCHS funds would not be used for the screening tests and that RHAs would need to fund this.

(2) I cannot recall whether I had a view on this particular point at the time. I can only make the following observations based on my reading now and my general recollection of how things were. In the Department, as in all

departments, there was a constant call on public finances for worthy and important projects. Looking at it now, I think I would only observe that it is the Minister's job to balance competing requests against limited resources and make decisions on how funds should be apportioned. Mr Clarke did not decide that the HIV antibody test should not be developed or introduced. Officials dealing with the screening test were keen that it should be centrally funded by the Department, seeing this as presentationally important and perhaps also that it may help with the speed of introduction. However there would have been contrary arguments. The meeting note records that the view was taken that the bid was "Hypothetical" (presumably because it was not yet developed and ready to be introduced). More widely, the comment that this "…should be expenditure for regions not Central Pre-emption" would have reflected the general pattern that a test used nationwide in each RHA would normally be part and parcel of the running costs of each health area, rather than a specialised centrally funded service. Hard decisions had to be made on what could be funded centrally.

(3) Mr Clarke clearly had some early doubts about whether the screening test was needed in addition to heat treatment. However he was later persuaded that it was.

5.14. The Inquiry refers me again to the briefing note on AIDS from Dr Smithies to the Secretary of State's Private Office, dated 19 November 1984 [DHSC0002309_053]. Dr Smithies stated that 13 people had died in Australia from AIDS as well as a haemophiliac in Newcastle who had received Factor VIII. In her note Dr Smithies set out what was being done in the UK to try to prevent HIV being transmitted in blood and blood products. She referred to the donor leaflet, the HIV screening test that was being developed in the US and at Middlesex Hospital and to self-sufficiency. Dr Smithies referred to the new experts working group on AIDS established in September 1984 with its first meeting to take place shortly after on 27 November 1984. The submission also covered the introduction of heat treated Factor VIII and health education measures.

5.15. The Inquiry has asked me whether this briefing note [DHSC0002309_053] was brought to my attention. I strongly expect that I would have seen this. There was a lot of media attention at this time, and press statements citing me were given the day before, 18 November 1984, [PRSE0003367] and again on the day of this submission, 19 November 1984, [PRSE0002251]. In that press release I set out more information on our push for self-sufficiency in blood products by the end of 1986, and explained we had an approach of education, screening and research to combat the spread of AIDS.

5.16. I have been asked about the NBTS working group on AIDS that was set up in September 1984 and was to meet for the first time on 27 November 1984. The Inquiry asks why this was not set up sooner. I am not able to speak from personal knowledge as to why this group was set up when it was but it does not mean that earlier advice would not have been available. In my experience, it was not uncommon for expert and working groups to be formed or re-organised so as to ensure that appropriate advice was better co-ordinated. For expert advisory groups, the CMO would have oversight of the network of expert advice that was available on a wide range of subjects.

5.17. I am asked which parts of the information in the briefing were new to me. I think I would already have been aware that some screening tests were being developed. I cannot say when I first knew about the working group on AIDS or the intention to heat treat blood.

5.18. The Inquiry asks if I took any steps in response to Dr Smithies' submission to the Secretary of State's Office. Other than the press releases (see below) I cannot now recall, but I think it relatively unlikely that I would have done so, in part because these were not my areas of direct responsibility and in part because Dr Smithies submission was not raising any points for Ministerial decision – it was a broad update on the current position and action already being taken or contemplated.

5.19. The Inquiry asks why I rather than Lord Glenarthur gave the press statements of 18 and 19 November 1984. As I have already referenced, there was a general preference to provide Ministers from the Commons for media work rather than the Minister in the Lords and there were media interviews surrounding this not just a written press notice. A minute from my Private Office to Lord Glenarthur's of 21 November 1984 indicates that I was voicing frustration that news about the heat treatment of Factor VIII from BPL had not been communicated to Lord Glenarthur in time for us to include in our media handling:

> *"PS(H) has seen the above telex and has commented:*
>
> *"It was good news that the blood labs released yesterday over the heat-treatment of Factor VIII: but why did they not - apparently - advise PS(L)? This news would have been very useful for me in my interviews on Monday. PS(L) may share my concern that all good news from Elstree should go to him for clearance and decision on mode of release in future"* ***[DHSC0002327_126]***

5.20. The Inquiry has asked whether I saw the minutes of the first meeting of the Advisory Committee on the National Blood Transfusion Working Group on AIDS after their inaugural meeting on 27 November 1984 [DHSC0002251_011]. From Dr Smithies briefing dated 19 November 1984 [DHSC0002309_053] the Ministerial team would have been aware that the inaugural meeting was due to take place on 27 November. However, the minutes do not appear to have been copied or forwarded to my Private Office. I do not find that unusual. In my general experience, minutes of advisory or working groups would not be routinely copied to Ministers. While there would obviously be exceptions, it would be more likely for key decisions or advice of such groups to feature in a relevant submission from officials to whom the minutes would have been copied and /or who would themselves have attended the relevant meetings. In this case, I note from the documents that the working group was being chaired by Dr Abrams who I am told was a Departmental Senior Principal Medical Officer, with additional DHSS observers.

5.21. The Inquiry also refers to the paper from Dr Smithies to Dr Sibellas dated 31 December 1984 [DHSC0001693] but, again, this does not appear to have been copied to my Private Office.

5.22. The Inquiry asks what steps were taken by me or, to my knowledge, the Department in response to the Working Group meeting. I can only comment that:

(1) At this stage, in November and December 1984, the test for HIV in blood was still in development. Whilst the Advisory Group had advised that the test must be used for all NBTS donors as soon as possible, this could not happen until there was agreement as to what test to use and the test was the finished product. We would have expected officials to be pursuing the best options for an effective test.

(2) Although Mr Clarke was to raise the question of whether screening was needed in addition to heat treatment, this was the course adopted, and both screening and heat treatment were introduced.

(3) On funding, as I have explained, Mr Clarke had decided that the test would need be paid for by the RHAs from their allocations. As to the funding of research into the tests, I have seen in the available papers (but would not at the time have been involved in) a minute from Dr Smithies to the CMO dated 28 November 1984 [DHSC0000565], in which Dr Smithies advised that no indication had been given to her by Professor Weiss and Dr Tedder that their research was being hindered by a lack of funding and she had asked them to let her know if that were the case.

5.23. The Inquiry has referred me to a minute from Mr Williams to Lord Glenarthur's Private Office dated 30 November 1984, which was also copied to the other Ministers' Private Offices, including mine [DHSC0002309_057]. Mr Williams' minute advised that three UK blood donors had been found to be HIV positive. Donations from one of the three had been given to three recipients who were then sero-positive. The same donor's plasma had been used in a batch of

Factor VIII that had been given to 38 haemophiliac patients. The other two donors had given 17 donations over the past five years.

5.24. Although I cannot be sure, I think it likely that I would have been shown this minute. The Inquiry asks if I took any steps personally on receipt of this information. It would not have been for me to do since Lord Glenarthur was dealing with these issues. The 'defensive press briefing' part of the minute highlighted key action that was already being taken: revision of the blood donor leaflet; developing the screening test; and the introduction of heat treated products. I knew that the test for HIV was being developed and we were amending and going to reissue the donor leaflet.

5.25. The Inquiry refers me to a draft submission from Dr Smithies dated 11 January 1985 which was intended to go to Ministers on the introduction of the screening test [DHSC0000562]. I note that a copy of the final as-sent version of this submission does not appear to have survived. However the Inquiry refers me to the fact that on 22 January 1985 Mr Clarke gave his approval. In this response, I note that Mr Clarke raised the question as to whether screening was required as well as heat treatment. However on 1 February 1985, the CMO confirmed to Mr Clarke the reasons why this was necessary [DHSC0002327_028].

5.26. Since the final version of the submission on screening is not available, I am unable to say with any confidence whether it was copied to my Private Office. The fact that Mr Clarke's response to the submission was copied to my Private Office suggests that I may well have been on the copyee list for the submission itself. I am sure that I would have agreed with the recommendation that Ministers should endorse the principle of the introduction of the screening test, and for an announcement that the development of a test was being backed by the Department.

5.27. The Inquiry refers me to the fact that the Expert Advisory Group on AIDS ("EAGA") was set up in January 1985 to look at the public health implications of AIDS. This was referred to in a draft press statement from Mr Clarke dated 1 February 1985 [DHSC0002311_053] and the EAGA had held its first meeting on 29 January 1985 [PRSE0002734]. The Inquiry asks why the EAGA was set up at this point and not before. I cannot speak to that from my own personal knowledge. The press statement sets out that the CMO had convened the expert advisory group and I therefore assume that the need for such a group would be identified and proposed by the CMO and the Medical Division. I have set out my general experience and understanding of such groups at paragraph 5.16 above.

5.28. In an oral question in the House of Commons on 16 April 1985 [DHSC0002267_034] [Hansard Vol 77 Cols 121] I responded to a supplementary question from Mr Robert Key MP about the screening test for HIV and said, "Yes, we hope to have a screening test within a few weeks". A minute was sent at some point in April 1985 by Mr Williams to my Private Office [DHSC0000555] informing me that this information was inaccurate. The minute stated: "It would be more accurate to say that we hope to begin evaluating screening tests within the next few weeks. The work is due to start on 13 May and full evaluation is likely to take several months" (original emphasis). It was stated that realistically, the test was unlikely to be introduced routinely into the NBTS until the "latter half of 1985".

5.29. I do not recall the precise basis for the statement that I made in the House on 16 April 1985. The issue arose as a supplementary oral question, following a question on a slightly different topic from Alfred Dubs MP. I would have had a briefing from officials for oral questions but I understand that the briefing note is not within the available papers. It is possible that:

(1) I made a mistake and simply confused the timing of the evaluation of the tests with the timing of the introduction of the tests. This is the most likely.

(2) The briefing contained an error.

(3) I had inferred the timing from earlier materials. I note for example that in the letter to all Regional Health Authority Directors on 20 February 1985, Mr Hart had said that the department hoped a screening test would be available "within a few months" [DHSC0002261_031] .

It follows that when I gave the answer that the test would be available within a few weeks of 16 April 1985, it would either have been because I genuinely understood that to be the case (as in (2) and (3) above) or I simply made a slip. I am unable to comment on why Mr Key said that the screening test was "promised for July". I understand that the screening test was introduced in October 1985. This fits with the information in the memo from Mr Williams informing me of the mistake. As set out above he stated that the evaluation of the test was to start on 13 May and full evaluation was likely to take several months. As was conventional for such cases, a letter was prepared for me to send to Mr Key to inform him of the error in the answer I had given [DHSC0000555].

June 1985 decision on the introduction of the HIV screening test

5.30. The Inquiry refers me to the following documents which I have set out in chronological order (the documents at (1) are additional to those referenced by the Inquiry):

(1) There is a minute from Mr Harris to Dr Smithies dated 5 June 1985 which was not copied to Ministers but attached an early draft of the Ministerial submission [DHSC0002482_031] and [DHSC0002311_055]. I note that Mr Harris's minute referenced a possible meeting with me on Friday 7 June, and also what was described as *"the starting point which CMO/PS(H) now want ie the speedy introduction of a screening test into BTS on available data, without waiting for confirmatory tests etc."* I do not now recall this but it suggests that the CMO and / I wanted to get on with the introduction of testing and perhaps that our initial inclination was do so even before confirmatory testing was available.

(2) A minute from Mr Harris to Mr Christopher France, dated 5 June 1985 which attached a draft Ministerial submission ("AIDS and the BTS") on the introduction of the HIV screening test [DHSC0002311_018].

(3) The final submission from Mr Harris dated 7 June 1985 which was addressed first to the CMO – and subject to his being content – to my Private Office. The submission was also copied to the Private Offices of Mr Clarke and Baroness Trumpington [DHSC0002311_019].

(4) A minute dated 10 June 1985 from Ms Hewlett-Davies in the Information Division to my Private Office [DHSC0002311_020] stating,

> *"I support strongly the proposal that publicity be given to the strategy if it is agreed. We should certainly offer, rather than have dragged out of us, the information about the time which will elapse before introduction of the test, and the very important reasons for that. And Ministers or CMO should be ready to accept invitations from radio or television to explain what is proposed."*

(5) A note to me from the CMO dated 10 June 1985 enclosing the submission of 7 June 1985, and setting out the CMO's view which was supportive of the recommended line in the submission but urged the importance of ensuring that the Public Health Laboratory Service (PHLS) kept to its schedule [DHSC0002311_021].

(6) Any written Ministerial response to the submission of 7 June 1985 is not – I note – amongst the available, surviving, papers.

(7) On 27 June 1985, Mr Williams minuted Mr Clarke's Private Office and the CMO [DHSC0003828_186]. Mr Williams noted that it had been agreed that Mr Clarke would announce the evaluation of the AIDS screening tests and the funding of PHLS to provide for such tests in answer to an inspired PQ. He attached a draft answer to the inspired PQ [DHSC0003828_187]; draft press release [DHSC0003828_188] and draft CMO letter to medical journals [DHSC0003828_189]. These materials make clear that by that date – 27 June 1985 – Ministerial clearance had been given to the recommendation in the 7 June 1985 submission. I note further to these documents that the CMO replied to Mr Clarke's Private Office about the draft Press Release commenting that,

> *"We need a properly set out case for the scientific reasons for this policy as it will be controversial.*
>
> *The press release is secondary to the above" [DHSC0002482_042]*

5.31. As regards the draft submission of 5 June 1985 at (2) above, I do not believe I would have seen this [DHSC0002311_018]. It was sent between civil servants and in Mr Harris's minute he called it a "draft submission which could go to Ministers through the CMO". There is a handwritten note on it saying "in the event this paper was not considered at the meeting on 6/6". I think it is unlikely I would have seen the draft version of a submission that was to be considered amongst civil servants, when the submission was subsequently amended before being put up to my Private Office via the CMO.

5.32. The Inquiry asks me about the decision tree on the last page of the draft submission [DHSC0002311_018] and whether I preferred any of the options there set out. I do not think that I can meaningfully comment on this because I would not have seen the decision tree. The eight options in the decision tree were not put forward in that form in the final submission of 7 June; instead the final submission concentrated on the decision between the three principal options of:

(1) Select an available test on current knowledge as soon as possible;

(2) Select a test after evaluation of tests by the PHLS; or

(3) To select a test after evaluation by PHLS and field trials by BTS.

5.33. Turning to the final submission of 7 June 1985 attached to a minute from Mr Harris [DHSC0002311_019], I would note firstly that this is clearly a revised, somewhat streamlined, version of the earlier draft paper entitled "AIDS and the BTS" described in the paragraph above.

5.34. It is not clear from the papers, and I do not recall why this submission came to me for the decision to be made on the HIV screening test and not to Baroness Trumpington in whose area of responsibility blood and blood products lay. Baroness Trumpington replaced Lord Glenarthur in the Parliamentary Under-Secretary of State in the Lords at the end of March 1985 so she had been in post just over two months by this point. As set out in paragraph 2.6, above, I can only now surmise as to why this would have happened. It may have been because Baroness Trumpington was away or unavailable for some reason, or perhaps because it was felt I should take this matter because I had seen the previous submissions and as she was relatively new in post. I also note that following a CMO meeting on 30 May 1985, I had asked the CMO about the overall position. The fact that CMO and I had recently discussed the matter might also be related to why the submission came to me (see Dr Harris' minute of 31 May 1985 to Mr M Harris [DHSC0001503]).

5.35. As set out in the submission, at that point in June 1985 screening for HIV in blood donations was not being routinely carried out in the UK. According to the submission there was testing in some other countries already eg Australia, parts of the US and the Netherlands and France and Germany were going to introduce a test later that summer. We needed to make a decision on how to go about choosing the test to be used in the UK. I was informed that there were the three principal options which I have summarised in paragraph 5.32 above.

5.36. The submission explained at paragraphs 5 and 6 that the choice was between introducing a test as quickly as possible which would be a defence against any accusation that we were taking too long, or taking more time and selecting a test that had been thoroughly evaluated and tested and that we knew was reliable.

5.37. At paragraph 6 of the submission the disadvantages of selecting a test that had not been thoroughly evaluated were set out:

> *"Adopting a test with a high level of false negatives (ie one which fails to detect antibodies that are present) would be worthless. Equally a test with a high level of false positives (ie one which detects antibodies which are not in fact present) would involve discarding quantities of blood and perhaps depleting the pool of donors. This could well lead to a shortage of blood and thus to postponement of non-urgent operations and a lengthening of waiting lists. The BTS processes over 2 million donations per annum. This requires a test that will give consistent results and be carried out easily."*

5.38. There was then a discussion of the options within the submission. At paragraph 7 the submission stated that the first option, selecting a test straightaway, was not recommended. This was on the basis of the view of UK experts who were said not to be happy with evaluations of trials from other countries. The submission recorded, "*There are worries about the lack of reliability experienced. It would be difficult to persuade the NHS to have confidence in an unevaluated test*". Even if this option had been chosen it would have taken around two months to introduce a test.

5.39. The second option, choosing a test based on PHLS evaluation alone, was also discussed and said to be not recommended. Introduction of a test after PHLS evaluation would have taken three or four months. The submission explained that the evaluation of tests by PHLS seemed to be rather limited in that they could not assess the rate of false positives.

5.40. The submission went on to recommend the third option – introduction of a test after PHLS evaluation and BTS field trials. This would take five months although the submission stated, "*It is hoped to bring forward the field trials and thus reduce the period needed for implementation*". This option was said to "*…enable the level of false positives to be measured*" and "*…allow operational convenience to be assessed*".

5.41. At paragraph 15 of the submission, the suggested strategy as recommended by officials was summarised in these terms:

> *"1. The test (or tests) should be selected after evaluation by the PHLS and field trials in the BTS. This would mean implementation of screening in October or November.*
>
> *2. Evaluation and field trials should continue to be conducted on new tests which emerge.*
>
> *3. Confirmatory testing facilities should be provided by the PHLSB.*
>
> *4. Alternative testing arrangements should be organised. A separate submission on this is planned. The PHLSB should be asked to establish laboratory facilities.*
>
> *5. The organisation of facilities for advising positive donors (and others) should be the subject of a separate submission."*

5.42. At paragraph 16 of the submission I was asked if I was content with this strategy and if was content for extra funding (£742,000 in 1985/1986) to be found for PHLS to enable this work to take place.

5.43. It is relevant to note that because this submission was sent first to the Chief Medical Officer, it would probably have come to me / other Ministers only once the CMO had seen it and it would have been sent on with the CMO's observations. As I have noted above, the CMO's observations came to me /other Ministers in the form of his note dated 10 June 1985 [DHSC0002311_021] also copied to other Ministers' Private Offices. Sir Donald said,

> *"There is a finely balanced decision here but I am in favour of the suggested line. I think, however, that we must do everything possible to ensure that PHLS is able to keep to its schedule.*
>
> *As far as the option to introduce a partially evaluated ELISA test forthwith is concerned I think the prospect of wasting a relatively small quantity of blood from false positive tests is not the major objection. The major problem is that the scientists concerned at PHLS do not yet have confidence that the suppliers could produce testing kits which are reliable on a large scale and which would continue to be reliable on the shelf. It would be worse to be in the position of having to withdraw a test once introduced than to be in our present position of carefully evaluating the tests. There could also be ethical problems in refusing to tell donors (who are volunteers in this country) the result of a test carried out on their blood if they wish to have it.*
>
> *Ministers should recognise, however, that support for a different view is likely to appear in the medical press (see Professor Bloom's letter*

> *attached[3]) and that considerable public pressure would develop if in the meantime a case of AIDS develops in a recipient of UK blood. Such a case or cases is likely to occur sooner or later due to infection one or more years ago prior to our warnings to people at risk not to donate blood." (original emphasis)*

5.44. I understand that no record of the Ministerial response to the submission of 7 June 1985 has been found amongst the DHSS papers. I do not know whether that is because the recommendation was agreed at a meeting or that there was a written response but it was not correctly archived. It seems clear from Mr Williams's minute of 27 June 1985, that we as Ministers did agree with the strategy set out in the final submission [DHSC0003828_186]. I note that the submission of 7 June 1985 was addressed to my Private Office and the surrounding materials show that officials had been intending to discuss it with me at a meeting, and had sense of early views expressed by CMO/by me. However, I should also note that the written record does not make entirely clear which Minister or Ministers in fact agreed the recommended line. In a subsequent briefing to me on 16 August 1985, Dr Smithies said at paragraph 5,

> *"DHSS waiting for comprehensive and proper assessment of all screening tests. Reports to officials and professional advisers from the USA for some months before and after FDA licensing of the tests suggested that the level of false positive results was high. Quite apart from donations needlessly being jettisoned all reactive donations would require record cards flagged, continued surveillance of the donor and possibly difficulties over confidentiality. It was for these reasons that it was agreed an evaluation of the available tests was required. Whilst DHSS informed Health Authorities that they were carrying out an evaluation of the tests at no time has any Health Authority been prevented from instituting tests should they wish. However in the BTS content RTDs advised DHSS of the consequences of unco-ordinated introduction of screening into the Blood Transfusion Service for the donors; the effect on recruitment of donors; the probability that introduction of screening attracts high risk donors and thus the need for alternative testing sites. All this pointed to a co-ordinated national implementation.* ***This was agreed with PS(L) and MS(H).*** *" (emboldened emphasis added)* [DHSC0000501].

[3] Although it is not attached in the version referenced by the Inquiry, I understand that the letter from Prof Bloom is likely to be that sent to Dr Harris dated 31 May 1985 [DHSC0002489_099]

This reference to a decision by PS(L) (Baroness Trumpington) and MS(H) (Mr Clarke) may suggest that it was they who took the final decision on this.

5.45. The Inquiry asks a number of questions about the final submission and the CMO's expressed views on it. Subject to the question of which Ministers took the final decision, and assuming that I was or may have been involved in the final decision, I would make the comments set out below. But I emphasise that as regards my own views at the time, this is significantly hypothetical because, unsatisfactory though it is, the surviving written records do not show who cleared the final submission.

(1) As above, I would infer that I did agree with the strategy set out in the final submission of 7 June 1985;

(2) There was no "zero timescale" option. All the options had timescales attached. It is clear that we were concerned about the timescales (Mr Harris's first minute of 5 June supports that CMO / I had given an early steer that we wanted speedy introduction of screening test without waiting for confirmatory tests etc.) And the CMO's note of 10 June shows him pressing that we must keep the PHLS to the timescales they had indicated. But this was a decision where the slightly longer timescales involved in waiting for both evaluation of the kits and field trials had to be balanced against the disadvantages of earlier introduction of tests that might not be so reliable.

(3) The Inquiry asks whether enquires were made about the level of blood wastage that might occur if we introduced an unreliable test quickly and there were a high level of false positives. I do not recall if any such enquiries were made and I have not seen anything in the available papers to suggest this happened. I believe it is unlikely that such enquiries were made because the CMO in his note to me of 10 June 1985 had said specifically that he did not think wasting "a relatively small quantity of blood" was the main objection to bringing in an unevaluated test [DHSC0002311_021].

(4) I am asked if I had concerns about the supply of tests. I think I would have noted the position as described in paragraph 8 of the submission. Clearly in evaluating and trialling the tests, officials were also going to have to ensure that there was sufficient supply of the tests to meet the large scale demand.

(5) The Inquiry asks I if I agreed or disagreed with the suggestion at paragraph 9 of the submission not to inform donors of a positive test result if the correct resources were not available [DHSC0002311_019]. I do not read paragraph 9 of the submission in that way, as the matter was not being raised for a decision. In particular, it did not appear to be part of the strategy ministers were asked to endorse. Reading it now, paragraph 9 of the submission stated that it was a "*...key assumption that donors whose tests are positive will be informed*" and that "*...(a)doption of any other approach would be dogged by many ethical, legal and public health problems*". However paragraph 9 was warning that it was *possible* that, for a short time, not telling donors might need to be adopted as a policy if the other facilities (for confirmatory testing *etc.)* were not ready when screening was implemented. And it noted – in effect – that this risk would be greatest if option 1 were adopted (i.e. select an available test on current knowledge as soon as possible). I am sure that I would have been concerned at the notion of donors not being told of positive test results, although it would also be ethically very questionable to tell patients of an initial positive result if no confirmatory test was available,

(6) The Inquiry asks if "*the development of a potentially cheaper British test by Wellcome*" was a factor. I do not believe that it was a factor in my / our agreeing to the recommended strategy and nor did the final submission put it in those terms at all. On the contrary, paragraph 8 of the submission noted that while the Wellcome test looked promising, there was a question mark of the speed at which it would be available at scale and, "*We should not delay implementation of screening until this can be supplied".* I would have agreed with that.

(7) As to the attempts to secure the necessary resources for the PHLS, I am unable to recall how this was ultimately achieved. The Press Release of 27 June 1985 given by Mr Clarke stated that the Department had given £57,000 to PHLS to enable them to carry out a full evaluation of all the test kits and that a further sum of £750,000 would be provided to them to enable them to set up the laboratory facilities to carry out the confirmatory tests following a first positive test and to test blood samples given in STD clinics [DHSC0001184]. The submission suggested that of the 1985/1986 costs, £500,000 could be found from the CFS budget and the remaining £242,000 would have to be found from as yet unidentified savings. For future years, there was going to be a PES bid.

(8) By reference to the CMO's note of 10 June 1985, the Inquiry asks what involvement I had in "deciding the strategy for evaluating the tests". As Ministers, we would not have been involved in the fine detail of how to go about evaluating the tests. The decision we as Ministers had to take was on the overall strategy and whether to accept a process that involved both evaluation of the tests and field trials. I infer that I did agree with the CMO's assessment. I think I would have noted and taken seriously the CMO's warning that there was likely to be medical support for an earlier introduction of existing tests. However, in deciding to agree the recommendation (and also in the context of what appeared to be divided medical opinion) I would have placed very considerable weight on the CMO's own analysis of the balance of risk. The CMO recognised in terms that this was a "*finely balanced decision*". I have been asked about of his reference to it being *"...worse to be the position of having to withdraw a test once introduced than to be in our present position of carefully evaluating the tests*". Reading the submission now, it strikes me that withdrawing a test that had been introduced nationwide as a safety measure on the basis that it had proved unreliable would indeed have been very difficult. We would have been open to criticism for not having evaluated or chosen the test carefully enough, and no doubt it could have produced very significant problems in terms of donors and donor recipients alike. I am sure that I would have agreed the recommended

strategy agreeing with the emphasis that the CMO had given to keeping to the predicted timescales. I note in that regard that the submission envisaged implementation "in October or November" and that the screening was in fact introduced on 14 October 1985 so that these timescales were held to.

5.46. The Inquiry notes that the first stage results of the evaluation of testing kits was available at the end of July 1985. On what looks like 29 July, a minute was sent from Mrs Fosh to Mr Clarke's Private Office, copied to mine stating that the results were available and that a letter and draft summary were attached [DHSC0002273_034] (minute) and [PRSE0002078] (draft letter and evaluation) This was a 'for information' type minute, it was not seeking a ministerial decision. A follow up minute was sent to Mr Clarke's Office on 31 July 1985 [DHSC0000825] and Mr Clarke slightly amended and approved the press release on 1 August, which was issued later that day [DHSC0002311_028] [DHSC0000513]. A letter was sent to NHS bodies on the same day [BART0000778].

5.47. The Inquiry asks if these test results were brought to my attention. They were copied to my Private Office and I expect that they probably would have been, given my earlier involvement. However, I cannot be sure especially because I was in the US from 29-31 July (see further below). The Inquiry also asks if the Organon Tenika Ltd, Ortho Diagnostic System Ltd and Wellcome Diagnostics tests were my "preferred options". I do not consider that reflects the nature of the exercise. This would have been a technical evaluation which – as was made clear in the summary of the evaluation – had been considered by an expert working group. By the minute to Mr Clarke's office of 29 July, Ministers were being informed of the outcome and the announcement to be made. We would not be asked for our own views on which kit should be preferred, nor would that have been appropriate when there had been this kind of a technical evaluation exercise.

5.48. The Inquiry asks what factors were considered by the Department in making the selection. Those involved in overseeing the evaluation would be much better placed to answer that. But the summary reported that the test kits from Organon Teknika Limited, Ortho Diagnostic Systems Limited and Wellcome Diagnostics "...*provided a clear distinction between positive and negative results, a low rate of false positives and gave reliable results with heat-treated sera*" whereas, "*The other kits were less satisfactory. In particular, they produced an unacceptable number of apparently false positive results, and generally gave unreliable results with heat-treated sera. Abbott Laboratories has since emphasised that heat-treatment of sera before testing was not part of the company's standard operating procedure*" [BART0000778].

5.49. The New Scientist published an article on 8 August 1985 [DHSC0000509] suggesting that the UK government had delayed the introduction of a screening test for HTLV III until a British test was available. As I have set out in paragraph 5.45(6) above, that was not supported by the submission I received. Nevertheless I must have asked Dr Smithies to brief me on the position as on 16 August 1985 she provided a briefing in answer to my request [DHSC0000501]. She stated that in the US the FDA had licensed two diagnostic tests in March 1985 but it was not the case that all blood banks in the US started using these tests. She stated that Abbott Laboratories who made one of the tests had to report that one hundred thousand tests were faulty. Further she reported that there were a large amount of false positive test results in the US. This is what we had wanted to avoid in the UK in deciding that it was, on balance, better to conduct evaluation and field trials before introducing the screening test. Dr Smithies mentioned Wellcome and says they were a late entry to the diagnostic kit field but their test had outperformed that of Abbott and they had confirmed they could supply the needs of the BST.

5.50. The article in the New Scientist was accurate insofar as a deliberate decision had been taken not to introduce screening immediately using commercially available kits. However, to the best of my knowledge and belief, it was

inaccurate in suggesting that this was motivated by a desire to await the availability of British kits. I note reading the documents now that "Support British Industry" was a criteria in the *draft* ministerial submission of 5 June 1985 which was then omitted from the final submission of 7 June 1985. I would infer that in working on the finalisation of the submission, very properly officials had decided that they did not wish even to raise support for British industry as a factor to weigh in the balance. I would have been very strongly against any such policy. See also paragraph 8 of the final submission which made clear that we should not delay implementation to wait for the British kits to be available at scale [DHSC0002311_019].

5.51. Dr Napier, Chairman of the Western Regional Transfusion Director Division and a member of the RTD working party on AIDS, wrote to the New Scientist and his letter was published on 22 August 1985 [DHSC0002277_075] and [PRSE0002548]. Dr Napier said in his published letter "*the current policy in Britain has been formulated as result of numerous discussions involving informed groups and is not the result of any arbitrary imposition*". He disagreed with the opinion in the original New Scientist article that false positive results were only of importance to donors and not NBTS or its patients. He described this statement as "grossly misleading" and said that it was inconsistent with NBTS's declared position.

5.52. The Inquiry draws to my attention a minute from Mr Williams to Dr Darnborough, Regional Transfusion Director about US Forces' screening of blood supplied to US Forces by the NBTS [NHBT0004235]. I cannot remember whether or not this matter was drawn to my attention or if I was aware of the arrangement at the time. The available records I have seen do not show this coming to Ministers' Private Offices. The Inquiry asks if the "UK Government made a deal with the USAF to screen blood for HTLV-III antibodies before NHS blood was tested". Based solely on the document the Inquiry has drawn to my attention, that does not seem to be correct. What Mr Williams appeared to envisage was that it would be the US Forces themselves who would be using Abbott tests to

screen blood supplied by the NBTS, not the NBTS screening that blood before it was supplied.

5.53. I am referred to an article in PR Week dated 29 August 1985 [DHSC0002277_081] which commented on the Abbott test having been rejected after the PHLS evaluation exercise and stated that Abbott were seeking to overturn the decision. As to this,

(1) I would refer back to the initial results of the PHLS evaluation of tests at [BART0000778]. These results stated that the Abbott test and one other that was evaluated gave an unacceptable number of false positive results and were unreliable when used on heat-treated sera. Abbott Laboratories had since emphasised that heat-treatment of sera before testing was not part of the company's standard operating procedure.

(2) A further briefing provided to Mr Clarke's Private Office on 2 August and copied to Baroness Trumpington's Office, gave details on why the Abbott test had not fared well in the evaluation [DHSC0002116]. Mr Clarke's Private Office supplied the Minister of State's agreement to holding to the results of the PHLS evaluation: [DHSC0002327_036].

(3) Dr Smithies' briefing of 16 August 1985 noted that the American Blood Bank Association had said that Abbot had reported that one hundred thousand tests were faulty [DHSC0000501]. Later in that briefing, Dr Smithies said,

> *"It was expected by all concerned in setting up the evaluation that Abbotts Laboratories who have an excellent record for diagnostic tests would have a satisfactory test. To the surprise of all their test was poorer in specificity (i.e false positives) / no better than Wellcome in sensitivity * (*no more false negatives), went quite haywire when specimens were heat treated (to inactivate any virus) and took more than twice as long to perform than the Wellcome test."*

Beyond the above, I do not think I can comment (as the Inquiry invites me to do) on what was "*different about the PHLS testing standards that meant that Abbott test failed in the UK*" but was "*used throughout the World*". I have set out

what was reported at Ministerial level concerning the relatively poor performance of the Abbott test.

5.54. The Inquiry has drawn my attention to a meeting I attended with the CMO on 22 August 1985. There is no minute of the meeting but it is referred to in a minute from Dr Ower to Dr Sibellas on 23 August 1985 [DHSC0101705]. The note records that the introduction of testing on donor blood samples would start on 14 October 1985. At the meeting we discussed the provision of alternative facilities for blood sample screening for HIV. This meant testing of blood for HIV outside of the blood donor system. This was important because there was otherwise a risk that those who considered that they may be HIV positive would report to give blood solely in order to get a screening test.

5.55. I do not recall why this meeting was called but seen in context of events and the CMO's interest in the need for public health education, it is likely to have related to the wider response to AIDS (see below in relation to my trip to the USA at the very end of July 1985, and follow up work in relation to it). Whatever the reason for the meeting, part of the discussions was clearly the provision of alternative facilities for HIV testing.

5.56. The minute records that the CMO explained there were two extremes. One view was that people "*should not be actively encouraged to have the test*" and the other was that "*every step should be taken to encourage those who think they are at risk*" to have the test. In the minute Dr Ower asks Dr Sibellas to address that issue in a paper that could be discussed with colleagues then sent to the CMO [DHSC0101705].

5.57. Dr Ower's minute contained some further discussion of the issue and expressed concerns about demands on public services if people had been encouraged to take the test and there were many positive results. Dr Ower says that those people "*might quite rightly expect facilities to be available to give*

them advice". On the other hand, it was acknowledged that if people who were positive could be identified and counselled and behaviour changed that this would slow the spread of the disease. Dr Ower commented that it was a difficult balance.

5.58. The Inquiry asks what option I preferred. However it is not clear from Dr Ower's minute (which was not copied to my Private Office) that I was being asked to make a decision at this time. Rather it suggests that officials had recognised that they were going to need to do further work on this and perhaps then submit to Ministers. The point that seemed to have emerged was the need for a clearer policy on this to be developed and Dr Ower envisaged that there would be further work in terms of liaison with the Regional Health Authorities. From Dr Ower's minute, it is clear that steps were already being taken to publicise the alternative testing. The minute refers to the fact the Department had already written to Regional General Managers asking them to publicise the testing facilities in their region and it stated that we would be following that up with either suggestions as to what other steps they could take, eg adverts in the local process, or the need to publicise their testing facilities.

5.59. I have not identified in the available papers any warning to me that the alternative testing facilities would be inadequate but this was clearly a work in progress at the time I left the Department in early September 1985.

5.60. A DHSS press release of 23 August 1985 cited a statement from me and gave the start time for HIV screening as mid-October [PRSE0002603]. I also dealt with the alternative facilities for testing. The press release said:

> "*It is important we reduce the risk of AIDS being spread through blood transfusions and blood products. This risk is already extremely small but screening all blood donations will reduce it still further.*
>
> *This is just one of the steps we are taking to control the risk of AIDS. Health authorities have been asked to make alternative arrangements, outside the NBTS, to provide testing for people who are worried they may*

have been infected with the virus. The PHLS has been given an extra £750,000 to provide laboratory facilities for this testing."

5.61. I have been asked about the statement in the press release that the risk of infection with HIV through blood and blood products was "extremely small". This wording would have been prepared in draft by officials and I would have expected it to have been cleared by the Medical Division officers such as Dr Smithies or others. To my understanding, the assessment of the risk would have reflected the fact that high risk donors had been discouraged from donating, and the overall case numbers in the UK were still low, albeit that the incubation period had to be taken into account. In relation to blood products, heat treatment had by now been introduced.

5.62. My role as Parliamentary Under-Secretary for Health came to an end on 2 September 1985 and the screening test for HIV in blood donations was introduced in mid-October 1985. I would have had no further role in the introduction of the screening test once I left my post.

Visit to the USA: 29- 31 July 1985

5.63. Finally in this section, the Inquiry asks about my visit to the United States from 29-31 July 1985 when I visited New York and Washington. I briefly address this under a separate heading because the visit was not specifically concerned with HIV screening of blood donations, although that was one of many issues discussed.

5.64. There is a report of my meetings in the US at [DHSC0002327_035]. The Inquiry asks me a number of questions about this visit, but it is not easy to give the kind of detail the Inquiry seeks after such a long period of time and the report of the visit and its annexes are the best guide. To the best of my recollection (which is likely to be fallible):

(1) I think it likely that I was asked to undertake the visit to the USA by Mr Fowler with a focus on public health campaigns, where the USA seemed a leader. On 27 June 1985, Sir Donald had sent the Secretary of State a significant paper on AIDS [DHSC0002114], which significantly drew on the position in the USA. From the report of my visit, the purpose would have been fact-finding / information sharing, looking at the lessons we could learn from the US experience. My Private Secretary wrote the report of the visit and she was with me on the visit. My recollection is that there were no other UK-based officials on the visit. I am sure that some British embassy officials would have attended various parts of the programme. I would have discussed the visit in advance with Baroness Trumpington.

(2) In terms of insights gained, the points listed in the report under education/prevention, were relevant to the public health campaign that was developed in the UK. However there were also points about HIV screening (see paragraph 6 of the report). The US had set up alternative screening centres in expectation of massive demand at blood donor centres, although there had been less use of these than expected. It was reported that this was because the homosexual community in the US was tending to behave as if they were infected (*i.e.* not to get tested but assume that they were infected). The US prediction was that screening of donations would virtually eliminate infection through blood transfusions.

(3) Under conclusions, the report of my visit made reference to education campaigns, treatment, resources, wider implications / civil rights as areas that I was saying needed to be considered and discussed further. These points would I think have contributed to the consideration that was already ongoing about the necessary further public health and health education response. For example, I referenced the possible need for an official inter-department working group which was then established. I think it fair to say from the action I was recommending that we were not yet doing enough to tackle AIDS cases early enough.

(4) I was flagging the need *both* to re-double efforts on education campaigns with the homosexual community and in relation to the public as a whole. Plainly I considered that there was more that needed to be done in these areas.

(5) The report included the observation (also in the conclusions section at paragraph 8) that, *"It is important to find ways of explaining that there is nothing that government can do to stop the projected increase in AIDS cases over the next 3 or 4 years because the potential victims are already infected"* (original emphasis). I think this echoed paragraph 2 of the report and the US prediction of the number of increased cases even if transmission could be stopped immediately. It reflected the fact that many would already have been infected with HIV but had not developed AIDS and were asymptomatic. That fed into the conclusions about the need for increased treatment centres, counselling, advice and information dissemination (treatment, resources and wider implications) in the conclusions of the report.

5.65. I was directly involved in following up on the actions that needed to be taken on the wider AIDS situation:

(1) While it plainly did not arise solely because of my trip to the USA, the DHSS press release of 6 August 1985 cited a statement from me on the development of counselling services, and the statement also sought to encourage public understanding of the problems facing AIDS sufferers [BMAL0000010_018];

(2) There is a note from Dr Sibellas to Dr Ower dated 8 August 1985 which references a meeting I had held on 5 August (shortly after my US trip) with a draft submission on AIDS health education and prevention [DHSC0002323_112] and [DHSC0002323_113];

(3) On 21 August 1985, shortly before I left the Department for the Department of the Environment, I received a briefing (which I had specifically requested) from Mr Murray, addressing a summary of action

taken and details of areas where further action was under consideration [DHSC0002275_083].

5.66. My work in following up action and planning after my US visit is what is likely to have led to the gentle rebuke I received from Baroness Trumpington for encroaching on her areas of responsibility without sufficiently involving her. On 28 August 1985, she wrote to me in the following terms,

> *"I find that a number of recent meetings have taken place on this subject to which I have not been invited and I am concerned that officials have not borne in mind my responsibility for our interest in this subject.*
>
> *I am aware of course of the important discussions you had during your recent visit to the United States and that you will naturally wish to be significantly involved in taking these matters forward. Nevertheless you will be aware of my concern over this matter (you will recall my minute of 25 July to Kenneth Clarke with particular reference to haemophilia treatment) and I am anxious that officials should be in no doubt that, as the Minister with particular responsibility, I wish to be kept closely informed at all stages.*
>
> *I am copying this minute to the CMO so that he can ensure that I am appropriately consulted. I hope you will agree that this is the right action." [DHSC0000496]*

Section 6: SELF-SUFFICIENCY, THE REDEVELOPMENT OF THE BLOOD PRODUCTS LABORATORY AT ELSTREE AND RELATIONSHIP WITH THE PROTEIN FRACTIONATION CENTRE AT LIBERTON

General questions on self-sufficiency

6.1. The Inquiry asks me what I understood about the Government's commitment to self-sufficiency when I took office and to explain the source or sources of my understanding.

6.2. When I took up my role as Parliamentary Under-Secretary of State for Health on 14 June 1983, I doubt that I would have had any prior knowledge of the Government's commitment to achieve self-sufficiency in blood and blood products. Since blood products were not within my portfolio of responsibilities, I am sure I would not have received a specific briefing about self-sufficiency issues in the early weeks after my arrival. I would have received early briefing on the subjects that were within my areas of responsibility. Accordingly I think that the knowledge I gained on self-sufficiency would have been in the course of being copied into other submissions as I have explained at paragraph 3.2 *ff* above.

6.3. Dr Walford's briefing paper to Lord Glenarthur of 22 June 1983 which was later copied to my Private Office had stated that,

> *"It is thought that the greatest risk to haemophiliacs at present is from the use of Factor VIII concentrate prepared from American plasma. Although the Blood Products Laboratory is to be redeveloped over the next three years at a cost of £21 million to achieve national self-sufficiency in blood products, until this time, some 50% of the Factor VIII concentrate needed*

> *to treat haemophilia will have to be imported, mainly from the USA." [DHSC0002309_123] and [DHSC0002309_124].*

6.4. Dr Walford's paper was copied to me again on 1 July 1983. On that occasion, my Private Secretary was copied into a covering minute sent to Lord Glenarthur about AIDS [DHSC0002309_024]. The minute stated, "*a further submission covering the imports of blood products, developments in technology, research and UK production of Factor VIII will shortly be put to Ministers.*"

6.5. The Inquiry also asks me if the policy on self-sufficiency changed during my time in office. Without giving a general account of the consideration of this issue by other Ministers, it is apparent from my own, personal involvement that throughout my tenure the Government remained committed to achieving national self-sufficiency in blood products. By way of example, the 18 November 1984 press release on AIDS and blood products that was provided to the BBC and others (which I have already referred to in section 4 of this statement) stated, "*The Government is already committed to self-sufficiency in blood products by trebling the manufactured output from British donors*" and went on to refer to the re-building of the Blood Products Laboratory, Elstree [PRSE0003367].

6.6. The press release the following day, 19 November 1984, quoted me directly in the following terms:

> "*Our multi-million pound development project at the Blood Products Laboratory, Elstree, is on target for completion in early 1986 and this should enable us to become self-sufficient in blood products […] by the end of that year. This will mean that we no longer have to import factor VIII from abroad."* [PRSE0002251].

6.7. The Inquiry asks what informed my statement that the development project at BPL meant that we would no longer have to import factor VIII from abroad. Although I have not seen any earlier drafts or submissions in relation to this specific press statement, the line taken would have received input from officials

working in this policy area. As I have addressed in Sections 4 and 5 of this statement, my Private Office was copied into a briefing note from Dr Smithies to Mr Fowler that was sent on the same day as my press statement about BPL (19 November 1984). The contents of Dr Smithies' note appear to reflect the information that I gave in my press statement. Dr Smithies' note stated, at paragraph 7:

> *"Self-sufficiency in blood products (mainly Factor VII) will be achieved once the new blood products laboratory (BPL) at Elstree is completed and sufficient plasma is supplied by the regions. This is hoped to be by the end of 1986 […]. We shall no longer rely on imported Factor VIII which is made from donors who are paid to give their plasma [DHSC0002309_053].*

6.8. To return to the Inquiry's question about whether policy changed, I have seen a draft briefing document produced by officials ahead of my visit to the USA in July 1985, so towards the end of my time as a junior health minister [DHSC0002337_049].The fourth paragraph of the briefing note made clear that the Government remained committed to achieving self-sufficiency in blood products:

> *"Fourthly, Britain is committed to achieving self-sufficiency in blood products in line with a World Health Organisation recommendation; we are already self-sufficient in blood. In 1982 we commissioned the building of a national Blood Products Laboratory, and the project is on target for completion by early next year. This is a major capital investment of over £35m [51m dollars]. Medical experts and Departmental officials were greatly helped in their endeavours by their recent visit to the AIDS conference in Atlanta. Continuing international co-operation is regarded as highly desirable"*

Statements made by previous administrations

6.9. I am asked whether I was aware of statements made by Ministers in previous administrations about aspirations towards achieving self-sufficiency in Factor VIII blood products. The Inquiry refers me to the following documents:

(1) Written Parliamentary Answer by David Owen dated 22 January 1975 [DHSC0000274];

(2) Written Parliamentary Answer by David Owen dated 7 July 1975 [DHSC0000281]; and

(3) DHSS Press Release referencing David Owen's speech to the World Federation of Haemophilia Congress on 29 April 1976 [LDOW0000044].

6.10. I note the summary of Dr David Owen's speech to the World Federation of Haemophilia Congress states that the then government expected to reach self-sufficiency in home-produced Factor VIII by mid-1977. The background to this was apparently a special allocation of £500,000 in 1975 and progress made to build up production capacity in the NHS. Dr Owen's statements to Parliament referred to the national objective of self-sufficiency.

6.11. I do not recall being made aware specifically of these statements when I came into the Department, or at any time thereafter. I do not think knowledge of statements made by previous governments would have changed my approach. As set out above, the policy of redeveloping BPL in the pursuit of self-sufficiency was established before I arrived and, in conjunction with other Ministers and officials, we continued to work towards that outcome throughout my time in the Department.

Influencing Regional Health Authorities

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

6.13. I recall in general terms that the arrangement during my time in office was that the DHSS allocated funds to the Regional Health Authorities and they each

then exercised their own discretion about where to allocate their resources. Regional Transfusion Centres were one of many calls on the resources of the Regional Health Authority. I would expect that officials would be better placed to explain the extent of the DHSS' influence and how it was exercised.

Northern Ireland and arrangements with Scotland for fractionation of plasma from Northern Ireland.

6.14. The Inquiry raises asks me:

(1) how and why the decision was taken to fractionate plasma from Northern Ireland at the PFC in Scotland in1 982 (and sub-questions related to this)

(2) whether there were any challenges for Northern Ireland to reach a formal arrangement with Scotland to process Northern Irish plasma.

(3) About the effect of the duration of discussions to reach an agreement between Northern Ireland and Scotland, if any, on Northern Ireland's ability to achieve self- sufficiency in blood and blood products.

6.15. While I was a junior Minister in the Northern Ireland Office at the time, I am afraid that I simply do not have any independent recollection of this issue at all. I would need to see contemporaneous documents on it in order to be able to offer any comment.

Cost of redevelopment of BPL

6.16. The Inquiry asks about a submission made to Ministers in September 1984 for a substantial increase in the costs for the redevelopment of BPL [DHSC0002309_047]. What appears to be a late draft of the submission was addressed "to Ministers" but the as-sent version with a copyee list is, I understand, not available in order to identify whether it was sent to my Private Office. At this point in time, I cannot specifically recall seeing this submission before. I therefore cannot now say what role, if any, I played in considering and

deciding upon the submission. However, it seems highly unlikely that I did play any role given that the documents that follow the September 1984 submission reflect that, at ministerial level, it was Mr Clarke who was involved at this stage in financial matters around the BPL redevelopment.

6.17. I am aware from reading the draft submission now that ministerial approval was sought for a substantial increase in the capital cost of the BPL redevelopment. The submission presented three options:

(1) abandon the project;

(2) redesign to the original budget, suitably inflated to £25.3m;

(3) accept the revised design solution at £38.8m.

Officials recommended the third option and invited ministerial approval to the revised scheme.

6.18. The Inquiry asks to what extent I shared the views expressed by the Minister of State in his minute of 25 September 1984. I assume the Inquiry refers to Mr Clarke's minute to the then Permanent Secretary, Sir Kenneth Stowe, of that date [DHSC0003964_035]. Mr Clarke's minute set out his response to the September 1984 submission. He described a "*...fairly woeful lack of cost control*" but conceded there was no practical alternative but to seek Treasury funding. Mr Clarke's minute closed with a request to be "*...kept in touch with what is done about this*".

6.19. Mr Clarke's minute does not appear to have been copied to my Private Office, so it is unlikely that I saw it at the time. I am not in a position to comment upon the views expressed at the time by Mr Clarke in circumstances where it appears that I did not see either the submission or Mr Clarke's response save to say that the increase was very significant indeed and therefore must have been suggestive of poor financial control.

6.20. The Inquiry asks what role I played in overseeing the BPL redevelopment project, in particular the costs and timetable. I have been shown certain documents which passed between officials and between officials and Ministers on this issue subsequently, but it does not appear from those documents that I had any involvement in overseeing the ongoing redevelopment project. These matters would have been dealt with by officials and, as indicated above, Mr Clarke appears to have taken the lead where ministerial involvement was required.

6.21. In section 5 of this statement, I have already referred to the submission dated 31 October 1984 that was sent by Mrs Banks to Mr Clarke's Private Secretary (Ms Bateman) and copied to my Private Office and to the Private Office of the Secretary of State [DHSC0002309_051]. The submission concerned HCHS central reserves for 1985 to 1986. The submission referred to the expenditure on the redevelopment of BPL (see paragraph 10) and to various other health related capital projects and Ministers' views were sought. I surmise that this submission may have been copied to me because it concerned other capital projects that were within my ministerial portfolio, rather than because of the references to the BPL redevelopment or AIDS.

6.22. Given my apparent lack of involvement in issues around the financing of the redevelopment of BPL, I do not think I can assist the Inquiry with why the cost of the redevelopment of BPL expanded so greatly beyond making reference to the reasons identified in the September 1984 submission.

Section 7: OTHER MATTERS

Hepatitis and Blood Products

7.1. The Inquiry asks about what brief was provided to me when I first took office about the risks of transmission of hepatitis in blood and blood products, the severity of the different types of blood borne hepatitis and the relative risks of infection from the use of commercially sourced blood and blood products.

7.2. As blood products were not within my portfolio of delegated areas of policy responsibility, I doubt that I would have had a specific briefing on these areas. I would have been, or become, aware that the greater risk of hepatitis infection from imported blood products was the background to the original policy for self-sufficiency in blood products, made all the more urgent by AIDS. But I do not feel able to comment meaningfully now – beyond the written submissions – as to how my knowledge specifically of hepatitis infection developed during my time as a Minister.

Role of the Chief Medical Officer(s)

7.3. My general understanding of the role of the Chief Medical Officer is that he was:

(1) The Head of the Medical Divisions of the Department; as such he had a large number of staff who reported to him;

(2) The chief medical adviser not just to the Department, but also to the Government as a whole.

7.4. Given the division of Ministerial responsibilities, I do not think that it fell to me to consider asking the CMO to issue guidance, advice or instruction to clinicians and health bodies about the risks of blood and blood products transmitting AIDS, nor do I recall having done so. The CMO clearly could issue guidance of various sorts but I do not feel able from my personal knowledge to comment on whether this should have been done in relation to blood products.

Section 8: NORTHERN IRELAND OFFICE

8.1. In this section of the Inquiry's request, it raises a number of general questions about my role as Parliamentary Under-Secretary of State in the Northern Ireland Office, 5 January 1981 - 13 June 1983. However, I have not been provided with any documents from this time and I regret that I simply do not have any independent recollection of blood product or plasma fractionation issues from this time, some 40 years ago.

8.2. During my time in as a junior Northern Ireland Minister, Humphrey Atkins was initially the Secretary of State (then Jim Prior from 14 September 1981), and there were two Ministers of State, Michael Alison (succeeded by the Earl of Gowrie from 15 September 1981) and Adam Butler. David Mitchell and I were the Parliamentary Under-Secretaries of State.

8.3. Health and social services issues did fall within my area of responsibility but I also covered a number of areas including difficult security aspects. Inevitably, given the ongoing Troubles, the security and political aspects took up a significant amount of ministerial time, particularly when I was duty minister in the absence of the Secretary of State and other ministers in London where considerable parliamentary time was given to the province.

8.4. My general recollection is that the liaison with DHSS on health issues was done by officials rather than at Ministerial level. Indeed, going from memory alone, I cannot remember any meetings with my opposite number junior health Ministers in the DHSS or in the Scottish and Welsh Offices. On major financial aspects, there would have been some liaison at Ministerial level. In the NIO, Michael Alison would have been involved because he was effectively our 'Chancellor' but if it was health and social services related financial issues, I would probably have been copied in.

Section 9: REFLECTIONS ON RELEVANT EVENTS

9.1. I have provided a list of my Parliamentary interventions as an annex to this statement.

9.2. Throughout its request on the issues addressed above, the Inquiry has sought my own views and opinions and I have tried to set these out as fully as I can in each of the relevant sections of my statement. Reflecting on matters now, I have set out earlier in this statement that:

(1) The first blood donor leaflet issues could perhaps have been pushed through more quickly in July 1983 than they were, though the issues being considered were rightly to be debated.

(2) There is clear force in the Inquiry's identification of tension in the use in the wording "no conclusive proof", but nor should that phrase be quoted out of the context in which it appeared. The wording should also have been amended sooner.

(3) Given its importance and profile the question of whether or not to ban imports of Factor VIII should appropriately have been raised at ministerial level.

(4) It seems there was certainly an avoidable delay in the revision of the blood donor leaflet in the version that came to be published on 1 February 1985.

9.3. Finally, I would wish to re-iterate the opening observations I made at paragraphs 0.2 and 0.3 of this statement.

Statement of Truth

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

Signed..... GRO-C .....

Dated.....5th April 2022.....

List of Parliamentary Interventions

Date	Reference	Event	Relevance
Parliamentary Under Secretary of State Northern Ireland Office- 5 Jan 1981 to 13 June 1983			
21 July 1981	HC Deb 21 July 1981 vol 9 cc117-8W Blood Donation (Hansard, 21 July 1981) (parliament.uk)	Written Answers (Commons)	Blood donation
Parliamentary Under Secretary of State for Health and Social Security – 14 June 1983 to 2 Sept 1985			
11 July 1983	HC Deb 11 July 1983 vol 45 c275W Acquired Immune Deficiency Syndrome (Hansard, 11 July 1983) (parliament.uk)	Written Answers (Commons)	AIDS
29 July 1983	HC Deb 29 July 1983 vol 46 c661W Blood Supplies (Hansard, 29 July 1983) (parliament.uk)	Written Answers (Commons)	Blood supplies
02 April 1984	HC Deb 02 April 1984 vol 57 c410W	Written Answers (Commons)	Blood supplies

	Blood Supplies (Hansard, 2 April 1984) (parliament.uk)		
16 April 1985	HC Deb 16 April 1985 vol 77 cc121-2 Blood Donors (AIDS) (Hansard, 16 April 1985) (parliament.uk)	Commons Sitting	Blood donors (AIDS)