Witness Name: Kenneth Clarke
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INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF KENNETH CLARKE

Contents

Section 1: My Role as Secretary of State for Health

General

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006, dated 09 April 2021.

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

1.1. I have been asked to describe, in broad terms, my role, functions and responsibilities as Secretary of State for Health, during my period of office from 25 July 1988 – 1 November 1990.

1.2. The Department of Health and Social Security was abruptly split by Mrs Thatcher in July 1988, in part to allow Mr Moore (my predecessor at the DHSS, who had been overwhelmed by the job) a smaller and more manageable role at the new Department for Social Security. Mr John Moore took responsibility for the new Department of Social Security, whilst I was assigned the new Health Department.

1.3. The description of the Department's responsibilities in the Civil Service Yearbook for 1989 reads as follows:

> *"The Department of Health is responsible (in England) for the administration of the National Health Service; for the social services provided by local authorities for elderly and handicapped people, socially deprived families and children in care; and for certain aspects of public health. The Department also makes reciprocal health arrangements with other countries; represents the United Kingdom in the World Health Organisation and in other international fora."*

1.4. When I came into office, the immediate topic on the agenda was NHS reform. As I wrote in my autobiography, Mrs Thatcher had committed herself to reforming the NHS (in a TV interview in January 1988), but without a clear idea of what this reform would actually entail. There had been no real development of ideas under Mr Moore's tenure. By contrast, I had a clear idea of what was needed from my previous experience in the Department, but it was an agenda that was not shared with Mrs Thatcher. I wanted to introduce the internal market, or 'purchaser-provider' split. Mrs Thatcher favoured a system of private health insurance with the State funding a basic minimum service for those who could not afford it for themselves, looking to an American model. By stark contrast I have always believed in the founding principles of the NHS, and care that is free at the point of use, funded from general taxation. But I wanted to see a more efficient use of the resources of the NHS, for the benefit of patients. I was also conscious of the fact that control of the NHS, through Whitehall, was over-centralised and there was a need to separate policy and operational decision-making.

1.5. I embarked on a lengthy series of political battles with Mrs Thatcher to get her to agree to my proposals and, when she eventually did, a further series of battles with not only the medical establishment, the opposition and the press, but also – at least initially – with the civil servants who had little interest in furthering the cause of radical reforms. The proposals were set out in a White Paper published in January 1989 ("Working for Patients") and, eventually, embodied in the National Health Service and Community Care Act 1990.

1.6. In addition, strikes and campaigns for increased pay were as much a feature in this term of office as they had been when I was Minister of State of Health in in 1983 - 1985. In particular, there was a lengthy strike by the Ambulance Service which lasted for about six months, from the summer of 1989 until February 1990, with the army having to be brought in to run ambulances when not even emergencies were being covered by the ambulance services.

1.7. These were the matters that occupied the greater part of my time when in office during this period. Against that background, it was inevitable that I should rely on an extremely able and dedicated team of Junior Ministers to manage the detail of most aspects of the Department's Work. As a matter of constitutional and parliamentary convention, I retained overall accountability for actions within the Department. But on a practical level, my Ministers were responsible for the decision-making in the areas allocated to them. They knew that they could come to me to discuss any areas of concern. In addition, I said to everyone that if they knew that a topic was contentious and was about to cause comment in the media or Parliament, I wanted to know about it at least the day before; we would then sit down and thrash out the problem and come up with solutions.

1.8. I do not now recall any substantial involvement with matters relevant to the Infected Blood Inquiry during my time as Secretary of State. However, looking at the papers that have now been supplied to me, it seems that I had some involvement from time to time, either:

a) because of a story that had been reported in the press and attracted my attention as a result; or
b) because matters were sufficiently politically prominent as to require my attention, together with – at times – other senior Cabinet Ministers. The addition of £20 million to the funds of the Macfarlane Trust in late 1989 is an example of this; so too are some of the discussions on the management of the HIV litigation in 1990.

1.9. I have dealt with these issues in my statement below, with the assistance of my legal advisors who have referred me to relevant documents. However, I am almost completely reliant on the documents to which I have been referred, and whose contents have been summarised below. I have virtually no independent memory and certainly no detailed memory of these events and am simply not in a position to add to the documentary record. If further relevant documents are identified and shown to me, I will need to consider whether anything in this statement needs to be altered.

1.10. A further matter, relating to the system of replying to Ministerial correspondence, is also important. As Secretary of State for Health, I should think that I received many hundreds of letters a week (I do not have access to exact numbers, however). The 'default' addressee would often be the

Secretary of State for Health. The letters would be passed directly to the Ministerial Correspondence Unit, for officials to draft an answer. Unless there was some particular reason why it was decided that the answer should come directly from me, answers would be passed to the Minister with responsibility for the area of policy in question. That Minister would check the contents of the letter and sign it. I would not see copies of the correspondence that was handled in this way.

Decision-Making Within the Department of Health

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

2.2. The Ministerial team at the time consisted of:

House of Commons

Minister of State:

- Mr David Mellor – Minister of State for Health from 25 July 1988 – 27 October 1989;
- Mrs Virginia Bottomley – Minister of State for Health from 28 October 1989 – 14 April 1992;

Parliamentary Under-Secretary:

- Edwina Currie, Parliamentary Under-Secretary (Health) from 25 July 1988 – 16 December 1988. Mrs Currie was in post until she was toppled by the 'salmonella in eggs' furore;
- Mr Roger Freeman – Parliamentary Under-Secretary (Health) from 16 December 1988 – 4 May 1990;

- Stephen Dorrell: Parliamentary Under-Secretary (Health) from 4 May 1990 -14 April 1992.

<u>House of Lords</u>: Those assisting me with this statement have not, to date, been able to find a record of formal appointment to the role of Parliamentary Under-Secretary of State (Lords).[2] A number of ministers spoke in debates for the Government, from time to time. Lord Trafford (Anthony Trafford) was appointed Minister of State for Health in the Lords on 25 July 1989, but he sadly died on GRO-C 1989. However, I remember in my autobiography the appointment of Baroness Hooper (Gloria Hooper) to assist with the passage of the NHS and Community Care Bill and I believe that she served as Parliamentary Under-Secretary in the Lords from 1989-1992.

2.3. The involvement of each Minister is apparent from matters set out in paragraphs below. Mr Mellor and then Mrs Bottomley were involved in some matters involving blood and blood products as well as AIDS policy. However, it is also clear that some decisions involved Baroness Hooper.

Q3: Decision-Making Within the Department

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

3.2. I addressed this issue in my first statement to the Inquiry, relating to the period when I was Minister of State for Health: from paragraph 2.1. As far as I can recall now, the essential features had not changed. In particular, whilst written

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[2] Lord Skelmersdale is listed in that role in the 1988 Civil Service Yearbook, but that was before the DHSS was split into DSS and DOH in mid-1988.

information was conveyed by submissions to Ministers, I regarded meetings as an essential tool for thrashing out the details of an issue and reaching solutions. Every meeting would have a medical officer in attendance, by long-established convention in the Department.

3.3. As Secretary of State, I was copied into a large number of the papers sent to more junior Ministers. This does not mean that I saw them all. The job of the civil servants in my Private Office was to sift the information flowing in, into what I ought to see, what they knew I would want to see, and what I did not need to see, although the Office was being kept abreast of events by the papers copied to it. Only the first two categories of papers/information would make their way into the red boxes sent to me, and which I would then read. I have already explained to the Inquiry (see paragraph 5.6 of the first statement) how I would underline the papers that I read personally, but that these personal Private Office papers have not, it would seem, been retained in the archives. Without them, the only way of spotting which papers I was personally shown is by identifying the occasions when comments or decisions were sent out of my Private Office, recording a reaction; or when there is some other record such as a meeting minute, letter or similar.

Civil Servants

4.1. I have been asked, to the best of my ability, to identify (by name and by position) the senior civil servants within the Department with whom I principally dealt, or from whom I received advice, in relation to the following issues: blood, blood products, the licensing and regulation of pharmaceutical companies and other matters relevant to the Inquiry's Terms of Reference.

4.2. I cannot now remember who gave me advice on these issues, which as I have explained, rarely came across my desk during the relevant period. The civil servants whose names I remember now are:

- Sir Donald Acheson, who I described in my first statement; and

- Andy McKeon, who my Principal Private Secretary and who was a key member of the small team I put together to drive the internal market reforms through.

4.3. Looking at some of the documents that have been supplied to me for this statement, I can see that, for example, Mr Strachan Heppell was closely involved in the events in late 1989, when the sums for the Macfarlane Trust were increased by £20 million. I have been told that, according to the Civil Service Yearbook from 1989, he was the Principal (Grade 2) at the Health and Personal Social Services Group at the Department. This illustrates that the best guide to those involved in the events of interest to the Inquiry is the documents circulated by officials on these topics (coupled perhaps with the Civil Service Yearbook, which the Inquiry will have access to).

Decision-Making Structure, AIDS

5.1. I have been referred to the text of a draft speech on "AIDS in the United Kingdom" by Norman M Hale in March 1988 [DHSC0105063]. I have been told that Mr Hale is listed as a Grade 3 Civil Servant in the Children, Maternity and Prevention Division in the 1988 and 1989 Civil Service Yearbook. The speech stated that the UK had established "a special network within Government" (p. 6) to enable decisions relating to AIDS to be taken "on the basis of the best scientific and medical advice available" (p. 5). The Inquiry has noted that he referred to the Cabinet Home Affairs and Social Affairs Sub-Committee on AIDS, cross-departmental co-ordinating groups at official level, the AIDS Unit within the Department, and the Expert Advisory Group on Aids ("EAGA").

5.2. I cannot now recall the detail of decision-making structures within the Department at the time and do not think I can comment on this speech (which I would not have seen), although I have no reason to disagree with the description given by Mr Hale. The Cabinet Home Affairs and Social Affairs Sub-Committee on AIDS is a committee that I attended, on occasion. I have referred to it in the context of anonymous screening for AIDS, below.

Public Health Messages

6.1. I have been asked what role, if any, I played in determining the Government's approach to public health messages and education on AIDS during my time as Secretary of State.

6.2. The leaders on public health messaging during the key points in time with respect to panic about AIDS and the stigmatisation of those who suffered from it were, as I remember, Mr Fowler and Dr Donald Acheson. The former played a key part in formulating the response to the AIDS crisis when he was Secretary of State for Health and Social Security. Also of vital importance was Dr Acheson, who had great expertise in the area of public health education. When I became Secretary of State for Health, Dr Acheson was still in post, and I would have expected to be advised by him on any public health education campaign needed. But I remember this as a period during which the political and press furore had subsided, and I do not remember having any personal involvement in this issue. That is not to say that public health campaigns or the production of information did not continue; they obviously did. But I do not remember being asked to make decisions upon issues arising in this regard.

Devolved Administration in the 1980s

7.1. I have been asked to describe, insofar as I am able to do so, the extent of my responsibilities and powers as Secretary of State for health policy and delivery in Scotland, Wales and Northern Ireland.

7.2. I do not believe that I had any such powers or responsibilities; the administration of, and policy responsibility for, the health service in these parts of the United Kingdom were managed at the level of the territorial administrations. There was a Department of Health and Social Services in the Northern Ireland Department, a Scottish Home and Health Department and the Welsh Office had sections dealing with health policy as well as an NHS Directorate in Wales. There was co-ordination and negotiation to achieve common objectives, when needed. So for example, the provisions of the 'internal market' when introduced, were modified to account for the circumstances of each of these administrations. But as I recall, independence could be jealously guarded; for example, I remember Sir George Younger, when Secretary of State for Scotland, resisting the introduction of the public health campaigns by Mr Fowler when Secretary of State for Health and Social Security, promoting the use of condoms against the threats of AIDS; Sir George felt that they were not appropriate or not needed, north of the border. Wales and Northern Ireland would be more likely to follow the policies being developed in England.

Interactions with the devolved administrations

8.1. I have been asked to describe the interaction of the Department of Health with the Scottish Office, Welsh Office and Northern Ireland office, on health policy in relation to: blood, blood products, the licensing and regulation of pharmaceutical companies and products, self-sufficiency, risks of infection from blood or blood products, the response to such risks, hepatitis and HTLV-III/HIV/AIDS; and financial support for people with haemophilia or other bleeding disorders who had been infected with HIV.

8.2. I do not think that I can add to the answer I have given to Q7 above. I cannot remember any specific examples of interaction on these issues now.

Ministers and Officials, Devolved Administrations

9.1. I have been asked for the names of any Secretaries of State, Ministers and civil servants from the Welsh Office, Scottish Office and Northern Ireland Office, and from the Scottish Home and Health Department and any other relevant departments of government within Scotland, Wales and Northern Ireland, with whom I regularly liaised on those matters which are within the Inquiry's terms of reference or its interests.

9.2. As I have stated above, I cannot remember any. If there are documents showing such interactions (and I have not been shown any), they will be a better guide than my memory now.

Interactions with other health bodies in Scotland, Wales and Northern Ireland

10.1. I have been asked to describe any interactions that I had, in my capacity as Secretary of State, with other health-related public bodies in Scotland, Wales and Northern Ireland, again in relation to matters relevant to the Inquiry's terms of reference.

10.2. I cannot remember any.

The Haemophilia Society

11.1. I have next been asked to describe my relationship and interactions with the Haemophilia Society, when Secretary of State for Health.

11.2. I cannot remember any direct interactions with the Society or its officers. I can see from the papers now supplied to me for the purpose of making this statement that the Society was obviously an active lobbyist for the interests of its members. In particular, I can see that Mr Robert Key MP, its Vice-Chairman, was effective in conveying the Society's views to Ministers in late 1989, when the topics of adding to the funds of the Macfarlane Trust and also the HIV litigation were being considered. I have addressed these events further below. But I do not remember any direct interaction with the Society (although I can see from the documents that I must have met some of its officials when informing them of the additional funds to be given to the Macfarlane Trust on 23 November 1989, question 39 below). Relationships with the Society are a matter that I would have expected to be handled at an official level and, if appropriate, by the Minister with policy responsibility for this area.

Section 2: Blood and Blood Products

12.1. I have been asked by the Inquiry about what, if any, advice or information or briefing was provided to me, when I first took office as Secretary of State for Health, about:

a. The National Blood Transfusion Service and how it was organised;
b. The safety of blood and blood products and any concerns about their safety;
c. The risks of infection from blood or blood products, in particular the risks of the transmission of hepatitis and HIV;
d. The nature and severity of different types of blood born hepatitis (in particular what was called Non-A Non-B hepatitis, then named hepatitis C in 1989);
e. Measures that had been or could be implemented to improve the safety of blood or blood products.

12.2. I am unable to remember now what information was provided to me. There would have been a very large number of briefing papers or other information provided to me as an incoming Secretary of State. However, none have been found for me now and it is impossible to say what information was provided, over 30 years ago.

13.1. I have then been asked by the Inquiry how my knowledge and understanding of these issues developed or changed during my time in office as Secretary of State. In the circumstances explained above, this is an impossible question to answer. If I did see papers or briefings on any of these subjects whilst Secretary of State, I have tried to indicate this in the Statement.

14.1. I have been asked by the Inquiry what knowledge I had, during my time as Secretary of State, about the way in which risks associated with the use of blood and blood products were assessed, communicated and ultimately decided upon with the Department. I am asked, who or what were the sources of my knowledge.

14.2. For the reasons explained above, I do not think that I can now assist. Some of the papers now shown to me (on Profilate or the recall of BPL blood products, mentioned below), show the systems in operation but the detail was handled either by officials or, if there was Ministerial involvement, by the Minister of State for Health.

15.1. I have been asked what knowledge I had about the way in which blood and blood products, were regulated and licensed for use within the United Kingdom. I am asked, who or what were the sources of my knowledge and what role, if any, I played in such systems.

15.2. I do not think that I can reliably say now, what knowledge I had then, in 1988-1990, about the systems for regulating and licensing blood products. I am aware that there was a licensing system, under the Medicines Act 1968; the Inquiry no doubt has details of this. As Secretary of State for Health, I would not have expected to play any part in this. The licensing of medicines was an area of specialist medical or clinical opinion and I would not have involved myself in that.

15.3. Further, if there were any issues regarding regulatory action, I would have expected a Junior Minister to handle them. See paragraph 19 below, where it is apparent that an issue about an adverse inspection report by the Medicines Inspectorate was dealt with by Mrs Bottomley. I have explained how she, like all other Ministers, could come to me if she wanted assistance.

Hepatitis C and screening tests

16.1. I have been asked to give a chronological account of my knowledge of, or involvement in, steps taken by, or on behalf of the Department of Health to reduce the risks of people being infected with hepatitis C (Non-A, Non-B hepatitis) in consequence of treatment with blood and blood products, during the period in which I was Secretary of State for Health.

16.2. I have been reminded, by reference to the papers, that an important development during the period in which I was Secretary of State, was the establishment of the Advisory Committee on the Virological Safety of Blood (hereafter, "ACVSB").

16.3. In December 1988 Ministers were asked to agree to the establishment of this new body, whose mandate would be to advise the Health Departments on the virological safety of blood supply. This was outlined in a minute from Dr Moore to Mr Harris (Deputy Chief Medical Officer) and Ms Kirk (Private Secretary to the Parliamentary Under Secretary of State for Health), dated 6 December 1988 [WITN0758013 and PRSE0003956]. Mrs Goldhill (my Assistant Private Secretary) was copied in. Paragraph 3 of the Minute noted the context for the establishment of the ACVSB: *"concern to maintain the safety of the blood supply has been heightened by greater public and clinical awareness of the potential for viral contamination and new developments in product liability legislation"*. The proposed role of the ACVSB included advising on current practice and policies for screening for infections, including Non-A, Non-B hepatitis (paragraph 11).

16.4. I have been referred to documents, summarised briefly below, outlining that there was some delay in establishing the ACVSB because of disagreements regarding the proposed membership (minute of 12 January 1989 [WITN0758014]). However, this appears to have been resolved, such that there was consensus amongst Ministers about the establishment of the ACVSB by the beginning of February 1989 (minute of 21 January 1989 [WITN0758015], minute of 24 January 1989 [WITN0758016] and letter dated 8 February 1989 [PRSE0000967]). The ACVSB performed a central role in informing Ministers about the scientific position regarding measures that could be taken to reduce the risks of people being infected with hepatitis C (Non-A, Non-B hepatitis) in consequence of treatment with blood and blood products, during the period in which I was Secretary of State for Health.

16.5. In particular, the ACVSB considered the scientific evidence in relation to screening tests of blood products for hepatitis C (Non-A, Non-B hepatitis), which I am asked about in the Rule 9 Request at paragraph 17.

17.1. I have been asked to provide a chronological account of what (if any) involvement and knowledge I had of decisions taken on whether, and if so, how and when to implement surrogate or screening tests for all blood donations for Hepatitis C.

17.2. First, I have been advised that – as the question indicates – there is a difference between *surrogate* testing of donated blood for hepatitis C (Non-A, Non-B hepatitis), and *screening* tests. The papers that I have been shown in relation to this issue, during the period in which I was Secretary of State for Health, focus on screening tests. I do not think that I am in a position to explain to the Inquiry what consideration was given to the former, or when – this may be a question for medical advisors.

17.3. In relation to screening tests, I have been referred to some documents showing the advice that was received from the ACVSB, as well as some of the Parliamentary discussion about the same. There was, in particular, discussion and debate both in the media, in Parliament and amongst the scientists advising the Government about a test marketed by an American company, Ortho Diagnostic Systems Ltd (referred to in some documents as the "Ortho test"), about which I have been asked some further specific questions at paragraph 18 of the Request (below).

17.4. However, I have no independent memory of this issue. Furthermore, the Ministerial documents were generally sent to the Private Office of the Parliamentary-Under Secretary in the Lords (first Lord Trafford and then

Baroness Hooper) who must therefore have been handling the topic. They do not, in general, show any involvement on my part.

17.5. I have been referred to material suggesting that during my time as Secretary of State, there were various articles in the media about testing for Hepatitis C in blood products and about the Ortho test. I have also been told about questions that were raised in Parliament in December 1989 and again in January 1990, in relation to Hepatitis C in blood products and screening tests. Mr Freeman, the Parliamentary Under-Secretary of State for Health, responded in the Commons on both occasions.

17.6. Thus in December 1989, Mr Freeman explained that a screening test for antibodies to Hepatitis C had only been available since the middle of the year, and that no confirmatory test was available. He explained that the introduction of a test for all blood donations was under review and would depend on the results of the evidence and other scientific evidence supporting its benefit (see the Hansard record of written answers to PQs about Hepatitis C and blood products, with a handwritten note, which provide some further detail behind Mr Freeman's response [WITN0758017]). In January 1990, Mr Freeman explained that "*at present there is no routine testing for hepatitis C carried out by the home authorities in any country from which blood products are imported to the UK. Such tests as are available are still being developed and evaluated*" (see the Hansard record [WITN0758018]).

17.7. The scientific judgment in favour of screening blood donations for Non-A Non-B Hepatitis in blood and the Ortho test in particular, took some time to crystalize. This is illustrated in the documents. For example, my attention has been drawn to a minute from Miss P Reenay about Non-A Non-B Hepatitis in Blood, dated 15 February 1990 [WITN0758019], to Dr Metters (DCMO) and Mrs Baldock, the Assistant Private Secretary to the Parliamentary Under-Secretary in the Lords (PS(L)), which has a handwritten note at the top that is evidently from Dr Metters. It states:

> *"Mrs Baldock,*
>
> *The clear advice from ACVSB is that, as yet, there is not enough scientific data about the test marketed by Ortho for the Committee to recommend that it be introduced".*

17.8. The subsequent documents relay, I gather, how the position of the ACVSB and their advice of screening tests developed. A minute from Mr Canavan to Dr Metters and Mrs Baldock (PS, PS(L)) dated 1 May 1990, about the screening of blood donations for Hepatitis C, advised them both of developments [NHBT0000061_130] and explains as follows:

> *"In France, Belgium, Luxembourg and Finland screening has recently been introduced for all donations and in Italy the screening is voluntary. However, at its meeting on 24 April, our Committee reaffirmed its view that the introduction of routine screening would not yet be justified. The new tests developed in the USA have not been approved by the Food and Drugs Administration and there are still unresolved difficulties concerning the tests. The Committee has advised that a pilot study should be carried out to learn more about the significance of a positive reaction to the test and the extent to which it predicts infectivity which could be transmitted in blood. A working party has been set up to draw up a protocol for the study and this will be considered at the ACVSB's next meeting on 24 July".*

17.9. The same point is repeated in the minute from Dr Pickles to Mr Ahearn in my Private Office, dated 11 May 1990 [NHBT0000061_137]. This minute appears to have come to my office because of press interest. It refers to some articles in the press, which were linked to a Lancet article, which showed high rates of positivity with a recently developed test for hepatitis C in recipients of blood products. At paragraph 5 it is explained that, *"before heat-treatment of blood products was instituted in 1985, transmission of non-A non-B hepatitis to haemophiliacs was commonplace and these findings reflect past infections. In the 4-5 years since heat-treated NHS8Y Factor VIII has been issued from BPL,* *there is no recorded instance of transmission of this infection, or indeed of any other".* At paragraph 6, it notes that the question nevertheless remained whether the NBTS should, as an additional measure, screen donations for hepatitis C.

17.10. A minute from Mr Canavan to Mrs Baldock, i.e. to the PS(L)'s private office, dated 7 August 1990 provided an update on the position of the ACVSB [NHBT0000189_201]. It indicated that at its July meeting the ACVSB had advised in principle that all blood donations should be screened for the Hepatitis C virus and that a full submission to Ministers setting out the case for screening, the financial implications and the results of a cost benefit study would be provided shortly. It was also indicated that results of the pilot study to evaluate the available tests were expected to be available for the ACVSB to consider in October 1990. Finally, it provided an estimate that the cost of screening blood donations would be £5-£6 million a year and that the issue of funding would be considered in the full submission.

17.11. I have been informed that a Ministerial submission was eventually sent in December 1990, i.e., after I had left the Department of Health.

17.12. The Request then asks me to set out what (if any) information or advice I received in relation to the case for screening, the financial implications, and any cost-benefit studies or analysis. I am asked to say who advised me in relation to the same.

17.13. As will be apparent from the summary above, so far as I am aware, I did not receive any information or advice on this topic (save for the update after the press interest, on 11 May 1990). The matter was handled by the expert assessment by and any advice from the ACVSB, coupled with the involvement of the DCMO, Dr Metters. The Ministerial portfolio seems to have been held by the Parliamentary Under-Secretary in the Lords, who did not escalate any issues up to me.

17.14. At paragraph 17b of the Request I have been asked if I was of the view, based on the information that I had received, that routine screening for the Hepatitis C virus should have been introduced. Based on what I can see above, the question is a somewhat artificial one – but I imagine that, in principle, I would have had no reason to question the expertise or the advice / judgment of the ACVSB.

17.15. At paragraph 17c of the Request I am asked about my understanding of how decisions on surrogate testing or screening were made within the Department during my time as Secretary of State. The decision-making process has been outlined above.

Ortho Symposium on Hepatitis

18.1. My attention is drawn to a letter dated 8 January 1990 [NHBT0000061_093] in which I, or a member of my staff, were invited to attend the Ortho Diagnostic Ltd Symposium on Hepatitis C on 8 February 1990 and to give an opening address. I have been asked if I was made aware of this invitation and why I did not attend. My attention has also been drawn to a handwritten note at the bottom of the letter, which says, *"not K Clarke"* and I am asked, who is likely to have made the handwritten note and why.

18.2. I do not know who made the note. As far as I can recall, the invitation was never brought to my attention, for the reasons set out below. In summary, it was not the type of event I would have expected to attend, or to speak at – it was a commercially organised event, sponsored by a manufacturer which, as can be seen at paragraph 17 above, was running a campaign to get its tests introduced.

18.3. The handling of the invitation was not a matter that I was aware of at the time.

18.4. But I have been told now (in order to answer the Inquiry's questions) that there is a handwritten note and a related completed diary questionnaire seeking advice on my attendance of the symposium [WITN0758020 and WITN0758021]. The note and questionnaire indicate that the advice was that I should not attend and that attendance at a Ministerial level was not warranted. I have also been made aware of a minute from Dr Rejman to Dr Pickles, dated 17 January 1990 [DHSC0002496_051, DHSC0002496_050, WITN0758022], enclosing a draft response to my diary Secretary, including a draft letter declining the invitation because the subject of Hepatitis C testing was being considered by the Advisory Committee on the Virological Safety of Blood and it would be inappropriate therefore for me to attend. It also recorded that Ortho Diagnostic Systems Ltd had mounted a publicity campaign to advertise its product, including through the lay press, and that two members of the Department hoped to attend as members of the audience but would not give any opening address.

18.5. My diary Secretary subsequently replied to Mr Davis on 23 January 1990, declining the invitation but noting that it was hoped that one or two members of the Department would be able to attend as members of the audience [DHSC0002496_049].

Adverse incidents and inspection reports

Profilate

19.1. I have been asked by the Inquiry to consider a submission dated 24 November 1989 [DHSC0001368], in which the Medicines Control Agency informed the Minister of State for Health, Virginia Bottomley, that there had been adverse inspection reports relating to the manufacturing standards for a commercial Factor VIII blood product, Profilate. Profilate was marketed in the UK by a US based firm, Alpha Therapeutic Corporation and had been licensed in the UK since 1985. It was estimated that it accounted for about 20% of the market in England and Wales for Factor VIII products, although it had supplied a larger proportion of the UK market in the years before the BPL facilities were developed (paragraph 1).

19.2. The submission explains that in February 1988, the Medicines Inspectorate of the Department carried out an inspection of the plant facilities used for Profilate. They listed four major deficiencies, including deficiencies relating to the risk of recontamination of heat-treated Factor VIII powder by untreated powder because of inadequate arrangements for the separation of the different stages in the treatment process (paragraph 2). Whilst other deficiencies were dealt with, a second visit by Inspectors in October 1989 confirmed that the deficiency remained and that conditions had deteriorated. On receipt of a further adverse inspection report the company said they had instituted a number of changes which should have reduced but not eliminated the risk (paragraph 3).

19.3. The submission included a risk assessment, which noted that Profilate produced by the heptane treatment process had been widely used in the UK and elsewhere for a number of years and that the deficiencies in the process revealed by the inspection report were of similar long standing (paragraph 5). Although there was a theoretical risk of hepatitis B, the submission noted that there was no clinical evidence in the UK of hepatitis B transmission from Profilate and that the 'at risk' pool of patients was small (paragraph 8). Profilate produced by the heptane treatment method was a 'first generation' factor VIII product and all these products were associated with some risk of transmission of non-A, non-B hepatitis (hepatitis C). There was no evidence to suggest that there was any higher risk from Profilate than from other first-generation products (paragraph 9). There was also a theoretical risk of HIV but there was no evidence of HIV transmission by the product (paragraph 10).

19.4. The Medicines Control Agency set out the possible responses. The first was *"immediate regulatory action"*, i.e. to suspend marketing and withdraw stocks (paragraph 12). Such action would *"remove very quickly any prospect of further exposure of haemophiliac patients to heptane treated Profilate"* (paragraph 13) but "*the clinical record of heptane treatment Profilate does not suggest that, on safety grounds, the evidence is there to warrant immediate suspension"* and *"such action would give rise to great anxieties amongst the haemophiliac community"* (paragraph 14). The second was *"non-immediate suspension"*, which *"would provide the company with time to exercise their right of appeal"* before the decision became public and took effect (paragraph 15). The third was an *"alternative to regulatory action"*. Profilate marketed in the US was at that time produced by a new method different to the heptane treatment method still used for the product marketed in the UK. The new method was claimed to produce a superior, i.e. safer product. The company had applied to have their UK product licence varied so as to market the US version in the UK (paragraphs 16 and 4). It was suggested that *"the company could be persuaded to begin withdrawal of the heptane treatment Profilate ahead of marketing of the new process product here"* and that the application to vary the UK licence could be expedited (paragraph 16).

19.5. In conclusion the Medicines Control Agency noted that *"the deficiencies revealed by the Inspectorate"* were *"a cause for concern"* but *"the clinical record of heptane treatment Profilate"* did *"not suggest that these apparently long standing deficiencies"* were *"such as to warrant immediate regulatory action"* (paragraph 18) and that a *"better alternative would be to open discussions with the company with a view to securing the early withdrawal of heptane treatment Profilate plus action to speed up consideration of the company's application to vary its Profilate licence so as to market the newer version of the product now sold in the US"* (paragraph 19).

19.6. Mrs Bottomley's response to the Medicines Control Agency is contained in a minute dated 6 December 1989 [DHSC0001366], which states: *"Mrs Bottomley has considered this and is not happy with the line proposed. She would prefer regulatory action to be taken and would welcome advice on the consequences of this"*.

19.7. The submission and minute were copied to Mr McKeon of my Private Office. I have been asked by the Inquiry about my recollection and what role I played in the decision made in response to this submission.

19.8. I do not have any recollection of these matters. I have explained in Section 1 that my Ministers, such as Mrs Bottomley, were trusted to make decisions in the areas that had been delegated to them. I would not have expected to be involved unless there was something that caused Mrs Bottomley concern, or she wanted my input for some reason. Furthermore, I have explained how the fact that a submission was copied to my office does not mean that I saw it.

19.9. I have been further asked to consider another submission dated 15 December 1989 [DHSC0001375], in which the Medicines Control Agency responded to Mrs Bottomley explaining that regulatory action could either take the form of an *"immediate suspension of the product licensing for which we have to be satisfied that this is necessary in the interests of safety"* or *"a proposal to suspend, giving the company appeal rights provided they gave notice within 28 days. Any suspension would not then take effect until the appeal rights had been exhausted which would take several months"* (paragraph 2).

19.10. The Medicines Control Agency advised that they did *"not have sufficient evidence to support immediate suspension"* (paragraph 3) and stressed that *"such action has to be seen also in the context that...we now think it most likely that the Licensing Authority will be able to agree their application for a variation of their existing licence before the end of January...Once that variation is agreed it will no longer be possible for the company to market further supplies of the heptane treatment Profilate in the UK. The company has, we understand, ample stocks of the new (solvent detergent treated) Profilate and will wish to supply it to the UK market without delay"* (paragraph 3).

19.11. The Medicines Control Agency suggested that as an alternative, they could inform the company that they proposed to suspend the licence, but not with immediate effect, unless they were willing voluntarily to cease to market the heptane treatment product. The company could then choose whether or not to exercise its appeal rights but it thought this was unlikely because *"any such action would in practice be likely to be overtaken by the grant of the variation* [of their existing licence] *before* [the] *end* [of] *January"* (paragraph 5). The

Medicines Agency stressed that in discussion with the company it would *"press them to exchange existing heptane treatment Profilate held by the health authorities in the UK for the new product"* and that they believed the company *"may be receptive to this approach and anxious to co-operate"* (paragraph 6).

19.12. Mrs Bottomley responded in a minute dated 19 January 1990 [DHSC0001374] stating that she was content to accept the advice set out in paragraphs 5 and 6.

19.13. The further submission and minute in response were not copied to my Private Office.

19.14. Again, I do not have any recollection of this matter. The fact that the second submission and Mrs Bottomley's response were not copied to my office strongly suggests that I had no involvement in the first matter either. I have already outlined why I would not have expected to be involved in such discussions.

Bio Products Laboratory

20.1. I have been asked to consider a memorandum, dated 11 May 1990, which I received through Mr Ahearn of my Private Office [NHBT0000061_137]. The memorandum drew my attention to two stories in the press about hepatitis and blood products. Firstly, there were press reports in relation to the recall of product from the Bio Products Laboratory ("BPL") because of a suspect hepatitis B contamination (paragraph 2). The memorandum noted that we were still obtaining details from BPL and asked, in particular, why we were not notified by them before learning of the story in the press (paragraph 4). Secondly, the press linked this story to an article in the Lancet, about hepatitis C, which had reported high rates of positivity with a recently developed test for hepatitis C in recipients of blood products. The memorandum noted that *"[b]efore heat-treatment of blood products was instituted in 1985, transmission of non-A non-B hepatitis to haemophiliacs was commonplace and these findings reflect past infections"*, but that *"since heat-treated NHS8Y Factor VIII* *has been issued from BPL, there is no recorded instance of transmission of this infection"* (paragraph 5). The memorandum noted that the question remained of whether the NBTS should, as an additional measure, screen donations for hepatitis C, to protect transfusion recipients (paragraph 6). The memorandum suggested that the *"line to take"* on hepatitis B was that *"the recall was simply a precautionary measure"* and that *"as a result of the treatment process we believe there is no risk to any patient who may have received plasma products"*. In relation to hepatitis C the *"line to take"* was that *"the Department considers that there is at present insufficient scientific information about this test"* and *"the matter of testing blood donations for hepatitis C is being kept under review"*.

20.2. I sent a memorandum in response, through Mr McKeon dated 15 May 1990 [DHSC0002414_081], in which I stressed my irritation that the first we knew of the recall by the BPL was when we were telephoned by the press in the late afternoon before the story broke the next morning. Whilst recognising that it was possible *"to overreact to what may be regarded by those closely involved as a routine matter"*, I emphasised that the possibility of infection from blood transfusion was a *"very sensitive issue particularly given recent publicity about AIDS and haemophiliacs"*. I requested that the need to inform the Department and Ministers in good time be impressed upon the BPL, and that if there was not a routine system for giving advanced warning of recall products then one should be introduced.

20.3. The Inquiry has also brought the following documents to my attention. First, an earlier fax dated 11 May 1990, sent by Mr Ahearn of my Private Office, requesting a background note with a short line-to-take covering the press reports [DHSC0002414_087].

20.4. Secondly, a memorandum from Mr J C Dobson dated 18 May 1990, which was sent to Mr McKeon [DHSC0002414_062]. I note that this memorandum is a response to a minute of 15 May 1990 from Mr McKeon to Mr Pickles, which I am not sighted on. The minute concerned the failure of the Central Blood Laboratories Authority (CBLA) to give advance notice to the Department about the recall of the blood products for possible contamination of hepatitis and sought to reassure Ministers that the senior figures in the CBLA and the NBTS were *"fully aware of the difficulties which have been caused by the episode and are determined to see that the mistakes are not repeated"*. The minute listed three *"lessons to be learned"*. First, that the Regional Transfusion Centre involved in the case failed to follow agreed procedures to notify CBLA at the earliest possible stage that a donation might be compromised. Secondly, that the decision to recall was made precipitately and that *"in this case, facts which subsequently came to light suggest strongly that the recall decision was unnecessary"*. Thirdly, in respect to handling publicity, it was agreed that *"following a decision to recall a product CBLA should agree with the Department on the tactics for handling any subsequent publicity"*.

20.5. Finally, a transcript of an interview given by Dr Richard Lane, Director of BPL, to Peter Hobday [DHSC0002414_105], in which Dr Lane sought to *"allay unnecessary fears in the public and particularly in the patients who might be concerned with the reports that have come out in press and on radio"*. Dr Lane explained that the recall had taken place as part of a routine procedure which was concerned with products that would have been made from one batch of plasma and with products that are given to haemophiliacs (Factor VIII and Factor IX). Dr Lane emphasised that by looking at the safety record of the products, patients could be reassured and he explained the three levels at which safety checks operated: first, the screening of the blood donation, secondly, the inactivation procedure and finally, that haemophiliacs, for the most part, are vaccinated against Hepatitis B, such that the risk of infection was *"infinitesimally small"*.

20.6. I have been asked why this matter was brought to my attention as Secretary of State. It is not possible to remember now, but it may be because of the matters set out in my response on 15 May – see paragraph 20.2. In other words, there was a sudden story breaking in the press of which we had no prior notice, and on which I might suddenly be questioned.

20.7. I have been asked whether I would have expected other matters concerning recalls of blood products to have been brought to my personal attention. No. As I have explained in relation to the Profilate matter, I would normally have expected any issues to be handled at the level of the responsible Minister of State, unless the Minister had any concerns which he or she wished to raise with me.

20.8. Finally in relation to this episode, I have been asked what role I had as Secretary of State in making decisions or giving opinions on the recall of blood products. I did not have any role. As I understand it, this was a matter for the Licensing Authority and for BPL.

21.1. The Inquiry has asked me to provide details of any further incidents where I played a role, as Secretary of State, in determining what action should be taken in response to risk identified with particular blood products. I cannot recollect any.

Anonymous Testing

22.1. I have been asked to provide an account of my involvement in the decision to approve anonymous testing of blood for HIV infection.

22.2. The concept was defined as follows, in a memorandum sent on my behalf as Secretary of State, to the Cabinet Sub-Committee on AIDS on 17 November 1988 [CABO0000195_042]:

> *"Anonymous screening (strictly, "involuntary anonymised screening") is the testing for HIV infection of blood from patients who have voluntarily given for other tests, but who have not specifically consented to an HIV test. This screening is done for surveillance not clinical purposes. Identifying details are removed before the test is performed so that it is not possible to identify the patient or inform him of the result".*

22.3. To assist with my response, the Inquiry has brought the documents below to my attention.

22.4. First, a report of the Working Group on the Monitoring of the Surveillance of HIV Infection and AIDS (the Smith Report) [BMAL0000013_027]. This Working Group was established in April 1987 to advise the Chief Medical Officer of the Department of Health and Social Security on the monitoring and surveillance of HIV and AIDs (paragraph 1.1). The Smith Report, which was published by the Government in November 1988 (see documents further below for details) examined the system of surveillance of HIV infection and AIDS in the population at the time, and suggested improvements. As noted in the Report, the objective of surveillance was to increase the understanding of the epidemiology of the infection and to provide information *"essential to those responsible for planning the provision of health care"* (paragraph 1.3). The Smith Report considered that *"sufficient information for the surveillance of HIV infection in the UK"* could be obtained through voluntary named and unnamed testing programmes, where the consent of the individuals involved has been secured to test the blood sample for HIV (paragraph 3.6.1). The report commented that:

> *"the success of voluntary testing programmes, named or unnamed, depends on the willingness of individuals to be tested for HIV antibodies. Generally, people have so far co-operated well in the testing programmes, for example in the GUM clinic study. There is, however, a risk that such co-operation could be withdrawn if being tested were to carry disadvantages, such as difficulties in securing a mortgage or insurance cover. If this possibility were realised, surveillance might need to depend upon involuntary unnamed testing"* (paragraph 3.6.5).

22.5. The report recommended that *"further information relating to the prevalence of HIV infection in the general population"* was needed because the testing programmes at that time mainly related either to *"the recognised risk behaviour groups…or self-selected low risk populations".* However, the recommendation of the report at that time was that *"the required information"* could be *"obtained* *by means of suitable voluntary testing programmes"* (paragraph 3.6.1), including through testing of approximately 20,000 – 30,000 pregnant women at antenatal appointments (paragraphs 3.10, 4.10-4.18).

22.6. Second, I have been referred to a note by the Minister of Health on the Smith Report, dated 13 May 1988 [CABO0000195_025]. Paragraph 5 of the note stressed that:

> *"There is, however, one aspect of the report that is likely to be controversial. This is the decision to recommend that large-scale surveillance of HIV infection, whether in the general population or in selected high-risk groups, should be based predominantly on voluntary testing of named samples, rather than on involuntary testing of unnamed samples. The latter is the testing of blood for HIV patients who have voluntarily given blood for other tests, but who have not specifically consented to HIV testing and, because identifying details have been removed, being unable to inform them of the result"* (also known as "anonymous" testing).

At paragraph 6, it was noted that:

> *"There is now a growing body of eminent medical and scientific opinion that is highly desirable that involuntary anonymous screening should be introduced to provide information about the overall prevalence of infection in this country…It is argued that surveillance based on voluntary screening of named samples would be subject to bias because those with reason to fear that they had been infected might be more likely to refuse consent to being tested. The BMA has recently written to the Chairman of the Sub-Committee expressing support for involuntary anonymous testing for surveillance purposes".*

22.7. I will address question 24 in full below, but I note that I have been asked there about ethical and legal problems in respect of anonymous testing and these are noted in this document at paragraph 7, which observed that there were *"acknowledged limitations"* of involuntary anonymous testing as well as *"complex legal and ethical issues to be resolved"*. In particular, the note refers to legal advice received, which stated that HIV antibody tests should be performed only with *"express consent"* and that *"to perform such tests even on an anonymous basis could leave the doctor liable to legal challenge for assault or negligence"* and further, that *"a doctor who was responsible for anonymised testing for HIV antibodies would be unable to identify and inform patients whose samples give a positive result"*, which could place the doctor in breach of their duty of care.

22.8. The note relayed that the Chief Medical Officer advised that the proposed survey of antenatal patients would nevertheless *"yield valuable information"* but suggested that the *"issue of anonymous screening should be the subject of public debate"* (paragraph 8). The recommendation of the Minister of Health was therefore that the Smith Report should be published along with *"our acceptance, in principle, of its recommendations"* (paragraph 9) but that *"the Government should seek views on anonymised testing as part of the surveillance system, having regard both to its possible advantages and to the legal and ethical difficulties involved"* (paragraph 11(3)). As can be seen from the remaining documents, this course was taken.

22.9. Third, my attention has been drawn to the Minutes of the Cabinet Home and Social Affairs Committee, Sub-Committee on Aids of 13 May 1988 [CABO0000195_006]. I did not attend this meeting – the Department was represented by the Minister of State for Health. But the full minutes record that:

> "*While voluntary tests, such as those proposed for pregnant women, could generate useful information, they suffered from the inevitable drawback that those who opted out would bias the sample in a way which could not be assessed and that any adjustment to the sample to seek to compensation* [sic] *for that bias could therefore only be of a very rough and ready order. Involuntary testing, on the other hand, would provide much more accurate information about the overall prevalence of the disease together with its*

incidence in different areas, among different age groups and between men and women. A series of such studies undertaken at different periods would provide information of a quality that could not be obtained in any other way about the overall rate of the spread of the disease." (p. 3)

22.10. The meeting decided that the Smith Report should be published; the immediate Government response should be to accept, in principle, its recommendations, but they should go out to widespread consultation; as part of the consultation process, views should be sought in particular on the question of anonymous screening for epidemiological purposes which (as noted in November 1988) *"the report did not recommend at that time, but which was receiving an increasing amount of medical and scientific support in the UK and abroad"* [CABO0000195_042 p.1]; and the legal and ethical issues raised by anonymous screening should be examined – specifically, the Law Officers and the General Medical Council were to be consulted.

22.11. Fourth, I have been referred to a letter from Mr Greig, of the Attorney General's Department, to Mr Brockman of the Department of Health, dated 10 November 1988 [DHSC0101224]. The letter provides the Solicitor General's response to a letter from the Department of Health, of 4 November 1988. I have not been shown this, but it is clear that the letter is a response from the Solicitor General to questions about the legal implications of anonymous testing. It advises that only the taking of blood without consent and not the testing of the blood taken would constitute assault, provided that consent was given to the act of taking blood. It states that *"the fact that some of the blood taken is used not for the primary purpose explained to the patient but for the purpose of anonymous testing will not render the taking of blood an assault"*. Neither, in the absence of fraud, or misrepresentation would there be any breach of civil law because *"unless the patient indicates a contrary intention, he does not retain any proprietary rights over samples of body fluid once he has allowed them to be taken"*. Regarding the duty of care owed by a medical practitioner to his patient, the advice was that *"the fact that some of the blood taken is to be used as part of an anonymous testing scheme does not however constitute any breach of* *that duty of care"*. Thus, there was *"nothing in law to prevent the Department carrying out a general anonymised screening of this nature"*. The letter concludes by noting that *"[o]ne matter which the Solicitor General does warn against is the risk of making public statements which suggest, misleadingly, that blood taken for other purposes would not be used for HIV testing whether anonymous or not"* because *"to do so might vitiate the consent"*.

22.12. The fifth document I have been referred to is a memorandum that was sent on my behalf dated 17 November 1988, to the Cabinet Home and Social Affairs Sub- Committee on Aids. It sought to set out the proposed Government response to the Smith Report [CABO0000195_042].

22.13. The memorandum recorded that the views of a *"large number of organisations, including health authorities and boards, professional medical and nursing bodies, legal bodies and voluntary organisations"* had commented on the report in relation to anonymous screening (paragraph 2). Paragraphs 3 – 7 of the memorandum concerns "anonymous screening" (or "involuntary anonymised screening"). Paragraph 3 defines the concept (set out above). Paragraph 4 notes that:

> *"[a]nonymous screening is supported by most respondents (including the Medical Research Council, the Health Education Authority, the British Medical Association and the National AIDS Trust) as the most effective way of obtaining invaluable information about the overall prevalence of HIV infection by age and sex in various parts of the country, and about the rate at which it is spreading in the population as a whole".*

22.14. The memorandum also noted the acknowledgement by Dr Smith (author of the Smith Report) that *"although his Group's report did not recommend the use of anonymous screening for the present he regards the scientific case for it as growing stronger all the time"*. Paragraph 5 refers to the limitations of anonymous screening. In particular, it was noted that the *"minority who opposed anonymous screening did so because of their doubts about the legal* *and ethical position"*. However, clear advice had now been obtained from the Law Officers [see above] that there was no *"legal obstacle"* to the type of anonymous screening envisaged.

22.15. Paragraph 6 notes the ethical issues and that ethical questions had been discussed by the Medical Council who had neither taken a *"firm view for or against anonymous screening, but stress their support for obtaining epidemiological data where possible by voluntary screening programmes"*. In the same paragraph, the memorandum also noted that, *"other bodies, including some like the Terrence Higgins Trust and the National Council for Civil Liberties which might have been expected to be concerned about the civil rights issues of anonymous screening, instead support it, provided anonymity and confidentiality are strictly observed".*

22.16. At paragraph 7, I therefore proposed that in the light of the outcome of the consultation and the clear advice from Law Officers, that the outcome should be:

i) to make clear to the Health Service the Government's view that there was no legal obstacle to surveys using anonymous screening (as defined in paragraph 3); and
ii) to ask the Medical Research Council to urgently draw up detailed proposal for a series of surveys based on anonymous screening of blood samples obtained for other clinical purposes, which would be funded as priority items.

22.17. At paragraph 16, I proposed a joint press-conference on our response to the Smith Report and the Cox Report. At paragraph 17i) I proposed that the Sub Committee be asked to agree the proposal on anonymous screening, *"to advise the NHS on the legal position and to ask the MRC to draw up a programme of work".*

22.18. Sixth, my attention has been drawn to a memorandum [CABO0000195_045] by the Minister for Health, 17 November 1988, which seeks the agreement of the Sub Committee to the proposals for presenting and responding to the report of the Working Group on Short-term Predictions of HIV Infection and AIDS in England and Wales (the "Cox Report"). The remit of that working group was to make predictions of the number of persons with HIV infections and AIDS over the next 2-5 years in England and Wales (paragraph 1), and it submitted its report on 31 October 1988 (paragraph 2 and Annex A). I summarised the conclusions of that report at paragraph 3. I noted that there would inevitably be considerable public interest in the report's conclusions (paragraph 9) and that there were a number of contentious issues, which included the *"relatively low estimates of future AIDS cases"* (paragraph 9(i)). I recommended announcing our response to the Smith Report at the same time as publishing the Cox Report, and to hold a specialist press briefing the same day involving perhaps myself, the Chief Medical Officer, Sir David Cox and Dr Smith and that there would be an accompanying press release and Parliamentary Questions (paragraph 11).

22.19. Next, my attention has been drawn by the Inquiry to the minutes of a meeting of the Cabinet Home and Social Affairs Committee, Sub-Committee on AIDS, dated 23 November 1988 [CABO0000195_012]. I attended this meeting, as did the Secretary of State for Social Services (the Chair), the Secretary of State for the Foreign and Commonwealth (Sir Geoffrey Howe), the Lord President of the Council (Sir John Wakeham), the Minister of State (Mr Mellor), the Lord Advocate and Solicitor General and the CMO (amongst others). It is apparent (p. 6) that I outlined the contents of the memorandum and sought the agreement of the Sub-Committee to the course proposed. The Solicitor General and the Lord Advocate reiterated their legal advice:

> *"... the law relevant to involuntary anonymised screening appeared to be clear. Provided that there was a valid reason for taking a sample of blood and consent was given to this, then the taking of the blood would not be an assault. That could not be affected by the subsequent anonymised testing*

> *of part of the sample. Nor would the use of some of the blood in an anonymous testing scheme constitute any breach of the duty of care owed to the patient. Whilst Article 8.1 of the European Convention on Human Rights declared that everyone had the right to respect for his private and family life, there was no doubt that anonymised screening was within the exceptions set out in Article 8.2 and would not be held to contravene the Convention".* (P. 8)

The importance of publicising any new policy to the public was stressed.

22.20. There was a full discussion of the proposals (p. 8) before the recommendations put forward in the memorandum were endorsed.

22.21. The eighth document that I have been referred to is the *"Line to take"* in response to the Smith and Cox Reports [DHSC0004776_072]. This document notes that the Government formally responded to the Smith Report on 23 November and that the Government had asked the Medical Research Council to draw up proposals for an anonymous testing programme within three months, which would provide a much better picture of the prevalence of the infection in the country. £1.7 million had been made available to the MRC in 1989/1990 for research into the spread of AIDS. Regarding the Cox Report, this document notes that it was published by the Government on 30 November and although the figures published were relatively small, there were *"no grounds for complacency"*. HIV-infected persons at the end of 1987 were estimated at 20,000 to 50,000. There needed to be a *"continuing public education effort"*.

22.22. Finally, the Inquiry has referred to a press release from the Department of Health dated 23 November 1988, publicising my announcement concerning anonymous testing [DHSC0101306]. It quotes me as follows:

> *"Anonymous screening is the testing, under conditions of total anonymity, for HIV infection of blood from patients who have voluntarily given it for*

> *other tests, but who have not specifically consented to an HIV test. Before any of the blood taken is tested for HIV identifying details are removed from the blood sample so as to render the test wholly anonymous. The balance of scientific opinion favours such testing as the best way to obtain information about the overall prevalence of HIV infection by age and sex in various parts of the country, and the rate at which it is spreading in the population at large. The Cox Report…explicitly recommends anonymous testing.*
>
> *The Government sees no legal obstacle to such testing. From the layman's point of view, we also see no ethical objection to the testing for scientific purposes of blood samples taken properly in the first place for another purpose from a patient no longer identifiable.*
>
> *We are therefore inviting the Medical Research Council to bring forward proposals within three months for a programme of anonymous screening."*

23.1. At question 23 of the Rule 9 Request, I have been asked to explain the position that I took on this issue at the time, and the reasons for which I took such a position. I have also been asked to state whether I remain of the same view now.

23.2. The views that I held at the time are outlined, in particular, in the memorandum of 17 November 1988 summarised at paragraphs 22.10 – 22.16 above, and in the subsequent discussion in the Cabinet Sub-Committee.

23.3. As for my current view, it seems to me that the reasons for the decision were well explored at the time, and that it served the public interest. That remains my view now.

Hansard Debate, 1 November 1988

24.1. At paragraph 24 of the Request, I am invited to consider the record at Hansard Volume 139, Columns 815-816 of 1 November 1988, where I am recorded as stating that anonymous testing was under *"active consideration"* but that it *"raises a number of difficult ethical and legal problems"*.

24.2. I have been asked, first, to explain the nature of these ethical and legal problems. In my view they were well outlined and discussed in the documents I have referred to above.

24.3. The essence of the problem was whether it was either ethically appropriate or legally permissible to test blood samples, on an anonymised basis, without the permission of the patients concerned. The reason for considering such a step was, of course, the public health imperative of understanding the prevalence of HIV infection, coupled with the problem that securing consent would imperil the accuracy of any surveillance, "*as any study of the prevalence of HIV infection that depended on a voluntary sample would inevitably be subject to a bias for which no statistically sound adjustment could be made*" (see p. 6 of the minutes of the Cabinet Sub-Committee meeting of 17 November 1988 [CABO0000195_042]).

24.4. I have then been asked whether, to the best of my recollection, specific consideration was given to the question of how to obtain informed consent. Again, the answer lies in the documents and, in particular, in the move from accepting the recommendations of the Smith Report (which did not recommend the introduction of involuntary anonymised screening) to the introduction of such screening, following the decisions of November 1988. The issue was not whether, and if so how, a patient's consent to testing or screening might have been sought. The problem was that to do so would inevitably mean that some were likely to refuse their consent, and that this would bias the results of any survey. The question was whether the solution to that problem of bias (anonymised testing) was appropriate or justified.

24.5. I have been asked what advice I received in relation to those problems. The ethical advice was received in the form of the response to the public consultation on the Smith Report. The Memorandum and Cabinet Sub-Committee report refer to (for example) the stances of the General Medical Council and the Royal College of Nursing, as well as bodies such as the Terrence Higgins Trust and the National Council for Civil Liberties.

24.6. The legal advice was provided by the Law Officers: the Lord Advocate and the Solicitor-General.

24.7. The Inquiry has noted that in a press release dated 23 November 1988, I later outlined that the Government saw *"no legal obstacle to such testing"* and stated that *"from the layman's point of view, we also see no ethical objection to the testing for scientific purposes of blood samples taken properly in the first place for another purpose from a patient no longer identifiable"* [DHSC0101306] (above).

24.8. I have been asked to outline the evidential basis for this latter statement. I would refer the Inquiry to the results of the public consultation on the Smith Report, as well as the Cabinet Sub-Committee discussions. By the time of those discussions, both legal and ethical issues had been thoroughly considered, consulted upon and addressed. I would add that the further testing of the sample, anonymised so that it could not be referred back to the patient, did that patient no harm but secured great public health benefits.

Section 3: HIV Haemophilia Litigation

Question 25:

25.1. At Q25 of the Rule 9 Request, I have been asked to provide a narrative account of my involvement with and knowledge of decisions made about the Macfarlane Trust during my time as Secretary of State.

25.2. On 17 November 1987, Tony Newton, the then-Minister of State for Public Health, announced that a £10 million ex-gratia payment would be made to enable the Haemophilia Society to establish a special trust to provide financial help both to haemophiliacs infected with HIV, and to their families. The Macfarlane Trust was then established on 10 March 1988 and the £10 million was presented to the Reverend Alan Tanner, Chairman of Trustees a week later.

Question 26:

26. During my time in office (from 25 July 1988 onwards), the Minister with responsibility for matters relating to the Trust was the Minister of State for Health. The principal office-holders were Mr Mellor until the end of July 1989 and then, from the end of October 1989, Mrs Bottomley.

Question 27:

27. I have been asked (Q27) what liaison there was between the Department of Health and the Treasury, with respect to the Trust's finances. I expect that there would have been discussions with the Treasury in 1987, when the initial contribution of £10 million was agreed.[1] Equally, there was discussion with the Treasury when a further financial contribution was being contemplated in late 1989 (see further

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[1] The minute of 14 November 1989, referred to at paragraph 29.5 below, records that this money was paid from the Department of Health's Centrally Funded Services, its CFS vote, but I was not in the Department at the time and this would have to be traced in the papers from that time.

below), and in the context of any settlement of the HIV litigation also discussed below. I am not aware of any other involvement or interest from the Treasury which would essentially have been concerned with further contributions from public funds rather than the management of the Trust.

Question 28:

28.1. The Inquiry has further asked how often and on what basis the Department reconsidered the amount of funding given to the Macfarlane Trust. I have set out how, in late 1988, the issue raised appeared to be that the Trust was slow to "get going" with payments, rather than that it was short of money. I have further set out the details of the discussions which led, in November 1989, to the announcement that a further £20 million would be added to the Trust's resources. I have done this by referring to the contemporaneous documents provided to me for the purpose of this Statement.

28.2. After taking office at the end of July 1988, I cannot remember any issues relating to the Trust being brought to my attention until in October 1988, when I can now see (from the documents provided to me) that that the Sunday Times carried an article on the Trust. On 9 October 1988, the newspaper reported that, nearly a year after the Trust had been set up, only £132,000 had been paid out. *"Haemophiliacs say many will die without receiving any of the money intended to relieve their suffering*", the report stated.

28.3. I can see now that this matter attracted the attention of the Minister of State for Health, who as I have noted was the Minister responsible for this area of policy. Thus, I have now been informed that:

28.4. On 13 October 1988, Dr Moore sent a briefing note to Ms Harper, the Private Secretary of the Minister of State for Health. It started: "*MS(H) has asked for a note on the Macfarlane Trust and the delay in paying potential beneficiaries alleged in the Sunday Times on 9 October*". The background to the Trust was set out, including the fact that it was not a compensation fund and that payments were only being made out on grounds of need [DHSC0003303_005];

28.5. On 25 October 1988, a reply was sent on behalf of the Minister: "*Thank you for your minute of 13 October. MS(H) is content to leave matters as they are for the present. However, he has commented that his* personal *view is that the Trust is being over-cautious in its approach.*" [WITN0758023, underlining as per original].

28.6. Neither of these documents were copied to my Private Office and I cannot remember any discussion with the Minister of State about them.

28.7. Although I cannot now remember how, it seems that the article may also have led to a request for information from my office. At any rate, a note was sent on 27 October 1988 from Mr Arthur to Mr Harris (an official in HS1) and to my Private Office (Mrs Goldhill) [WITN0758024]. It was a response to a request for a "note on the Macfarlane Trust and in particular how it relates to the dependants of haemophiliacs with HIV." The note from Mr Arthur set out the early history of the Trust (see above), and the process of appointing Trustees, and arranging for the disregard of benefits, etc. It further stated:

> *"The Trust's initial priority was to contact all potential beneficiaries to establish a likely level of demand whilst formulating an allocation policy. From November 1987 onwards, those haemophiliacs with HIV and their dependents who were in need were invited by the Haemophilia Society to apply for help. In May 1988 they were invited to formally register with the Trust. So far, only about 800 people have registered which is some 400 less than had been anticipated. Those who have not registered have probably decided they are not in financial need."*

28.8. Details of the Trust's allocation policy, which was evidently a cautious one, were set out. The note set out that no individuals had ever been refused on the basis of being a dependant, and that the Trust would be willing to investigate individual complaints if a name and address could be supplied.

28.9. I see that I sought clarification from officials on 9 November 1988 [WITN0758025] on a number of issues including why only £132,000 had been paid out by November 1988; whether the Trust had plans for the £10 million; and how long they expected the sum to last, asking for the answers as soon as possible. I gather from the documents now provided that my questions were answered on 17 November 1988 [DHSC0020286]. I was told that the initial priority of the Trustees was to contact all potential beneficiaries to gauge the level of demand whilst formulating an allocation policy, but that the amount paid out was now rising rapidly as more applications were being received. The sum paid out had risen to £200,000 and would double shortly as back-dated payments were made. I was informed that a major priority was providing support to the dependents of those who had died as a result of HIV infection; they were investigating ways to help with mortgage payments and life insurance. As for the longevity of the funds, I was informed that there was no fixed timescale but that the Trust recognised they would bear financial responsibility for those affected for "*many years to come*". The author noted that "*We are maintaining a close contact with the officers of the Trust and the Trustees. In our view they appreciate the urgency of the need and are not in any way complacent.*" There is no record of any further action, that I have been shown.

28.10. The Trust was not accountable to the Department or to me; it was an independent charity with its own Trustees. The impetus for the notes summarised above was obviously concern that, the Trust having been set up, it did not seem to be actually distributing the money that had been given very speedily: but I did not intervene in the matter. The matter was within the responsibilities of the Minister of State for Health, as can be seen from the earlier minutes summarised at paragraph 28.4 above. Furthermore, the Trust was an independent body.

28.11. Overall, I am not aware that I was personally involved with any actions with respect to the Trust at this time.

28.12. I have been made aware, from the correspondence and documents shown to me now, that there was correspondence on the topic, as well as questions in the House. It is apparent that questions about the Trust tended also to raise the question of compensation for haemophiliacs, not least as litigation on this issue had begun (see further below).

28.13. For example, I can see from the documents that a letter was sent by Mr Watters at the Haemophilia Society on 12 July 1989 in which he referred to the preliminary hearings in the HIV litigation and expressed his belief that the situation merited compensation, on the basis that 1,200 haemophiliacs had been infected with HIV, whilst only 300 people had commenced legal proceedings [WITN0758026]. Lord Trafford responded on behalf of the Government on 21 August 1989, reminding Mr Watters of the £10 million ex-gratia payment to the Macfarlane Trust and making it clear that the question of compensation was a matter for the courts [DHSC0003989_067]. I have explained in Section 1 of this Statement how letters would be managed by the Ministerial Correspondence Unit; this one was plainly handled by Lord Trafford and I would not have seen it.

28.14. There were a series of mentions of the Trust in the Houses of Parliament. For example:

a) Mr Roger Freeman announced on 18 August 1989 that over £1 million of grants had been awarded by the government to AIDS voluntary organisations, aside from the Macfarlane Trust [WITN0758027].

b) On 23 October 1989 [WITN0758028] Mr Mellor (Minister of State) provided a written answer to questions asking whether I would a) consider giving grants for legal fees which had arisen solely as a result of haemophiliacs being infected with HIV; b) what advice had been given to the Trust regarding the imposition and levels of means testing to be applied to those haemophiliacs infected with HIV; and c) what the means test at the time was and whether the income and capital limits of the Trust would be published in the Official Report. David Mellor explained that all information in terms of allocation could be found in the Trust Deed in the House Library, and that the Trust considered it inappropriate to help with legal fees.

c) Mrs Bottomley replied to a question on 6 November 1989, asking whether I would implement a scheme of compensation over and above the £10 million granted in November 1986 for haemophiliacs infected with HIV [WITN0758029]. I can see that Mrs Bottomley responded on my behalf; she reiterated that the £10 million was an ex-gratia payment and not compensation, and that the government was not closed to representations about further funding at a later date.

d) Much the same topic was covered again on 9 November 1989, when a question was asked as to whether I would support a compensation scheme to alleviate the physical and financial distress of families of haemophiliacs [WITN0758030]. Mr Freeman responded, stating again that the government had provided an ex-gratia £10 million payment to assist in the setting up of the Macfarlane Trust.

e) There was a Parliamentary debate on haemophiliacs with AIDS on 13 November 1989 which addressed issues such as the long-term plight of those haemophiliacs infected with HIV and what critics viewed as the means-tested nature of the Macfarlane Trust (as set out above, it did make payments in response to evidence of need) [DHSC0002939_002]. Mr Freeman responded to the debate on behalf of the Department. Whilst, as I have noted, Mrs Bottomley was the minister responsible, she had only just returned to the UK from Brussels.

Supplementing the Trust's Funding

Question 29:

29.1. I have been asked to consider a briefing note dated 7 November 1989 sent by Strachan Heppell to my Private Office ahead of a meeting on 8 November 1989 to discuss various proposals including increasing the Macfarlane Trust's funds [DHSC0004415_156]. It is apparent that Mr Heppell and Mrs Bottomley had met with Mr Key MP, who was also the Vice-President of the Haemophilia Society. I was told that the Leader of the House, Sir Geoffrey Howe, had also asked for a meeting in advance of the adjournment debate on 13 November 1989, referred to above.

29.2. The note from Mr Heppell set out a series of options, including increasing the Macfarlane Trust's funds to £25m or £30m over the next 2 – 3 years. It was suggested that this would give each family around £25,000 "about the average German and Danish figure". By contrast Mr Key MP suggested that the Haemophilia Society would like to settle out of court for £75,000 a family, he suggested.

29.3. Mr Heppell noted that, on the finance front, there was no obvious money in the budgets for the current year. The Treasury was likely to resist any further calls on the contingency reserve[2]. The money could be found for future years by top-slicing the HCHS programme, i.e. the allocation for the NHS Hospital and Community Health Services. In other words, the budget for more general NHS spending would have to be reduced to allow the additional funds to be released to the Trust. This was in line with the general requirement set by Mrs Thatcher and the Treasury, that the cash budgets set for each Department would not be exceeded, or supplemented.

29.4. I do not remember this note, until drawn to my attention recently, and I do not recall a meeting on 8 November 1989. I understand there is no record of the meeting to refresh my memory. It seems that my reaction to the minute, however, is recorded in my response to the various submissions set out below.

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[2] The details of the previous funding appear to be recorded in [DHSC0002375_050], although this is not something I was involved in, in 1987. The Treasury released £9 million for AIDS services. There was a debate on the impact on other AIDS priorities.

29.5. A further covering letter and submission were sent to my Private Office on 14 November 1989 [WITN0758031, WITN0758032, WITN0758033, WITN0758034, WITN0758035, WITN0758036, WITN0758037, WITN0758038, WITN0758039, WITN0758040, WITN0758041, WITN0758042] from Mr John James entitled *"PES 1989: Centrally Financed Services and sums top sliced from HCHS Capital and Revenue"*. The letter gives an overview of the process for top-slicing, and the pressures on such central funds. The covering letter noted that since the Public Expenditure Survey, the issue of providing further financial support for haemophiliacs who had contracted AIDS had surfaced. It noted that the additional funds required for the coming year (in 1990/91, the sum of £5 million) would have to come either from the CFS vote (i.e., the Centrally Funded Services) or from the HCHS, "*ultimately at the expense of the general allocation*". I was invited to consider what portion of revenue and capital sums should be pre-empted from the 1990-91 HCHS budget (and therefore not distributed to health authorities). The underlying submission [WITN0758043] set out further details of the 1990/91 public funding allocations more generally. I was advised that keeping central pre-emptions to a minimum was a priority.

Question 30:

30.1. A further note dated 17 November 1989 was sent from Ms Stuart to my Private Secretary Mr McKeon, setting out two options for providing additional resources to the Macfarlane Trust and the consequences for Central Funding Schemes (CFS) and Hospital and Community Health Services (HCHS) [DHSC0002949_010]. The two options were:

a) Paying a lump sum (£10,000) to each affected family in 1990-91 and thereafter advancing money in cases of need, implying an immediate commitment of £7 million, followed by further topping-up over the next 2 years;
b) Amending the Trust deed to increase the scope of payments to affected haemophiliacs.

The means of making provision for either of these additional commitments were discussed in detail.

30.2. Ms Helen Shirley-Quirk responded on my behalf on 21 November 1989 [DHSC0004415_114] expressing my preference for the first option. I commented on the programmes that we might be able to cut back, in order to fund this commitment, such as reducing the allocation to the Health Education Authority for AIDS campaigning.

30.3. MsShirley-Quirk received a response from Ms Stuart on 22 November 1989 [WITN0758044] setting out further proposals for the funding of the £7 million contribution from the HPSS Votes, to the £19 million grant to the Macfarlane Trust (i.e., about the contribution from Health and Personal Social Services, the general health and community services budget).

Letter to the PM

Question 31:

31.1. A letter was sent to the Prime Minister by me on 17 November 1989 [HMTR0000001_006] in which I set out the proposal to increase funds available to the Macfarlane Trust, as a solution to the demand for further assistance to those haemophiliacs infected. The letter, which was prepared before I had responded to the detailed submission on finances of 17 November, left open which of the two options was to be put forward. The potential addition of £20 million allowed for an average payment of £24,000 per patient. I cannot now exactly recall how the £20 million figure was chosen, but a key consideration would have been the scale of the average payment; we were looking for figures that would make a difference. We would have discussed what seemed a reasonable sum and balanced that against how much could reasonably be taken out of the Department's other commitments.

31.2. The letter concluded that the likely cost of settling the litigation could amount to £86 million or more; I personally cannot recall how this figure was arrived at but see paragraph 46.26, which records an official receiving a call from the Haemophilia Society. The Haemophilia Society gave the figure.

31.3. It was widely agreed at the time that any increased allocation could and should not be tied to any deal relating to the litigation. As set out in my letter, I felt that whilst a £20 million increase could be viewed as a palliative, it was still very difficult to fund the increase within existing resources. I have been asked whether I anticipated that further funds would eventually be required and whether, if so, that guided our approach to adding a figure to the fund. If by this question it is meant that I anticipated having to find more money because the Department lost the HIV litigation, the answer is "no". As the letter to the PM made clear, the view was that the Court would find in favour of the Defendants. More generally, as I have set out, as far as I can now recall we were seeking to find a reasonable sum, not somehow making only a limited allocation because more might have to be found in the future.

31.4. I have been asked about a note from Paul Gray to the Prime Minister dated 17 November 1989 at paragraph 31(d) of the Rule 9 Request [CABO0100003_005]. I see that the letter suggests the Prime Minister has an "*early chat*" with John Major and me. Indeed, Mr McKeon received a response to my letter to the Prime Minister [WITN0758045] in which a meeting was proposed between the Prime Minister, the Chancellor of the Exchequer and me.

31.5. In his note to the Prime Minister, I see that Paul Gray expresses his surprise at the suggestion of the early announcement of a further £20 million injection into the Macfarlane Trust. He commented that there had been no warning that it was coming and there was no evidence it had been cleared with the Treasury. He highlighted the dilemma facing decision-makers: "*acceptance of liability at this stage would have enormous repercussions, but public pressure for some further action is intense*".

31.6. I have been asked if I discussed the proposal for an injection of funds with colleagues in the Treasury before going to the PM. I cannot remember. I may have had a chat with Mr Major; it is impossible to recall. The letters suggest that Mrs Thatcher was taking an interest in the matter.

31.7. There was a formal response from the PM's Office on 19 November 1989 [HMTR0000001_007], proposing a meeting with the PM and the Chancellor.

31.8. I have been made aware of a letter (dated 20 November 1989) from Mr Saunders to the Chief Secretary to the Treasury (Mr Norman Lamont) ahead of our meeting with the Prime Minister [HMTR0000001_008]. Mr Lamont was instructed to support my proposals, so long as I (i.e., the Department of Health) agreed to absorb the costs of proposal, and to "*join with him in resisting any pressure for more generous treatment*". The costs that would have to be absorbed related to an alteration of the Trust's trust deed to allow non-discretionary payments, of £10,000 to each of the 1,200 sufferers in the first instance. This would be funded by £7 million from the Department of Health in 1990, followed by a further £13 million from the Department over the subsequent three to four years.

31.9. I see that I did meet with the Prime Minister, the Chief Secretary to the Treasury and the Attorney General the next day, on 20 November 1989 to discuss my proposal of 17 November. As referred to in paragraph 31(f) of the Rule 9 Request, Paul Gray provided my Private Secretary with an account of the meeting [HMTR0000001_012] on the same day. I cannot add to the minute of the meeting now. I have been asked why Mr Lamont and not Mr Major attended. I do not know, but the Chief Secretary was the lead Minister for public spending and would always take the lead in any detailed discussions regarding about public spending with all other government departments.

31.10. The account of the meeting on 20 November records my proposal that the additional £20 million would be funded from within the Department's new budget resulting from the Autumn Statement decisions. I have been asked whether I considered alternative funding avenues. As to that, the reality was that the Treasury would not be expected to agree to provide money from the contingency reserve. As the instructions to Mr Lamont makes clear, the proposal would be agreed only if the Department of Health could find the money.

31.11. According to the minute of the meeting, the point was raised that it would be "*desirable, as well as avoiding any acceptance of legal liability, to avoid conceding any moral obligation*". I do not know who raised this point. But I would have agreed that, if a "moral obligation" had been accepted, it almost certainly would, in the context of the ongoing litigation, have been seen or portrayed as an admission of fault. As the letter to the PM [HMTR0000001_006] had set out, "*We believe the Court will find in favour of the defendants, and I am strongly of the view that the case should go to trial, and that we should not take any action that implied an admission of fault.*" Discussion of a "moral obligation" could have been used to suggest this and to undermine the defence.

31.12. According to the note of the meeting [HMTR0000001_012], it was apparently suggested that I would consider whether information about haemophiliacs' life expectancy was available. The context of that suggestion appears from the note:

> *"In presenting such a package, it would be desirable, as well as avoiding any acceptance of legal liability, to avoid conceding any moral obligation. Rather the emphasis should be on the special circumstances of this particular case - although distinguishing the position of the haemophiliacs from other difficult cases like vaccine damage was not easy. It was also reasonable to point out that, without the treatment they were given with the blood products, many of the haemophiliacs would have died; your Secretary of State would consider whether information about their life expectancy was available."*

31.13. I cannot add to the information in that note, now.

Question 32:

32.1. I have been asked to consider a minute dated 22 November 1989, signed "K.C" [HMTR0000001_013] and addressed to the Prime Minister. This would have been drafted on my behalf and signed by me after I had read the draft and made any amendments that I wished to make. Attached to the memo is a draft statement setting out my proposals for additional financial support to haemophiliacs infected with HIV; I intended to publish the statement by way of a written PQ in response to Robert Key's question "*To ask the Secretary of State for Health whether he will make a statement on the financial support available for haemophiliacs who have been infected with HIV*". The draft statement above was updated on 23 November 1989 [DHSC0003342_004].

32.2. There are various handwritten amendments to the draft statement [HMTR0000001_013]. They are not mine; based on the documents provided to me by my lawyers, it is possible that they reflect Strachan Heppell's involvement, but I do not know. There is one note at the bottom of the first page which reads "*Govt accepts need to replenish*". This suggested amendment was reflected in the final draft [DHSC0003342_004] which read "*I am satisfied that the Government should now make extra resources available to the Trust*"; i.e., the "replenishment" related to what was being done now, in 1989. Looking back, it seems the amounts offered were the best solution available. There was no mathematical calculation or objective needs assessment; it was an exercise of a broad judgment in which the overall sum of £24,000 per family seemed to be a reasonable outcome, having regard to the size of the funds that would have to be made available by the Department. We shared the widespread public sympathy for the victims of this terrible tragedy and wanted to do what was possible.

32.3. I would have been aware that there would be many individuals who felt the amounts to be added to the Trust were insufficient. For example, I note the reference by the Inquiry to the letter dated 29 November 1989 to me from Professor Ludlam, Director of the Haemophilia Centre in Edinburgh [LOTH0000069_022]. This set out his view that the sum of £20,000, whilst "*clearly of some benefit*" fell "*a long way short of what might be considered a reasonable settlement as compensation.*" He noted that the campaign for no-fault compensation would continue, and urged the Department to try and "*devise a system of reasonable compensation*". As a matter of detail, I did not see this letter; the response came from Mrs Bottomley as the responsible Minister. I have set out how the sums found represented the exercise of a broad judgment. Such exercises were always difficult, not only because funds were finite but also because of the potential for similar claims be made by other patients on the grounds that they, too, had suffered after receiving licensed treatments (my letter to the PM mentioned Copper 7 inter-uterine devices and benzodiazepines as "waiting in the wings"; that was in the context of litigation, but the same parallels could also be drawn with respect to making *ex-gratia* funding available).

32.4. I have been asked why I arrived at the view that *ex-gratia* payments should be disregarded for the purposes of security payments and legal aid, as I explained in the first page of the minute [CABO0100002_008]. As for the first issue, that had already been agreed when the Macfarlane Trust was set up. It was to avoid the problem of payments from the Trust meaning that individuals would no longer be eligible for social security payments, with the potential effect that the payments from the Trust would, in effect, be "clawed back" by the State and individuals might be no better off.

32.5. The issue with disregarding the payment for the purpose of Legal Aid assessments was similar, as the minute explained. It noted that a number of haemophiliacs were suing for compensation and continued:

> *"The one-off payment we are proposing to make for each family would render them ineligible for Legal Aid. It would clearly be politically unacceptable if it appeared we were seeking to prevent the court action from proceeding by means of this additional support, being made as a gesture of sympathy."*

32.6. I believe that both these points were agreed.

Question 33:

33.1. I wrote to the Chief Secretary (Mr Lamont) on 23 November 1989 [DHSC0002536_027] in relation to the timetabling of the £10,000 payments for each family. I put forward the case for enabling the additional payments of £10,000 per family to be made this year, rather than in 1990/91 as earlier discussions had implied. That meant making an additional payment of £7m to the Trust in the existing financial year, rather than the next. I asked the Chief Secretary to agree an advance from the Contingency Reserve in 1989, which would then be offset by an equal reduction in UK HPSS cash limits [i.e., Health and Personal Social Services] the following year; that is, there would be a corresponding reduction in budgets in 1990/91.

33.2. I have been asked why I wanted to make these earlier payments. The reasoning was set out in the letter. We wanted to get any payments out, not delay them. I can see that I was conscious that some who had AIDS might die. I have already noted how the story about the Macfarlane Trust being slow to get payments out had caused comments in the press. Clearly, if payments were to be made it was important to get them out.

Campaigners' Meeting with the PM

Question 34

34.1. Paul Gray wrote to the Prime Minister on 21 November 1989 ahead of her meeting with Robert Key and four other Conservative back benchers on 22 November 1989 [CABO0100003_002]. Mrs Bottomley attended for the Department of Health. The minute to the Prime Minister explained that the extra £20 million allocation to the Macfarlane Trust should be announced by way of a written PQ, put down by Mr Robert Key MP. I have now been shown a briefing for the PM for the 22 November meeting [DHSC0003989_043] which dealt with various aspects of the litigation including dates set for preliminary issues, options for out-of-court settlement and a discussion on the extra injection of £20 million into the Macfarlane Trust.

34.2. Paul Gray then sent an account of the meeting to Mrs Bottomley's Private Office, copied to Mr McKeon, PPS at my Private Office as well [DHSC0002536_031]. According to this note, the Prime Minister agreed that no action on the scale suggested by pressure groups could be acted upon because there could be no question of the government accepting legal liability in the run up to the legal proceedings. The minute recorded that the Prime Minister felt haemophiliacs had been given the best treatment available on the-then current medical advice and without it, many haemophiliacs could have died. She did not accept that blame rested on the NHS,but she indicated that there would be a response, albeit not on the scale that campaigners wished to see.

34.3. I note that campaigners pressed the point that they/sufferers wished to see substantial lump payments to each family; it is clear that they wanted to see a departure from the "needs-led" approach of the Trust. Mr Key stressed the need to facilitate the payment of lump-sum payments by the Trust.

34.4. I cannot remember what, if anything, I was told of that meeting now. As to what impact the meeting had on the development of policy, it seems to me that this emerges from the minute discussed at paragraph 35 below.

Increase in Lump-Sum Payments

Question 35

35.1. I have been asked to consider a handwritten note dated 23 November, written on the minute of 22 November 1989 to the PM (see paragraph 32.1 above) [CABO0100002_008]. The handwritten note, which looks from the content as if was made by a member of the PM's Office, reads:

> *"Prime Minister subsequently discussed the announcement with Mr Clarke this morning, and it was agreed he would consider the possibility of increasing the initial across-the-board payment of £10,000 within an unchanged overall £20m package."*

35.2. I cannot recollect a subsequent discussion with the Prime Minister. I have no reason to think I did not agree to consider the possibility of increasing the initial lump-sum payments of £10,000, within the overall £20 million package. This looks to have been a reaction to the points made by campaigners when they met with the MP and Mrs Bottomley.

Question 36

36.1. I have been asked to consider a response to my letter of 22 November 1989 (see paragraph 33 above) from the Chief Secretary in which he agreed to the proposals for funding higher lump-sum payments from the Macfarlane Trust [DHSC0002536_032]. The new proposal was that the non-discretionary payments should be £20,000 and that, to enable these payments to be made immediately, a further £12 million should be made available from the Central Reserves in 1989-90. The Chief Secretary was willing to approve a discretionary claim on the Reserve of £19 million in total, in light of the assurances upon the reduction in the HPSS (Health and Personal Social Services) cash limits for 1990-91, i.e., the following year. He noted that contributions would be sought, on a proportional basis, from colleagues in Scotland, Wales and Northern Ireland (as the Trust paid out UK-wide).

36.2. I have been asked how the decision to double the lump-sum elements to £20,000 was arrived at. I am unable to remember the detail, but it was clearly as a result of the discussion with the PM on 23 November and in response to the points made by campaigners who saw her and Mrs Bottomley, about the preferences of families.

36.3. I do not know how the figure of £20,000 was arrived at; presumably it was thought that it would be sufficient to assist those who would be able to claim it.

36.4. The announcement to the House of Commons on 23 November 1989 was to the effect that an additional £19 million would be put into the Trust.

36.5. It is clear from the minute from Mr Lamont that whilst the Treasury advanced £19 million in 1989, some £7 million would have to be 'recouped' from Departmental budget in the following year (1990/91).

36.6. I have been asked where the recoupments came from. According to the Treasury minute, the proposal was that £1 million was to be sought from territorial departments, £1 million from HCHS, and the rest from centrally financed services. Ultimately, some £2 million was found from underspends emerging over the course of 1990-91, £1m from the other territorial departments and the remaining £4 million of the £7 million, came from centrally funded services: the Disablement Services Authority; the Special Hospitals capital allocation; and the Health Education Authority (HEA) AIDS budget, which faced a £2m cut. See the minute of 30 November from Mr McKeon, [WITN0758046].

36.7. There is a minute from Mrs Bottomley in response on 6 December 1989 [WITN0758047] recording her concerns about cutting the HEA AIDS funds in such a way. The matter was resolved as set out in the minute of 14 December

1989 [DHSC0002536_014], which met her concerns by limiting the reduction in the HEA budget by £1 million.

36.8. Ms Wheeler of the Department's Finance Division wrote to officials in the "other territorial departments", i.e., Welsh, English and Scottish offices, on 22 December 1989 [WITN0758048; WITN0758049, SCGV0000230_060] updating them as to the progress on arrangements to make additional payments and seeking a proportionate contribution towards the overall cost of the scheme.

Parliamentary Announcement, 23 November 1989

Question 37

37.1. The additional funding was announced by way of a written answer to a PQ on 23 November 1989 [HMTR0000001_023]. This was followed by a Departmental press release entitled "*Government trebles help for haemophiliacs with AIDS virus*" [DHSC0020267].

37.2. I do not remember why I made the announcement rather than Mrs Bottomley.

37.3. I have been asked whether the speed at which the lump-sum payment element was increased from £10,000 to £20,000 was typical of government decision-making. Not all government decision-making is slow; these decisions reflected the fact that senior decision-makers became involved, with time made for in-person meetings. It also reflected the sympathy which all concerned felt for the suffering that the victims have experienced. I do not think that it led to any particular problems. A problem did emerge about the payment of lump-sums to families, unaccompanied by evidence of need; but that problem would presumably have arisen whether the payment was for £10,000 or £20,000.

37.4. The announcement was clear that social security benefits would be disregarded. A range of social security benefits were available to haemophiliacs with HIV infection. Special arrangements had already been made for disregarding such payments from the Macfarlane Trust. I understood this to be the continuation of that policy, and that it was agreed with Mr Newton, as Secretary of State for Social Security.

37.5. I have been referred to an internal Treasury minute from Mr Francis to Mr McIntyre dated 1 December 1989 [HMTR0000001_020]. This states that the Department for Social Security did not consult the Treasury before Tony Newton agreed to disregard special payments from the Macfarlane Trust for the purposes of social security, and refers to problems with the existing regulations as, in particular, lump sum payments were treated as capital for social security purposes. There were proposals to create a new Macfarlane Trust to overcome the difficulties.

37.6. I do not know why the DSS did not consult the Treasury about its treatment of these payments; this was a matter for the DSS.

37.7. I have been asked how the matter of disregards for legal aid was resolved. As far as I was aware, I was not involved in this, but have no reason to think that the issue was not sorted; it does not appear to have been raised as an issue by lawyers in the HIV litigation.

Macfarlane No. 2

Question 38:

38.1. Following the announcement on 23 November, Strachan Heppell received a letter dated 29 November 1989 from the Chairman of the Trust, Reverend Tanner [WITN0758050] in relation to the way in which the Macfarlane Trust could be used as a vehicle for making the payments. In summary, Strachan Heppell and Mr Dobson had been involved in discussions as to how the lump sum payments were to be made in a way that could properly be commended to trustees of the Macfarlane Trust [DHSC0003849_065] in that they did not cause a breach of trust. The Trust deeds required payments to be made on the basis of need.

38.2. The minute proposing that a new discretionary Trust should be set up was sent to Mrs Bottomley's office [WITN0758051] and it seems was considered by her. I was not aware of the suggestion that a new discretionary trust had to be set up to make the lump sum payments and do not believe that I was involved in any of these arrangements.

38.3. My attention has been drawn to a suggested reply to two PQs on 1 December 1989 drafted by Mr Canavan in relation to the implementation of lump sum payments. The suggestion of a discretionary trust was mentioned again, in order to avoid breaching the terms of the existing Trust. The letter from Mr Kendall to Mr Saunders dated 1 December 1989 confirms the concern about potential breaches of Trust, were across-the-board payments of £20,000 to be made directly from the Trust to recipients without evidence of need [DHSC0003351_013]. Any changes to the Trust Deed to overcome the issue of flat rate payments could have affected the Trust's charitable status.

38.4. Mr Saunders replied to Mr Kendall on 7 December 1989 agreeing with Mr Kendall that the Macfarlane Trust could not make or contribute to the flat rate £20,000 payments, and expressing his surprise that the Department of Health thought the mechanism would be possible [HMTR0000001_026]. He raised the issue of financing the £5 million shortfall in meeting the cost of the proposed payments and suggested that the most obvious source of funds would be savings within a cash-limited Department of Health Vote in the 1989-90 financial year.

38.5. Mr Kendall responded to Mr Saunders' submission on 18 December 1989 [HMTR0000001_026] agreeing with the points raised in relation to the Trust. Mr Kendall agreed to the suggestion that there be an increase in the call on the Reserve to a maximum of £24 million. The points in favour of creating a new Trust were considerable and the issue remained that the Department would not be able to use the existing Trust's records on the grounds of confidentiality. It was for that reason that the creation of a new trust was preferred to direct departmental control of payments.

38.6. The arrangements for payments of lump sums to haemophiliacs with HIV were finalised on 29 January 1990 [WITN0758052] by way of the new Macfarlane (Special Payments) Trust. A Department press release announced the same on 30 January 1990 [WITN0758053].

38.7. I do not remember this issue, about needing a second Trust, being brought to my attention. I cannot comment why the issue had not – apparently – been foreseen in the Department. The minute which I have referred to at paragraph 31.8 suggests that officials had been alive to the need to alter the Trust's deed to enable lump-sum payments to be made; I do not know exactly why and when it was decided that this would not be enough and a second Trust was needed.

Question 39:

39.1. As noted at paragraph 39 of the Rule 9 Request, there was an extraordinary meeting of the Trustees of the Macfarlane Trust on Wednesday 29 November 1989 [MACF0000002_020]. The minutes of the extraordinary meeting record the previous meeting between the Trust, the Haemophilia Society and me on 23 November 1989.

39.2. My attention has also been drawn to a draft note of the 23 November meeting [WITN0758054, WITN0758055]; this seems to be a civil service note.

39.3. According to this note, the following people were present, as well as me: Mr Heppell, Miss Stuart, Miss Christopherson, Mrs Keswick, Mr Canavan, Mrs Shirley-Quirk, Reverend Tanner, Mr Watters and Mr Williams. I had called the meeting to outline my proposals for the additional payment to the Trust, it states. Reverend Tanner welcomed the idea of a lump sum payment but felt the £20,000 proposed could be considered inadequate when compared with compensation settlements reached in other countries. The issue of the Trust Deed was also discussed; I assured those trustees present that the Department would consider other ways to make the payments, if necessary.

39.4. I have been asked if I recall the meeting. I do not think that I can usefully add to the written record to which I have referred.

Question 40

40.1. I have been referred to a minute from Mr Heppell to Mr Canavan (copied to Mr McKeon "for information", as well as Mrs Bottomley's Private Office) dated 13 December 1989 [WITN0758056]. This set out the final arrangements for establishing the new Macfarlane Trust, including their handling. I have been asked if I was made aware of this minute. Given the passage of time, I cannot say. There does not seem to be any record of any response from me (it was copied to my office for information only), however, and the discussions had been taking place at official level.

40.2. At paragraph 3, Mr Heppell notes that he explained there was to be no publication of the increased payment (i.e., £24 million in total) into the "No.2 Fund". I have been asked by the Inquiry if I agreed. I cannot say, for the reasons I have explained.

Letter from Mr Ashdown MP

Question 41:

41.1. I have been asked about a letter sent by me to Mr Paddy Ashdown MP on 12 December 1989 [SWHT0000008_002]. It was in response to a letter of 16 October from Mr Ashdown, but no copy of that initial letter is available. My reply expressed sympathy for those haemophiliacs who had contracted HIV. I explained that the Macfarlane Trust had provided significant financial help to a large number of infected haemophiliacs and their families, and that an additional £19 million would be made available to the Trust, bringing the total to £29 million.

41.2. Mr Ashdown replied to my letter on 21 December 1989. He referred to two letters that I had sent on 12 December, pointing out that one of them was a standard response to a lady whose brother had just died from HIV infection as a result of treatment received as a haemophiliac [SWHT0000009]. He wrote "*Surely your department can do better than send a standard letter in response to the concerns and views of a bereaved relative.*"

41.3. I am sorry that Mr Ashdown felt that the reply was unsatisfactory and that it did not acknowledge his constituent's grief. But without sight of Mr Ashdown's letter to me on 16 October, to which I was responding, it is difficult to comment further.

Question 42:

42.1. I have been referred to the General Secretary of the Haemophilia Society's Report dated 11 January 1989 [HSOC0024277]. This contains an account of the meeting, I believe, on 23 November 1989. The Society stated that I had said that the money put forward (£19 million, eventually increased to £25 million), was not for negotiation; the Haemophilia Society was neither required nor expected to accept it.

42.2. I have been asked if I remember the meeting and who attended it. As I have explained, I think this must be a reference to the meeting of 23 November 1989: see paragraph 39 above which considers this and refers to the civil service note of the meeting.

42.3. Whilst I cannot remember whether I said that the money was "*not for negotiation*", it is true that the government was not conducting a negotiation with the Haemophilia Society. The Society could not have been expected to agree that the sum being put forward was sufficient (and presumably would have only been criticised by its members if it had done so). They were not being asked to settle or relinquish any claims.

Question 43:

43.1. I have been asked to reflect on the increased payments made to haemophiliacs in November 1989, and whether they were an effective response to the financial hardship of those who had suffered from infection with HIV/AIDS.

43.2. It seems to me that they were a reasonable means of responding to and alleviating suffering and hardship. The sum of £20,000 represents a little more than £44,000, in today's money, which is a substantial sum. It was coupled with (i) the continuing ability of the Macfarlane Trust to make payments on the basis of need; and (ii) social security assistance. It has to be set against the background of the constraints on public funds and that there were many groups of people who suffered terrible diseases without being able to claim additional support from the State – including other sufferers from AIDS. The argument had been that the payments to haemophiliacs could be 'ring-fenced' on the basis that haemophiliacs were already disadvantaged because of their illness [WITN0758057]; but clearly this was difficult terrain.

43.3. I have been asked what goals were pursued, and in particular the place of:

a) The relief of hardship;
b) Satisfying public opinion;
c) Dissuading the Haemophilia Society from supporting ongoing legal action;
d) Concern about unfavourable precedent in other countries;
e) Avoiding setting an unacceptable precedent;
f) Any other considerations.

43.4. As to this, I do not think that items c) and d) played a part. To the best of my memory, we knew that the litigation was unlikely to be ended by the increased payment to the Trust. As for other countries' provision, the documents referring to this show that the suggested payment of £20,000 was broadly in line with the "better European schemes", even if Canada was expected to announce the payment of £60,000 over four years as an out of court settlement of litigation. Essentially, we tried to find a sum that, viewed overall, was reasonable and offered real assistance, taking into account all the arguments. I do not think that I can break the elements down any further.

43.5. I have been asked if I regret the decisions that I took, or those of others, with respect to this increase in funds of £24 million in November 1989. I do not; we had the responsibility of looking at the whole picture, balancing all the demands on public finances whilst trying to recognise the needs of those for whom we all had the greatest of sympathies.

HIV Litigation

Question 44:

44.1. I have been asked to provide a narrative account of my knowledge of and involvement in the Department's response to the HIV Haemophilia Litigation. I have done so in the form of answering the Inquiry's questions, below.

Question 45:

45.1. In terms of my own background as a barrister, I was used to the conduct of civil litigation, including actions for negligence, and the process of settling claims, although I had not been involved any medico-legal claims when at the Bar. As far as I can recall, I did not know Mr Justice Ognall or any of the lawyers involved and if I had, this would not have had any impact on my decision-making.

Question 46:

46.1. I cannot remember when I first learned of the claim. I have been told that a letter was sent by J. Keith Park & Co. solicitors, acting on behalf of a number of haemophiliacs, addressed to me as the Secretary of State for Health on 26 July 1988 [DHSC0002526_007]. It set out the specific heads of claim and particulars, but also indicated that it would be many months before a Statement of Claim would be served.

46.2. I cannot remember whether or when this was drawn to my attention. It seems unlikely that it was. The first submission to which I have been referred, in preparation for this Statement, is dated 26 June 1989, but that went to the PS to the MS(H), i.e., to Mr Mellor's office, and was not copied to my office.

46.3. The submission from Mr Dobson to Mr Mellor's office [MHRA0017681] informed Ministers of an action being taken by a number of haemophiliacs infected with HIV through blood products and a smaller number of people infected by blood transfusion and asked for their views on (i) resisting the plaintiffs' attempts to proceed by way of a group action; (ii) ultimate liability and (iii) other ways of handling the litigation and inevitable controversy associated with it. It expressed optimism with regards to the prospect of successfully defending the case. It set out the case for consolidating cases into a group action. It noted that Counsel had indicated that he would argue the duty of care in respect of the choice of patient treatment lay with the Health Authorities and not with the Department. It looked at alternatives to litigation, such as no-fault compensation.

46.4. This submission was supplemented by another from Mr Hagger [DHSC0043529]. In relation to the duty of care point raised in Mr Dobson's submission, Mr Hagger advised that the argument that the duty of care rested with the HAs and not the Department could not be applied to the Licensing Authority (LA) or the Committee on the Safety of Medicines (CSM). Mr Hagger went on to advise thoroughly as to the pros and cons of the LA and CSM applying various defences in the case of infected blood products. Both submissions invited ministers to agree that no-fault compensation was not an option.

46.5. I have been made aware of a minute dated 24 July 1989 from Ms Woodley to Mr Arthur conveying Mr Mellor's thoughts on the litigation process, in response to these submissions. It seems he was cautious about the duty of care point; his concern was that HAs acted under the Department [WITN0758058]. There is nothing to suggest I was involved at this stage.

46.6. The Main Statement of Claim was served on 27 July 1989 [WITN0758059]. This was reamended on 22 January 1990 [ARMO0000716].

46.7. A briefing note for the CMO's meeting with the Minister of State for Health on 30 August 1989 has now been brought to my attention [WITN0758060 and WITN0758061]. The note sets out a helpful background to the litigation and parties involved: the Secretary of State for Health was listed as one of the Central Defendants, along with the Attorney General, representing the Committee on the Safety of Medicines (the CSM) and the Licensing Authority. The briefing's circulation list confirms that the matter was being handled by the Minister of State for Health.

46.8. I can see that on 25 September 1989 [WITN0758057] I was sent a briefing, in preparation for the visit of the Australian Health Minister, which noted briefly that there was a court case being brought by about 500 haemophiliacs, without much further detail.

46.9. It looks as if the Minister of State for Health brought the matter to my Private Office's attention in mid-October 1989 [WITN0758062], by which time there was a Sunday Times campaign for compensation. His concern was that the Department would "lose" no matter what the outcome of the court case was, and he raised the issue of 'topping up' the Macfarlane Trust. I have dealt with this topic already.

46.10. A Summons for Directions on the HIV Litigation was set for Monday 23 October 1989 and the duty of care issue was discussed in great detail in advance of that hearing. I have now had sight of a minute from Mr Wilson to Mr Davey (Private Secretary, Minister of State for Health) about the Valium and HIV litigation; it seems leading Counsel in the Valium case was of the opinion that in preliminary hearings, the argument should be made that a public body set up to protect the public at large had no duty of care to individuals, and was also advising that the point be taken in the HIV litigation. The Minister of State for Health was asked for his instructions to Counsel on the matter.

46.11. Mr Dobson elaborated on the duty of care point in a minute dated 18 October 1989 [DHSC0006279_018]. He explained that the argument to be made would be as follows: in making policy for the NHS, Ministers were obliged by resource constraints to make choices between desirable objectives. It would be argued that decisions made in those circumstances should be treated as a political judgment in respect of which courts were traditionally reluctant to intervene.

46.12. There were two key issues with this in relation to the HIV litigation: the first was whether the potential argument extended to the competence with which policy objectives were pursued and the second was whether Ministers would be willing to use what might be regarded as a 'legal subterfuge' to avoid detailed scrutiny of past decisions. There was reference to asking Treasury Counsel for his advice in a conference that was apparently scheduled for 19 October 1989.

46.13. I am aware that Mr Mellor was against making the argument set out above; he felt that the government would be heavily criticised and that could put public confidence at risk. He felt that the Valium / Librium situation raised different issues. He sent a minute with this view to my Private Secretary on 23 October 1989 [DHSC0041034_009], asking me to consider the papers.

46.14. A memo from Mr Wilson dated 26 October 1989 has since been brought to my attention in which he passed on Counsel's oral advice to Mr Dobson and Mr

Davey directly in relation to the duty of care policy issues [WITN0758063]. Counsel had advised that it would be difficult to raise the duty of care issue in the Valium case and not in the HIV case as that could create the impression that there was an implied difference in the government's attitude between tranquiliser dependency and haemophiliacs with HIV. Counsel advised that the duty of care issues ought to be raised in respect of the Licensing Authority and the CSM in <u>both</u> the HIV and Valium cases. However, he suggested that, as an alternative, the scope of the responsibilities of the Secretary of State under NHS litigation should be framed in terms of the issue of justiciability: policy questions (e.g. on priorities and resource allocation) should be struck out as non-justiciable. The Minister of State's view were sought, but this minute was not copied to my office.

46.15. Mr Dobson sent a comprehensive paper to MS(H)'s Private Office on various aspects of the HIV litigation process on the same day, 26 October 1989 [DHSC0002536_078, DHSC0002536_079]. This was copied to my Private Office. The paper elaborated on the duty of care argument and set out issues to be addressed by way of instructions to Counsel in relation to possible defences. The covering letter stated:

> *"... And it is likely that Treasury would resist <u>any</u> additional expenditure so long as Counsel advises that we have a good chance of winning the case. Our advice therefore remains that ministers should continue with the litigation and should not signal any readiness to provide additional funding ..."*

46.16. The key lines of defence in fighting the negligence allegations included the uncertainties in scientific knowledge of the virus and the considerable efforts made once the nature of the threat became clear.

46.17. We were also advised as to other options for the future. These included an out-of-court settlement; an explicit increase in funding to the Macfarlane Trust; ex-gratia payments on a no-fault compensation basis; a Commission of Enquiry; and publication of the government's position.

46.18. The paper also referred to the fact that the Haemophilia Society sought legal advice "some time ago" on whether actions for negligence might succeed and they were advised against pursuing such actions.

46.19. There is no record of a response from me to these minutes. In practical terms, this was the point at which Mrs Bottomley took over from Mr Mellor. She was briefed on relevant issues relating to AIDS on 1 November 1989 and by Mr Heppell on the litigation / funding issues. By 7 November 1989, she had met with Mr Robert Key MP, on behalf of the Haemophilia Society, and a meeting was set up with me for 8 November. The question of further financial support for the Trust was raised.

46.20. I requested [DHSC0002536_078, DHSC0002536_079] and received [WITN0758064, WITN0758065 and WITN0758066] a briefing on the topic of compensation for haemophiliacs on 7 November 1989 from John Canavan in relation to the Macfarlane Trust and proposals to increase the fund. By that stage, some 600 infected haemophiliacs were taking co-ordinated Court action and the Haemophilia Society's campaign for an out-of-court settlement was growing. It was estimated that such a settlement could cost between £40 to £120 million, depending on the numbers of dependents.

46.21. Strachan Heppell met with Reverend Tanner and Mr Watters of the Haemophilia Society on 9 November 1989 and my Private Office was provided with a note of the meeting on 10 November 1989 [DHSC0004415_155]. The Society was keen to promote an out-of-court settlement but only if the amount was sufficient to win the support of the plaintiffs' solicitors; it was noted that the Society would be content to label the settlement something other than "compensation" as they were aware of the difficulties facing the government in that regard.

46.22. It seemed that the Society had been criticised for accepting an "inadequate" £10 million from the Macfarlane Trust and there was a strong drive to keep any settlement separate from the Trust as the plaintiffs felt that the assessment for access to funds from the Trust was too prescriptive. They wanted about £100,000 per family.

46.23. No commitment was made on the part of the government; indeed, Strachan Heppell recorded his own view in the note that to concede any liability by way of settlement could undermine the future of the NHS and the figures suggested by the Society were very high indeed. If the government accepted such figures, there would have been implications for others infected with HIV through other treatment.

46.24. A PQ was directed at the Prime Minister on 13 November 1989 [BNOR0000241] asking whether she would consider waiving the Legal Aid requirements to enable all HIV positive haemophiliacs to issue claims against regional HAs. She was also asked whether she would consider granting a further ex-gratia payment prior to any legal settlement. Virginia Bottomley responded that the Lord Chancellor's Department had advised Legal Aid would continue subject to the usual criteria.

46.25. The Prime Minister was sent a signed letter by a number of MPs demanding a personal intervention to provide further financial assistance to those haemophiliacs infected with HIV [WITN0758067]. The argument was made that a court award might come too late for some of those haemophiliacs infected and the Prime Minister was urged to establish an out-of-court compensation scheme. I have explained how she became involved above.

46.26. I have now been made aware, by reference to a minute sent to Mrs Bottomley's office, that Mrs Farr (an official in Mr Heppell's office) had a telephone conversation with Mr Watters of the Haemophilia Society on 16 November 1989 [DHSC0002536_061] in which the latter confirmed that a sum of £86 million

(£71,000 per case) would be required to bring the haemophilia litigation to an end. The note was copied to my Private Office.

46.27. I have already explained how I met with the Prime Minister, the Chief Secretary to the Treasury (Norman Lamont) and the Attorney General on 20 November 1989 to discuss the proposal to make a further £20 million available to the Macfarlane Trust. Mr Paul Gray provided my Private Secretary with an account of the meeting [HMTR0000001_012] on the same day.

46.28. As well as the discussion on funding for the Trust, the Note sets out the Attorney General's advice on the legal merits of the claims brought against the Government. The note records that he stated: "*As regards the timetable for legal proceedings, the preliminary issue of whether the NHS has any duty to an individual which, if broken, might give rise to action for damages, would be heard on 13 December. He thought that the court was likely to rule that there was no such duty. If the courts so found, however, those bringing the case would be likely to take it to appeal.*" (Emphasis as in the original). My own view was that I "*agreed that the Government was on strong grounds in resisting legal liability.*"

46.29. Mrs Bottomley was informed on 23 November 1989 that there was to be a conference with counsel on 29 November 1989 to discuss preliminary issues in the HIV litigation [WITN0758068]: these included the duty of care point as well as questions of policy. The minute was copied to Mr McKeon of my Private Office. Mrs Bottomley was asked for her decision upon how the 'duty of care' arguments should be presented, in both the HIV and the Valium cases. By this time the additional funding to the Macfarlane Trust had been agreed.

46.30. My own views were set out in a minute to Mrs Bottomley's office on 1 December 1989. I felt that Counsel should argue the duty of care point in respect of the responsibilities of the Secretary of State for Health and the NHS legislation, on the grounds that there would be far-reaching consequences for the government if it were found to owe a duty of care to an individual patient [WITN0758069]. This was, of course, in accordance with Counsel's advice.

46.31. There was a hearing on 5 December 1989 before Mr Justice Ognall at which he decided he would not try the preliminary issues [WITN0758070].

46.32. A submission from Mr Wilson dated 18 December 1989 has been brought to my attention in which Mr Wilson sought Mrs Virginia Bottomley's views on whether to appeal the High Court decision not to hear preliminary issues, and whether the government should indicate that it would not seek an order for costs against plaintiffs who wished to withdraw from the action [DHSC0046948_041]. The submission was again copied to my office.

46.33. Mr Wilson explained that Counsel had advised against seeking leave to appeal for various reasons, including causing delay to the litigation overall, possible changes to the Statement of Claim which would add a further case to answer for the Secretary of State even if the 'justiciability' point was resolved in the defendants' favour; and it would, of course, still be open to the Defendants to argue the preliminary points as part of the main trial. As for the costs point, it was felt that an 'open' letter to plaintiffs could be construed as putting pressure on litigants to deter them from pursuing the claim further, but a specific letter to the solicitors who had raised the point would be acceptable.

46.34. Mr McKeon responded to Mr Wilson with my thoughts on his submissions on 3 January 1990 [WITN0758071]; I agreed with Mr Wilson's conclusions and expressed my view that: "*... if Counsel's advice is sought on a particular case then it should be followed unless there are compelling political reasons to the contrary.*"

46.35. Mrs Bottomley apparently agreed, as set out in Mr Davey's response to Mr Wilson dated 4 January 1989 [WITN0758072].

46.36. The Defence of the Department of Health and the Welsh Office in the HIV litigation was served on 8 March 1990 [WITN0758073]. This was followed by the service of Further and Better Particulars of the Re-Amended Main Statement of Claim on 20 March 1990 [WITN0758074].

Question 47:

47.1. I have been asked to consider various documents relating to the issue of whether the Department should have (i) pleaded a limitation defence in the litigation (ii) abandoned such a defence or (iii) reserved its position.

47.2. In a submission dated 30 May 1990 [DHSC0038699_023], Mr Canavan sought Mrs Bottomley's views on the subject. He noted that the Health Authorities and the CBLA had taken the point. The Central Defendants (which included the Department for Health) would not benefit unless they too raised the point. He concluded that there was no merit in pursuing option (i), i.e., pleading the limitation defence; this was because Counsel felt the Court would be inclined to grant an extension of time in any event, and even if the Court did not, the Department, if successful, could be accused of winning on a technicality. Mr Canavan submitted that option (ii) was arguably the most attractive in that it would demonstrate the Department's cooperation and dedication to more serious issues. Option (iii) was not favourable as there was the risk the Department could be viewed as holding the limitation issue over the plaintiffs as a threat. This submission was copied to my Private Office, as well as that of the Parliamentary Under-Secretary for Health (Mr Freeman).

47.3. As set out in the memo dated 6 June 1990 [DHSC0046957_044] Mr Freeman felt strongly that the limitation defence should not be pleaded at all.

47.4. Mrs Bottomley was persuaded that the Department should reserve its position, as set out in the memo dated 19 June 1990 [DHSC0046957_043] but added that she would defer to my legal expertise on the matter, so was copying the minute to me.

47.5. It was my view that we should not abandon the limitation defence and should therefore pursue option (iii): reserving our position [DHSC0046957_026]. To me it seemed a sensible approach; if litigation is to be fought, arguable points should generally not be abandoned. The Court would make a judgment on whether the limitation period should be waived.

Question 48:

48.1. There was an interlocutory hearing in the HIV litigation on 26 June 1990, during which Mr Justice Ognall made plain his views on the matter before him [DHSC0046964_024] and invited parties to reach a compromise. His views were set out in a written note. He referred to the "legal difficulties" facing the Plaintiffs, but added that he thought that the case was "unique" and that the public would expect that the Government's appraisal of its position was not "confined solely to the law of negligence, or problems of proof". He argued that the plight of the plaintiffs was a "special one". I did not have any difficulty with his remarks; he was seeking to be helpful in setting out his views to the parties. I had encountered this before, with other judges doing the same, in my own legal practice.

48.2. This intervention led to commentary from various officials. The CMO wrote to me and Mrs Bottomley on 20 July 1990 [HSOC0017025_004] expressing his hope that, for humanitarian reasons, the government would find some way to make an ex-gratia payment to the infected haemophiliacs:

> *"I hope Secretary of State* [sic] *will take account of my view that the problem of HIV infection in haemophiliacs can in fact be regarded as a unique catastrophe. The key feature… is that HIV infection in addition to almost inevitably causing a very unpleasant progressive illness and death results in a substantial proportion of cases in infection of the female sexual partner and also on average one quarter of the subsequently conceived children. In both wife and children the infection will also prove fatal …*

> *... the tragedy goes beyond anything which has ever been described as a result of a therapeutic accident and is very likely indeed never to occur again.*
>
> *I hope therefore, that for humanitarian reasons the Government will find some way to make an ex gratia settlement to the infected haemophiliacs in relation to this unique tragedy. I cannot personally see how this could be regarded as implying any responsibility for other accidents such as benzodiazepine dependence, cerebral palsy following obstetric misadventure etc."*

48.3. I have been shown a copy of a statement of a witness in this Inquiry [WITN0123001] and asked by the Inquiry if I wish to reply to certain allegations in it. At paragraphs 179-180 of his statement, the witness alleges that between 1988-1990 I was advised by Dr Acheson *"...to settle claims with those affected out of court, to prevent the government from being forced to hand over sensitive documents. It was reported at the time that Clarke* [sic] *was reluctant to settle, insisting haemophiliacs had to prove their case in court."* The witness continues: *"I concluded that Mr Clarke was too busy* [redacted] *to care about the people that were dying. He was responsible for not taking action prior to and at the time I was infected. In my view the suggestion made by Acheson* [sic] *clearly shows action deliberately aimed at preventing incriminating documentation entering the public domain".*

48.4. I have explained my actions when Minister of State for Health in the early 1980s in my first statement and will not repeat them here. But I hope that the lengthy quotation from Dr Acheson's memo to me of 20 July 1990 clearly shows it is wholly unfair to suggest that the CMO's advice was given in order to prevent the disclosure of sensitive or incriminating documents. His arguments were purely humanitarian. For my part, I too was never motivated by any desire to avoid disclosure of "incriminating" or "sensitive" documents in the proceedings, as I have pointed out below at paragraphs 49.5-49.7 below. I am not aware there were any. I have also explained why it was that I was not keen to settle the litigation in detail below, despite the sympathy that I, with others in government, genuinely felt for those who were claiming.[3]

48.5. Turning back to the sequence of documents, Strachan Heppell wrote to Mrs Shirley-Quirk, Mrs Bottomley and the CMO attaching a note from Mr Dobson following wide consultation with colleagues in the Department as to how Ministers might respond to the litigation in light of Mr Justice Ognall's comments [DHSC0046964_006, DHSC0004360_147, WITN0758075, DHSC0046964_006]. He suggested that there were really only two ways forward: either to continue to firmly resist the action against the government whilst being ready to consider further help through the Macfarlane Trust, or to agree to an out-of-court settlement.

48.6. The accompanying submission set out Leading Counsel's views, amongst other things. He had "confirmed his earlier view that we had a very good chance of a successful outcome for the great majority of cases" (para. 6) of DHSC0004360_147. He noted that if we successfully defended the case it should discourage further litigation. He felt that a "political" gesture to bring the case to an end might be advisable, but this was ultimately a political rather than a legal one. Officials noted that support had already been made available through the Macfarlane Trust and raised the concern that no-fault compensation might be implied by settlement. But a range of options were set out to explore further possible concessions. They noted also that the Law Officers might be consulted.

48.7. Mr Jex replied to the above notes on behalf of Virginia Bottomley on 27 July 1990 and expressed her view that the Department should maintain their present position; once the Government moved towards conceding cases such as this,

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[3] I have also been referred to paragraph 191 of the same statement, which refers to a reply from "Clarke to Acheson", again in the context of a cover-up. I do not know what the witness is referring to here, as I did not reply to the CMO's memorandum of 20 July 1990 and there seems to be some confusion about what the documents actually say. I have explained that I would have had no part in covering up or destroying documents, as implied.

there would be inevitable long-term implications for the Department [DHSC0046964_008].

48.8. Mrs Shirley-Quirk responded to the notes above on my behalf on 31 July 1990 [DHSC0046964_007]. My view at the time was also that we should continue to fight the action and pursue the Department's legal defence.

48.9. Mrs Shirley-Quirk received a letter from the Welsh Secretary of State for Health's Private Office on 13 September 1990 conveying the Secretary of State's concerns that the Department may have manoeuvred itself into a "tight position" [WITN0758076]. He noted that all the expenses of litigation were being borne by the public purse and the Defendants were not in a united position. Although the Secretary of State for Wales agreed with my approach, he wanted to see the views of the Law Officers and then to discuss further.

48.10. I have been asked about my response, as set on 31 July 1990. Specifically, I have been asked:

a) What my reaction was to Mr Justice Ognall's remarks: please see above at paragraph 48.1 and 48.6.

b) Whether I had a view on whether Mr Justice Ognall should be asked to recuse himself; no, this did not cross my mind as far as I can recall – see paragraph 48.1.

c) Whether the case of the plaintiffs was unique or sufficiently exceptional as to justify a special approach: there are many cases in which it is in the interests of both parties to settle, that is not an exceptional situation at all.

d) Whether I agreed with the wider points made by the CMO in his minute: I agreed broadly with the points he was making about the strength of the humanitarian needs and I shared the desire to help victims if we could.

But I did also have to remember all the other worthwhile claims for health expenditure, and my overall responsibility for public funds. Furthermore, I doubt that others who were pressing parallels with other claims or categories of medical accidents would have accepted the distinction he was trying to draw, between the haemophiliacs and such other cases.

e) What my understanding was of the strength of the Central Defendants' position: as to this, Leading Counsel's advice had been set out in Mr Dobson's minute and I had no reason to second-guess that.

f) Whether I agreed that the final judgment was a political not a legal one: we believed we had an excellent chance of winning but there is always some uncertainty in litigation and therefore litigation risk. This, as well as political judgments (including how to satisfy the views of responsible members of the public) all had to be taken into account.

g) What was meant by Mr Dobson's reference to "modest additional help" through the Macfarlane Trust: I do not know now, as it is not obvious what this referred to, from the papers I have been shown at the present time. But I note that in the press statement of 20 September 1990 (RFLT0000005), I stated "*We have made it clear that we will review our expenditure of £34 million so far and top up the funds of the Macfarlane Trust if that becomes necessary*."

h) Whether the Prime Minister should be minuted "in the light of her earlier interest" and what this interest was; I assume that this was a reference back to the role she had played in November 1989.

i) I have been asked whether I think her involvement would have made a difference and I have been referred to a letter from Andrew Turnbull to Mr Alcock dated 18 October 1990 [CABO0000044_002]. This states that the Prime Minister had noted that she had taken the line in the House that no more money should be made available until the legal position on HIV had been clarified. "*Any addition*[al] *concession made now would not resolve the matter and would simply be swallowed up. In her view, the best course was to get the fundamental legal issue on the Government's liability settled as soon as possible. She believed the courts would uphold the principle that the Government could not be considered negligent…*" On the basis of this later opinion, I can only conclude that she too would have been against an offer of settlement at this stage.

j) I have been asked what influence Mrs Bottomley's views had on mine: I agreed with them, but I formed my own views.

k) The minute from Mr Jex is the only minute from Mrs Bottomley's office dated 27 July 1990 that has been drawn to my attention.

48.11. On 18 September 1990 Mr Dobson reported Counsel's views on the handling of Ministers' recent decision to continue with litigation [DHSC0020866_091]. He passed on Counsel's views as to a draft letter addressed to Mr Justice Ognall, in response to his comments of 26 June 1990, and another to the Plaintiffs' solicitors. The Solicitor General had been consulted, and was content with the overall tone and content of the revised letters. A revised draft letter was sent to Mrs Shirley-Quirk on 1 October 1990 [WITN0758077 and WITN0758078].

September 1990

<u>Question 49:</u>

49.1. On 7 September 1990, Pannone Napier Solicitors, the Plaintiffs' lead solicitors, wrote to the Treasury Solicitor proposing a compromise in light of Mr Justice Ognall's comments of 26 June 1990 [DHSC0020866_134]. The claims were assessed at being worth, on a preliminary assessment, £80 - £90m.

49.2. I have referred to Mr Dobson's minute of 18 September 1990 above. This submission also circulated the letter from Pannone Napier. Mr Dobson stated "*The arguments put forward in the letter contain nothing which would lead us to review our advice to Ministers.*" [DHSC0020866_091 at para. 9]. I would probably have taken the same approach, although I cannot be sure that I saw it; there is no record of a response.

49.3. The minute also recorded that the RHAs thought that the case might settle for £50 - £60m, inclusive of the £24m already paid to the Macfarlane Trust. I have been asked for my views on this figure, but it is impossible to remember now what they may have been.

49.4. On 20 September 1990, the Court of Appeal gave judgment for the plaintiffs on the Department's application for public interest immunity ("PII") [DHSC0003620_039]. I made a statement on the same day, as set out in the press release attached to the Rule 9 Request [RFLT0000005] and was interviewed on the BBC's World at One [DHSC0046936_077 and DHSC0046936_078].

49.5. I did not play any part, so far as I can see or remember, in the formulation of the claim for public interest immunity and I was not asked to sign the PII certificate in this case. But my attention has been drawn to a Hansard record of a written answer to a PQ asked by Alfred Morris about the withholding of documents [HSOC0001459], which sets out the legal background to the PII claim.

49.6. The point that I subsequently made in my written answer to this question, on 15 October 1990 is that the claim was a matter of duty, not tactical advantage. Documents were withheld from disclosure because the Department of Health considered that a claim for public interest immunity applied to them. PII is a principle of law and, when it applies, could not be waived by the Crown. This was recognised by the Court of Appeal when Gibson LJ stated: "*The Department does not* [raise the matter of public interest immunity] *in order to* *put difficulty in the way of plaintiffs, or to withhold from the court documents which might help the plaintiffs. The Department raises the matter because it is the duty of the Department in law to do so in support of the public interest in the proper functioning of the public service…*" [DHSC0003620_039 at p. 14]

49.7. The other point that may be made was that Counsel's favourable assessment of the merits of the Central Defendants' case (see the Advice of October 1990, below) was made after the Court of Appeal's judgment in the PII application and took that into account.

49.8. Returning to the discussions of a possible settlement: the Permanent Secretary, Mr France, wrote to Mr Heppell (with Mr McKeon copied in) on 27 September 1990 in relation to the settlement proposed by the plaintiffs' solicitors [DHSC0002537_354] and the developments on the Health Authorities' side of the litigation. Mr Dobson had previously advised in his minute of 18 September 1990 [DHSC0020866_091] that the solicitors for the Regional Health Authorities had formed the view that the case may settle for £50 - £60 million. In Mr France's letter of 27 September, he notes how Bruce Martin (a key player in litigation for the RHAs) had reported that the plaintiffs' solicitors had indicated that they might settle for a much lower figure: £23m plus £5m in costs. A second basis of settlement had also been aired, which would have involved extracting the Health Authorities only from the litigation. I have been asked if I was concerned the RHAs might come to an independent settlement. I would have been concerned about a departure by the RHAs but cannot remember any discussion of this issue.

49.9. It seems that I was due to meet Mr Martin, the lead RHA Chairman, on 2 October 1990. I cannot remember this meeting and, as far as I am aware, have not seen a minute of it. There is a copy of the briefing sent to me at [WITN0758079].

49.10. I was briefed ahead of my meetings with the Chief Secretary on 1 October 1990 (see paragraph above); a key point for consideration was the Treasury's interest in the discrepancy between Pannone Napier's public claim for £80-90 million and their private approach to Regional Health Authorities suggesting settling at a much lower figure (£23m plus costs).

Counsel's Advice, October 1990

Question 50:

50.1. Counsel for the Central Defendants provided written advice on liability and quantum in October 1990 [DHSC0007039_001 and DHSC0007039_002]. I cannot remember now when or if I read it, although I must have been made aware of its overall contents.

Treasury Meeting, 2 October 1990

Question 51:

51.1. I have been asked about my meeting with the Chief Secretary to the Treasury, Norman Lamont on 2 October 1990.

51.2. I have been referred to a Treasury minute from Mr Edwards dated 28 September 1990, to the Chief Secretary [HMTR0000001_039]. It stated that the most pressing issue for discussion was whether or not the Department should signal to representatives of HIV-infected haemophiliacs a readiness to explore settlement options. Mr Edwards recorded that, as far as the Treasury was concerned, indicating such a readiness would be very expensive as well as dangerous in terms of future pressures on the government (both financial and legal). He set out a series of risks, including the risk that individual sufferers could well pursue court cases, even after an out of court settlement. The Treasury view was in favour of continuing the court case.

51.3. I have been asked if my understanding of the legal advice on the Department's position in the litigation was the same as that expressed by Mr Edwards in this minute. With respect, I cannot now recall exactly how I would have reacted to the legal advice at every stage in this matter. I have referred to the written Advice from Counsel delivered in October 1990, which I had no reason to disagree with.

51.4. I have further been asked if I agreed (or agree) with the Treasury assessment of financial payments as "*at the top end of the league for generosity*" [page 3 of the document]. I do not personally have any further information to add to the information that I referred to in late 1989, when the Department was informed that our payments were at the "better end" of the European schemes, albeit they did not match Canadian payments. The information then gathered was attached to the Treasury note.

51.5. Mr Edwards describes me as being "instinctively disinclined" to discuss an out-of-court settlement with the plaintiffs, but considered that *"the Government is likely to encounter severe criticism whatever it does".* Mr Edwards reported that I had not yet made up my mind, which I consider was accurate.

51.6. I have also been asked about the report that I was "*understandably anxious to minimise the amount of paper written on this subject*". I assume I was worried about potential leaks, which would be damaging when discussing the possibility of settling litigation.

51.7. In his minute of 1 October 1990 to the Chief Secretary, Mr Edwards refers to the Sunday Times campaign [HMTR0000001_041]. The press coverage of the claims for compensation was considerable. I have been asked to consider the two articles provided with the Rule 9 Request entitled "*Clarke urged to settle AIDS claims*" [RFLT0000038] and "*Haemophiliacs demand end to official secrecy*" [BPLL0002803]. I read the reports but press reports did not influence my thinking.

51.8. I have been asked what I can recall of this meeting on 2 October 1990, but I have no independent recollection of it and would refer to the minute of 2 October, below.

51.9. Mr Edwards' minute of 2 October 1990 [HMTR0000001_042] follows the discussion with me on the same day and sets out the government's position at the time: a choice between negotiating an out-of-court settlement and proceeding with litigation. The strategy of continuing the case rather than negotiating looked "clearly preferable", the Treasury minute stated. The minute also refers to my mention of a possible extra payment of £10 million to the Macfarlane Trust. I am not able to add to the papers now and cannot now remember what that refers to.

51.10. Mr Edwards emphasised in his note that eschewing negotiation and proceeding with litigation was "clearly preferable" as far as the Treasury was concerned, and "probably from the point of view of the Government as a whole". That was the argument set out by Mr Lamont and it was a perfectly reasonable one.

Question 52:

52.1. At paragraph 52, I have been asked to consider a letter dated 3 October 1990 from Mr Heppell to Jayant Desai at the Treasury Solicitor's Department [DHSC0046936_091] in which the Department's response to Mr Justice Ognall's comments were set out, with the intention that this should be provided to the Judge.

52.2. I have also been referred to a minute from Mr Powell (Solicitor) to Mrs Shirley-Quirk about a proposal to release the letter by way of a press statement [WITN0758080]. This was discouraged, unless or until the Judge gave his agreement to its release.

52.3. I have been asked what role I played in drafting the letter that was to be conveyed to Mr Justice Ognall. I did not play any direct role, although drafts were included in material sent to my office. I did agree with the points contained in it, so far as I can recall. I do not have anything further to add about it.

52.4. There was a further procedural hearing on 5 October 1990 [WITN0758081] in front of Mr Justice Ognall in which he apparently deplored the publication of part of the proceedings on 26 June 1990 in which he made his comments (to which the above letter referred). In a letter to Mr Heppell on the same day (5 October), Mr Powell advised that everyone involved should not say anything further about the proceedings. Mrs Shirley-Quirk received a letter on this issue from Mr Powell dated 23 October 1990 [WITN0758082]; Mr Powell set out what Ministers can or ought not to say in public following Mr Justice Ognall's remarks on 5 October 1990.

Question 53:

53.1. I have been asked to consider Treasury papers showing a draft letter being prepared in advance of an occasion when the Chief Secretary expressed his views to me. I have considered Mr Edwards' minutes of 5 October 1990 [HMTR0000001_043] and 15 October 1990 [HMTR0000001_046]. Broadly speaking, they convey the Treasury view that "any attempt to negotiate an out-of-court settlement would be a bad mistake." Full reasons were given for that view. I cannot remember whether Mr Lamont conveyed these views to me at the time, but I note that a later minute (23 October) shows that we did speak on 22 October and that there was agreement that there were no grounds for offering an out of court settlement.

Discussion with the PM, 18 October 1990.

Question 54:

54.1. I discussed the HIV litigation with the Prime Minister and the Lord Chancellor on 18 October 1990. I have been referred to a record of that meeting made by Mr Andrew Turnbull [CABO0000044_002]. I have been asked to give further details of the views of those present. I do not think that I can add to that very clear note, which appears to set out the views of all concerned at the time.

Question 55:

55.1. I have been referred to a letter dated 18 October 1990 from Mr Heppell to Mr Brand setting out my instructions to the Central Defendants' Counsel [DHSC0046936_041]. I instructed counsel to advise on legal liability on the understanding that the Department would fully defend the action; to advise on the prospects of securing an expedited hearing; and to report back on his meeting with the plaintiffs' Counsel. I have been asked to comment on the reasons for these requests, but I do not have any specific recollection of the reasons for asking about those further matters.

Question 56:

56.1. On 23 October 1990 I had a telephone conversation with the Chief Secretary, as recorded in a Treasury minute of the same date [HMTR0000002_002]. I have already referred to Mr Lamont's views. I have been asked about the agreement that Mr Lamont and I would not seek to raise the issue at Cabinet and if we were concerned that Cabinet colleagues would disagree with us. We went to Cabinet if the government needed to decide an issue collectively. This was a matter that had been considered by the Department of Health and the Treasury, in particular, and did not require Cabinet discussion. I believe that members would have been surprised to have had the matter referred to them (together with all the background papers and the legal advice, as would have been required). The decision was certainly not based on any concern that Cabinet colleagues would disagree with us.

56.2. I do not think that I can provide any further details of the conversation or the views of the Chief Secretary.

Question 57:

57.1. I cannot remember having any further discussions on this topic before I left the Department of Health on 2 November 1990.

57.2. The Inquiry has referred me to DHSC0046962 _187 which refers to a meeting between Counsel and me on 1 November 1990:

> *"Kenneth Clarke met Counsel on 1 November to discuss this. The line was confirmed that there should be no offer from the Department. However, our Counsel would make known to the Plaintiffs that if they were to offer a settlement around £20 to £25 million plus costs this might be considered. Any settlement have to be acceptable to all plaintiffs and end the litigation. No money has been agreed with Treasury for an out of court settlement, and this could be difficult to obtain as the prospects for successfully defending the action are reasonable."* (P. 2)

57.3. As stated above, I cannot remember this. It may help if I point out that my memory of that immediate time is now dominated by the events that led to Mrs Thatcher's resignation as Prime Minister on 28 November 1990. For example, I have been reminded that it was on 1 November 1990 that Sir Geoffrey Howe resigned as Deputy Prime Minister.

Department of Education

Question 58:

58.1. I have been asked what role I played, formal or informal, in decisions on the HIV litigation after I left the Department to become the Secretary of State for Education and Science. I do not think that I played any role.

Question 59:

59.1. I have been asked to reflect on the apparent distinction between the main body of plaintiffs in the litigation and a group who were thought to have stronger claims having sero-converted at a late stage. This smaller group was mentioned in my meeting with the Prime Minister and the Lord Chancellor on 18 October 1990 [CABO0000044_002]. I understood that this group had a stronger claim, but it was by no means certain.

59.2. My attention has been directed to a letter from Dr Pickles to Mr Dobson dated 8 October 1990 [DHSC0046936_074] in which she set out her belief that there was no question of negligence by the Department or the CSM in relation to any cases, including late sero-converters. She suggested in her letter that whilst there may be suggestions of clinical mismanagement, those cases were for the Health Authorities to defend rather than the department. See also paragraph 52 of Counsel's Advice on Liability, which makes the point that these might prove to be claims in clinical negligence for the Health Authorities to handle, as well as discussing the potential case against the Central Defendants in this regard.

59.3. As set out above, the Department issued a press release on 20 September [RFLT0000005] and I was interviewed on the BBC's World at One [DHSC0046936_077 and DHSC0046936_078]; I confirmed that if there was evidence of negligence on the part of the Department and fault was likely to be established, the government would pay. I do not think that there is any tension between these positions; the claims of late sero-converters against the Central Defendants might be stronger, but they had not been identified as likely to succeed.

Question 60:

60.1. I have been further asked to consider a letter from David Watters of the Haemophilia Society urging members to contact MPs and to contact me in an attempt to encourage an out-of-court settlement [BART0002264]. I may well have received letters from MPs or others, but they would not have influenced my assessment of the handling of the litigation.

Question 61:

61.1. I have been asked to consider a letter dated 9 October 1990 from Davies Arnold Cooper to the Treasury Solicitor referring to the testing of unstored sera samples by the PHLS [DHSC0046936_054]. I do not think I had any involvement in this aspect of the litigation.

Reflective Questions

Questions 62-67:

62.1. I have been asked to reflect on the litigation process and whether an alternative approach should have been adopted. Overall, this was a very difficult matter, with difficult judgments to be exercised. I have no criticisms to make of those involved, who did their best to weigh up and balance the many competing considerations and to make reasonable decisions. I cannot say what views I would have reached, had I remained Secretary of State for Health and been approached with the Plaintiffs' Counsel's offer of settlement. The role and views of all those involved, in government, in the process have been discussed above. I have been asked whether the Treasury or the Prime Minister inhibited judgments I might otherwise have made. Decisions were made after discussion with colleagues and I took account of others' views; this is a normal part of decision-making.

62.2. I have been asked whether I think that, in retrospect, a different approach should have been taken, to either the additional payments to the Macfarlane Trust, or to the litigation. I have made it clear that I this was a very difficult matter, with difficult judgments to be exercised; I do not have criticisms to make of the approach that was adopted nor do I wish to suggest that it was wrong.

62.3. I am also asked to reflect on the adequacy of the funds available to the Macfarlane Trust, and whether the aims of the Trust and the approach it was directed to take to the payments that it made were appropriate and effective.

62.4. As I understand it, it was made clear to everyone at the time that the £10 million awarded by the government to the Macfarlane Trust in 1987 was not compensation, but was directed at meeting needs. I was not involved in setting it up, and have no particular insight into how it responded to this task. I have explained how the sums available were increased in 1989, and that the approach to lump-sum payments was a response to representations made. The figures arrived at were judgments upon what was possible, but would provide some real help and meant that overall, some £34 million had been provided for this group of individuals and their families.

62.5. As for the question about why a compensation scheme was not set up, we took the view that the Department could not reasonably provide general compensation schemes for all groups of individuals who had suffered from harm as a result of treatment, without proof of negligence. I refer the Inquiry to the points I made in the House of Commons on 15 October 1990 on compensation claims against the Department [HSOC0001459]. But we still tried to make exceptional payments, on a reasonable basis, to provide financial assistance for haemophiliacs who we recognised had suffered and continued to do so. There was a balancing exercise, and we did our best to balance the compassion we all felt with realism both about overall public finances and the demands on those resources from other groups suffering from health-related needs.

62.6. I cannot answer for the judgments made by subsequent administrations on these issues – I have no real knowledge of developments subsequently.

Section 4: Subsequent Years

Question 68:

68.1. I have been asked to comment on the use of the term "compensation" in the first edition of my autobiography "Kind of Blue: A Political Memoir" published in 2017.

68.2. I dictated my autobiography from memory and without reference to any papers. The word "compensation" which appeared in the first edition was purely a slip of the tongue as I was dictating, which was not picked up by me prior to publication.

68.3. My publisher and I were contacted by solicitors about the word "compensation" and the publisher agreed through solicitors to amend the text so that the term "ex-gratia payments" was substituted for "compensation" in the next edition. I was content with this, as the change corrected what was purely an inadvertent error.

Question 69:

69.1. I have been asked at Q69 about my remarks to the Guardian in 2018. I was reacting to a demonstration outside Parliament, in which pictures of me were paraded, representing the 'arch-enemy'. Perhaps a degree of exasperation might be permissible. But I consider what I was quoted as saying in the Guardian as an accurate statement of my involvement in the matters being considered by the Inquiry. I refer to the matters contained in my first statement made to the Inquiry, which sets out my involvement for the Inquiry.

69.2. My main involvement with infected blood issues as the Secretary of State was in relation to the haemophilia litigation and the development of various funding schemes between 1988 and 1990 when I was Secretary of State, as set out above in this statement.

Letter from Mr Rossi MP

69.3. My attention has recently been drawn to a letter dated 4 May 1983 to a constituent from Mr Rossi MP [DHSC0003824_178] (as he then was), and to the suggestion that this shows that Ministers such as myself knew that the "no conclusive proof" 'line' used in 1983 was inaccurate, or similar.

69.4. It should be apparent to the Inquiry from what I have explained about Ministerial roles and positions that there was a distinction between Ministerial Health and Social Security portfolios within the Department of Health and Social Security at the relevant time. Mr Rossi was the Minister of State for Social Security from 5 January 1981 to 11 June 1983, and therefore had no responsibility for blood products in May 1983, or involvement in these matters. He quite properly explained that he held no official position in respect of health matters when he responded to his constituent in this letter. As it is on House of Commons, not DHSS, headed paper, it will have been drafted in his constituency office. It would not have been handled via the DHSS Ministerial Correspondence Unit and he would not have received any briefing or information from the DHSS before he wrote it.

69.5. Furthermore, the text of the letter shows that he was merely quoting from the newspaper article that he was discussing: *"As regards 'AIDS', I will ask for figures if they are available, and agree with you that it is an extremely worrying situation, particularly as I read in the weekend press that the disease is now being transmitted by blood plasma which has been imported from the United States."* I cannot see that the letter sheds any light on the DHSS's position or knowledge at the time, or the on the "line to take" which was developed in response, it would appear (see my first statement) to this press interest at that time.

Section 5: Other issues

Question 70:

70.1. I have been asked a series of questions relating to the issue of whether I considered the Government responded to the risks posed by infected blood and blood products in a timely manner. I can only give a properly informed answer to these sorts of questions by reference to my own periods of time in office in office in the Department of Health and Social Security, and then the Department of Health.

70.2. The AIDS epidemic was a tragedy and the suffering endured by those infected from the early 1980s through to today is considerable. However, as a Department, I believe we acted as swiftly and as efficiently as we were able, given the clinical and legal advice made available to us.

70.3. As set out in my first statement, there were two crucial issues in relation to the risks posed by infected blood: whether the NHS should have stopped prescribing Factor VIII to haemophiliacs and whether heat-treatment of Factor VIII could have been developed more quickly. In respect of the first issue, clinicians and specialist doctors clearly decided that the balance of risk associated with blood products did not justify the detrimental effect that withdrawal of Factor VIII would have had on haemophiliacs.

70.4. As for the issue of heat-treatment, all I can recall from the time is the then CMO Donald Acheson informing me that heat treatment had been approved and was being used. With the caveat that I am not scientifically trained, I have no reason to suspect that a breakthrough could have been achieved at an earlier stage.

70.5. In meetings at the Department there was a medical officer present. As a politician, you relied on the advice of the medics. On issues such as haemophilia, I would have trusted the clinical judgments and advice given by medical colleagues.

Question 71:

71.1. I have been asked if there are any decisions that could have been made which would have improved the government's response to the risks posed by infected blood.

71.2. Again, I will answer this by reference to my periods of time in office in the Department of Health and Social Security, and then the Department of Health. Whilst I certainly wish that the tragedy could have been avoided, as I have said above and in my first statement, Ministers followed clinical advice. Those doctors advising us clearly had scientific cause to believe that the initial risk associated with blood products was outweighed by the benefits enjoyed by haemophiliacs who had long been unable to easily access clotting treatment. I believe that my colleagues within the Department and the government more widely acted reasonably, and did so on the clinical advice provided to them.

71.3. I do not think that I can give informed comments on matters such as the timing of decisions concerning issues such as the redevelopment of the Blood Products Liability Laboratory (BPL). Of course it would have been desirable if self-sufficiency in blood products had been attained at an earlier stage; the need to secure the objective of self-sufficiency was accepted when I came into the DHSS. But I am not in a position to evaluate the decisions taken to achieve this, their justification and their effects, prior to 1983.

71.4. I do not believe there were any structural difficulties that increased the risk of infected blood or blood products being used in any part of the country or prevented a more effective response to those risks.

71.5. Finally, I have been asked whether there are any lessons to be drawn from the infected blood crisis which are applicable today.

71.6. Whilst I would hope that a comparable crisis never occurs again and lessons have been learned in relation to blood products, looking back at my time in office I believe the Government and Department of Health at the time acted as best they could given the circumstances. Once we were made aware of the risks associated with imported blood products, officials acted expeditiously to neutralise the risk through heat treatment and sourcing other products, and to provide education on transmission.

71.7. No doubt comparisons will be drawn between the infected blood crisis and the Covid-19 pandemic, and more specifically, the way in which the governments of the time dealt with the respective risks they faced. I cannot speak with any authority in relation to the present government's decision-making; however, I believe that the best approach for officials is to assess the facts and data provided by respected clinicians and to make a balanced decision in the interests of the public.

71.8. There are no other issues arising during my time as Minister for Health or Secretary of State for Health that are relevant to the Inquiry, as far as I can recall.

Question 76:

Parliamentary Interventions

76. I have provided a chronological list of all my Parliamentary contributions during my time as Secretary of State for Health in Annex A.

Questions 77 and 78:

Later role

77. I was Chancellor of the Exchequer from 27 May 1993 to 1 May 1997. I do not believe that I had any involvement in matters relevant to the Inquiry's Terms of Reference during that period. If there were any issues involving the level of funding to go the Trusts and Schemes providing support, such questions would have been addressed to the Chief Secretary to the Treasury.

78. I have not had involvement in issues relevant to the Inquiry in any other role or at any other time.

Statement of Truth

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

Signed GRO-C

Dated 12/07/2021

Annex A – List of Parliamentary Contributions

Date	Reference	Event – please note whether the entry is Commons or Lords, and whether it is e.g. Written Answer, Oral Answer, Debate	Relevance	Link
01 November 1988	HC Deb 01 November 1988 vol 139 cc814-6	Commons Sitting	NHS (Review)	https://api.parliament.uk/historic-hansard/commons/1988/nov/01/nhs-review#S6CV0139P0_19881101_HOC_94
01 November 1988	HC Deb 01 November 1988 vol 139 cc858-914	Commons Sitting	Charges for Dental Appliances and Treatment	https://api.parliament.uk/historic-hansard/commons/1988/nov/01/charges-for-dental-appliances-and#S6CV0139P0_19881101_HOC_296
01 November 1988	HC Deb 01 November 1988 vol 139 cc589-90W	Written Answers (Commons)	Department of Health	https://api.parliament.uk/historic-hansard/written-answers/1988/nov/01/department-of-health#S6CV0139P0_19881101_CWA_289

02 December 1988	HC Deb 02 December 1988 vol 142 cc437-9W	Written Answers (Commons)	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1988/dec/02/aids#S6CV0142P0_19881202_CWA_242
15 December 1988	HC Deb 15 December 1988 vol 143 cc690-1W	Written Answers (Commons)	AIDS	https://api.parliament.uk/historic-hansard/written-answers/1988/dec/15/aids#S6CV0143P0_19881215_CWA_304
21 December 1988	HC Deb 21 December 1988 vol 144 cc311-4W	Written Answers (Commons)	NHS Expenditure	https://api.parliament.uk/historic-hansard/written-answers/1988/dec/21/nhs-expenditure#S6CV0144P0_19881221_CWA_299
16 January 1989	HC Deb 16 January 1989 vol 145 c35W	Written Answers (Commons)	Blood Transfusion Service	https://api.parliament.uk/historic-hansard/written-answers/1989/jan/16/blood-transfusion-service
14 February 1989	HC Deb 14 February 1989 vol 147 c173W	Written Answers (Commons)	Regional Health Authorities (Funding)	https://api.parliament.uk/historic-hansard/written-answers/1989/feb/14/regional-health-authorities-funding#S6CV0147P0_19890214_CWA_520
17 February 1989	HC Deb 17 February 1989 vol 147 cc419-20W	Written Answers (Commons)	Ambulance and Blood Transfusion Services	https://api.parliament.uk/historic-hansard/written-answers/1989/feb/17/ambulance-and-blood-transfusion-services#S6CV0147P0_19890217_CWA_188

06 April 1989	HC Deb 06 April 1989 vol 150 c290W	Written Answers (Commons)	Drug Abuse	https://api.parliament.uk/historic-hansard/written-answers/1989/apr/06/drug-abuse#S6CV0150P0_19890406_CWA_465
05 May 1989	HC Deb 05 May 1989 vol 152 cc477-91	Commons Sitting	General Practitioners (Contract)	https://api.parliament.uk/historic-hansard/commons/1989/may/05/general-practitioners-contract#S6CV0152P0_19890505_HOC_130
08 May 1989	HC Deb 08 May 1989 vol 152 c322W	Written Answers (Commons)	Blood Products	https://api.parliament.uk/historic-hansard/written-answers/1989/may/08/blood-products#S6CV0152P0_19890508_CWA_294
23 November 1989	HC Deb 23 November 1989 vol 162 cc11-2W	Written Answers (Commons)	Haemophiliacs	https://api.parliament.uk/historic-hansard/written-answers/1989/nov/23/haemophiliacs#S6CV0162P0_19891123_CWA_6
14 March 1990	HC Deb 14 March 1990 vol 169 cc547-66	Commons Sitting	Family Health Services Authorities And Health Boards (Appeals Function)	https://api.parliament.uk/historic-hansard/commons/1990/mar/14/family-health-services-authorities-and#S6CV0169P0_19900314_HOC_428

15 March 1990	HC Deb 15 March 1990 vol 169 cc684-731	Commons Sitting	National Health Service and Community Care Bill	https://api.parliament.uk/historic-hansard/commons/1990/mar/15/national-health-service-and-community#S6CV0169P0_19900315_HOC_458
15 October 1990	HC Deb 15 October 1990 vol 177 cc659-62W	Written Answers (Commons)	Haemophiliacs (Aids)	https://hansard.parliament.uk/Commons/1990-10-15/debates/0f14770e-df73-447b-b4c8-85f8ac6d854b/Haemophiliacs(Aids) https://api.parliament.uk/historic-hansard/written-answers/1990/oct/15/haemophiliacs-aids#S6CV0177P0_19901015_CWA_315