Witness Name: Professor Sir Kenneth Calman
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INFECTED BLOOD INQUIRY

ANNEX TO FIRST WRITTEN STATEMENT OF
PROFESSOR SIR KENNETH CALMAN

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Section 1: Introduction

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4.1. There is a summary of the role of CMO England and its responsibilities in the BSE Inquiry report, volume 15, chapter 4, paragraphs 4.17 to 4.27, which includes evidence from Sir Kenneth's predecessor in England, Sir Donald Acheson.[1] A document on the BSE Inquiry report website entitled 'Appointment of Chief Medical Officer' (March 1991) sets out the CMO's principal duties and includes a job description.[2]

4.2. The Department produced a document for the BSE Inquiry on the position of the CMO, which stated (as at 1998) [WITN3430100]:

> "*The Chief Medical Officer (CMO) is the Government's principal medical adviser and head of the Medical Civil Service. He carries the rank of Permanent Secretary and is appointed by the Prime Minister, on the advice of the Secretary of the Cabinet Office. Within the Department of Health he is responsible to the Secretary of State for all medical matters within both the Wider Department and the NHS Executive and is the professional head for all medical staff. He is also CMO to the Department for Education and Employment, the Home Office, the Department for Social Security, and the Ministry of Agriculture Fisheries and Food (since 1997) and provides medical advice to other parts of Government such as the Department of the*

[1] BSE Inquiry website: https://webarchive.nationalarchives.gov.uk/20060525120000/http://www.bseinquiry.gov.uk/report/volume15/chapteb3.htm#56656

[2] BSE Inquiry website - Evidence - M39.4: https://webarchive.nationalarchives.gov.uk/ukgwa/20080103051959/http://www.bseinquiry.gov.uk/evidence/mbundles/mbund5.htm.

> *Environment, Transport and Roads, the Department of Trade and Industry and the Foreign and Commonwealth Office. In these capacities, the CMO is uniquely positioned to provide medical advice to Ministers on the widest possible range of matters affecting the nation's health, and has direct access to Ministers in all departments.*"

4.3. There is further discussion of the role of CMO, its responsibilities and the Departmental context (as of 1994) in the Banks report, which is discussed further below in the section on the structure of the Department.

4.4. With regard to the background to the role of a Deputy CMO in supporting CMO England, the Inquiry may be assisted by the "Report on the Review of the Senior Open Structure, DHSS (April 1986)", known as the Moseley Report.[3] The report noted the role of CMO was overloaded with responsibilities (§5.7). The report recommended reducing the number of DCMO posts from three to two (§5.11). The aim was to address the lack of clarity about the role and purpose of the DCMO post, which inhibited the individual DCMOs from "*extending the CMO's physical capacity*". "*Such an objective seems to require that each Deputy should have prime responsibility for a defined area of the CMO's responsibilities, subject of course to a 'management by exception' approach which enables the CMO to make a personal contribution within a particular area if he deems it necessary*" (§5.8).

4.5. In August 1988, Patrick Benner and Dr Malcolm Godfrey produced an internal report entitled "Review of Deputy Chief Medical Officer Posts (DCMO) in the DHSS" (August 1988).[4] The report found the CMO post was *"very seriously overloaded"* (§8) and said:

> *"How does this degree of overload arise? Paper comes into the CMO's office on a scale which normally applies to Ministers rather than to*

[3] BSE Inquiry website - Evidence - M39A.5: https://webarchive.nationalarchives.gov.uk/ukgwa/20080103051959/http://www.bseinquiry.gov.uk/evidence/mbundles/mbund5.htm].
[4] BSE Inquiry website - Evidence - M39A.4: https://webarchive.nationalarchives.gov.uk/ukgwa/20080103051959/http://www.bseinquiry.gov.uk/evidence/mbundles/mbund5.htm]

officials. There is an abnormally heavy commitment to meetings (both internal and external), and essential representational functions and international work have to be dealt with. Demands being made on the CMO in the field of public health are also unusually heavy: to illustrate that, we need only mention AIDS. But this, though of very great importance, is only one subject amongst many, and there is a large but less conspicuous volume of continuing work which is scarcely less important. Then there is the steadily increasing effort to manage the NHS more efficiently and also, of recent months, the Government's review of the NHS. All this comes on top of the CMO's normal dealings with the medical profession. He also acts as medical adviser to the Government as a whole and is the Chief Medical Officer not merely to DHSS but also to several other Departments."

4.6. The authors recommended the retention of three DCMO posts and "*a redistribution of work amongst the four most senior medical posts involving a greater and more systemised delegation of functions to the DCMOs*" (§28).

Q.5 WHO role between 1998 and 1999

5.1. See Personal Statement.

Q.6 Involvement in Other Inquiries or Litigation

6.1. See Personal Statement.

Q.7 Evidence to the Penrose Inquiry

7.1. See Personal Statement.

Q.8 Evidence to the BSE Inquiry in 1998

8.1. See Personal Statement.

Section 2: Structural and Organisational Matters

Q.9 Involvement in Committees, Working Parties or Relevant Associations

9.1. General information about the role of such committees is set out in (1) "Review of the Department of Health's arrangements for obtaining external medical and scientific advice" (March 1995), known as the Evans Report.[5] The Evans Report made recommendations on advisory committees (see the BSE Inquiry Report, Vol 15, paragraph 4.77). One of its recommendations was for a single secretary, normally a professional member of staff, to advisory committees (there had previously often been joint secretaries, one administrative and one professional); and (2) "The Use of Expert Advisory Committees", a DH document of October 1995 which arose out of the Evans Report [DHSC0042299_213].

Q.10 The Expert Advisory Group on AIDS

10.1. See Personal Statement.

Q.11 Senior Colleagues in the SHHD and the Department of Health

11.1. See Personal Statement.

Q.12 Organisation of the Department of Health, with regards to the safety of blood and blood products

12.1. There is a more detailed account of the paired structure of DH in the BSE Report, Volume 15, Annex 1: "*By 1994, there were paired medical and administrative divisions supervised by Divisional Management Boards led jointly by administrative and medical Grade 3s. A year later the parallel structure was replaced by fully integrated divisions comprising both administrative and medical staff.*" (See the BSE Report at volume 15, chapter

[5] BSE Inquiry website - Evidence - M39.3: https://webarchive.nationalarchives.gov.uk/ukgwa/20080103051959/http:/www.bseinquiry.gov.uk/evidence/mbundles/mbund5.htm

4, paragraph 4.28). This integration arose out of recommendations made in the Banks report, the "Review of the Wider Department of Health", completed in June 1994.[6]

12.2. The Banks report was a review of the "wider" Department of Health, i.e., the Department excluding the NHS Executive (the "head office" of the NHS) and the various Health Agencies such as the Medicines Control Agency (formerly the Medicines Division). See pp 2-3 of the Report for an account. At Annex B of the Banks report is a detailed diagram of the structure of that wider part of the Department of Health, in April 1994.

12.3. The diagram indicates the part of the medical administration with chief responsibility for the safety of blood and blood products was HEF(M)1: microbiological infection. However, HP(M)1 was responsible for communicable diseases including AIDS and hepatitis, and HC(M)1 for hospital services.

12.4. In addition, from April 1989, the Medicines Control Agency was responsible for licensing and classifying medicines, and licensing manufacturers and wholesale dealers; monitoring and following up adverse reactions; and inspecting and enforcing statutory requirements for manufacture, distribution, sale and labelling, etc. Formerly, before April 1989, this had been the Medicines Division, but it became a full Executive Agency from 11 July 1991 (see the evidence to the BSE Inquiry at https://webarchive.nationalarchives.gov.uk/20060525120000/http://www.bseinquiry.gov.uk/report/volume15/annex15.htm). It had greater autonomy as an Executive Agency. The Government had ceased to fund the Medicines Division/MCA with effect from 1 April 1989 and it was expected to be self-financing, via fees to the pharmaceutical industry.

[6] BSE Inquiry website - Evidence - M39.2: https://webarchive.nationalarchives.gov.uk/ukgwa/20080103051959/http:/www.bseinquiry.gov.uk/evidence/mbundles/mbund5.htm

12.5. There are various charts relevant to the organisation of DH between 1991 and 1996 on the BSE Inquiry website, but with a focus on BSE.[7]

Summary of CMO Reports – England

12.6. This Annex complements the summary of the introductory sections of the CMO Reports in Sir Kenneth's statement by making reference to issues of relevance contained in the main body of the CMO Reports.

CMO's Report 1992 [DHSC0007014]

12.7. Chapter 6 on communicable diseases addressed HIV infection and AIDS as well as other sexually transmitted diseases. The report (at page 150 onwards) gives detail about the progress of the AIDS epidemic in England, as well as the monitoring systems used to track it. Some 1,388 cases of AIDS were reported in England in 1992. This brought the cumulative total of AIDS cases reported since 1982 to 6,433, of whom 3,942 were known to have died, although the report acknowledged the possibility that the numbers of living patients with AIDS was underestimated. A further 2,294 individuals were reported to have HIV infection in England during 1992, bringing the cumulative total of such reports since 1984 to 16,768. Table 6.1 at p152 set out the AIDS cases known deaths by exposure category and date of report, including the number of cases linked to blood: 229 individuals from January 1982 to December 1992 (from a total of 6,433 individuals infected) of whom 227 had died (out of 3,942 total deaths). A further 29 cases were attributed to blood or tissue transfer (e.g. transfusion) in the United Kingdom, of whom 22 had died. 43 had been infected by the same source, but abroad (26 deaths).

12.8. Table 6.2 on the following page gave corresponding information about HIV antibody-positive people: across the period of November 1984 to December 1992, the cumulative totals of those infected via blood factor products was 1085 (out of total infections of 16,768); the figures for transfusion infections were given as 151, both UK and abroad categories being counted together.

[7] https://webarchive.nationalarchives.gov.uk/ukgwa/20060525120000/http:/www.bseinquiry.gov.uk/report/volume15/annex16.htm

However, it was thought that a relatively large number of people infected with HIV may be unaware of their infection. *"In December 1992, guidance was issued on additional sites for HIV antibody testing, voluntary HIV antibody testing for women attending antenatal clinics, and partner notification"* (PL/CO(92)5).

12.9. There was a section on HIV in blood donation (155):

> *"During 1992, 2.9 million blood donations were tested with anti-HIV - 1+2 combined tests. Twenty-six donations (from 15 males and 11 females) were found to be HIV-seropositive, or 1 in 111,540 (0.001%). The number of new donors tested was 349,000, of whom 13 were seropositive, i.e. 1 in 26,850 (0.004%). No donations were found to be anti-HIV-2-seropositive during 1992."*

12.10. Further figures were given in the table at 6.3 (p156). The report noted the progress of the epidemic worldwide (WHO estimated that by the end of 1992 approximately 13 million people worldwide had been infected with HIV, of whom 2.5 million had developed AIDS). It noted that the government strategy on HIV and AIDS had been given renewed impetus by publication of the strategy for health in 1992, in which HIV/AIDS and sexual health was designated a key area for action, and set out the public health campaigns that had been funded and run throughout 1991 and 1992.

12.11. The topic of hepatitis C in blood donations was also addressed (p166):

> *"During the year, 2,912,503 blood donations were screened for anti-HCV (antibody to hepatitis C virus): 12,108 (0.4%) were positive on the initial test, of which 7,745 (0.27%) overall were repeatedly positive. Supplementary testing of the repeatedly positive samples by recombinant immunoblot assay (RIBA) confirmed 970 donations (0.03% overall) to be positive; 2,379 (0.08%) gave an indeterminate result, 4168 (0.14%) were negative, and 228 results are still awaited. The male: female ratio was 2.04:1 for donations confirmed to be HCV*

positive, compared with 1.12:1 and 1.26:1 for indeterminate and negative samples, respectively.

Among the new donors, 0.56% of samples were initially screen-positive, with 0.38% repeatedly positive. Unfortunately, 17% of these repeatedly positive samples from new donors have not yet undergone RIBA, but of those tested 0.12% are RIBA positive - a significantly higher proportion than is found across all donations.

It is hoped that continued improvement of screening and supplementary tests will lead to fewer false-positive results on initial screening and a much reduced number of indeterminate results." (p166)

12.12. Other topics covered included Local Research Ethics Committees (p188): DH guidelines issued in August 1991 required each District Health Authority ("DHA") to establish a Local Research Ethics Committee ("LREC"). The task of these committees was to advise NHS bodies on the ethical acceptability of research proposals involving human subjects. "*The guidelines are much more stringent than previous arrangements, and should help to ensure increased accountability to the public; they have been widely welcomed*". It noted that LRECs would have a wide membership, including at least two lay members. "*Whenever research is proposed, an LREC would look after people's best interests by careful examination of important issues", including consent and confidentiality*."

CMO's Report 1993 [DHSC0007015]

12.13. Further detail on HIV and AIDS data was given at pages 141 to 151, including of the PHLS' publication of results from anonymous HIV surveys and public information campaigns.

12.14. More detail of the NBA's creation was set out at p180, where the report noted that in April 1994, the NBA would take over responsibility for the Regional

Transfusion Centres. It gave figures for those blood donors found to be HIV positive or to have evidence of antibodies to HCV.

12.15. The Report discussed surveillance for Creutzfeldt-Jakob disease ("CJD"), and public concerns about this; there had been considerable media coverage. The report noted (p182) that "*There remains no scientific evidence for any link between* [classic] *CJD in man and bovine encephalopathy (BSE) in cattle.*"

CMO's Report 1994 [DHSC0007016]

12.16. Information about the Government's strategy on HIV infection and AIDS was set out at p159, with information on prevalence from the voluntary reporting systems and the unlinked anonymous HIV surveys (established in January 1990), both implemented by the PHLS. Guidance on issues such as the management of HIV-infected health care workers and the offer of HIV testing amongst all women attending for antenatal care was summarised, and there was an account of public education campaigns.

12.17. The Report mentioned the National Blood Authority (p215), noting that from 1 April 1994 it had taken over responsibility for the Regional Transfusion Centres ("RTCs") from the RHAs. "*The Authority has produced proposals to restructure the network of RTCs and is currently considering responses received during the widespread consultation on its proposals… The aim of these proposals is to improve the quality and service provided to hospitals, patients and blood donors; proposed changes primarily concern administration, processing and testing.*"

CMO's Report 1996 [DHSC0007018]

12.18. The report notes that DH had commissioned work to look at "*the feasibility of using the unlinked anonymous serosurvey samples to determine and monitor prevalence of hepatitis C as well as HIV infection*" (p201).

12.19. The report mentioned at pp234-5 that the National Blood Authority had implemented the first stages of major reorganisation plans for the blood service.

Q.13 & Q.14 SHHD relationships with SNBTS and the PFC

13.1. See Personal Statement.

14.1. See Personal Statement.

Q.15 SHHD relationships with the UKHCDO

15.1. See Personal Statement.

Q.16 SHHD relationships with commercial pharmaceutical organisations

16.1. See Personal Statement.

Q.17 DH relationships with the NBTS

17.1. See Personal Statement.

Q.18 DH relationships with the BPL

18.1. See Personal Statement.

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Q.20 DH relationships with individual clinicians

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Q.21 DH relationships with commercial pharmaceutical organisations

21.1. See Personal Statement.

Section 3: Relationships between officials and Ministers

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Q.23 Procedures for Securing Information about Risks

23.1. See Personal Statement.

Q.24 Civil Service candour with Ministers

24.1. See Personal Statement.

Q.25 Ministerial and CMO roles

25.1. See Personal Statement.

Q.26 Ministerial Engagement

26.1. See Personal Statement.

Q.27 "Party-political positions" and the decision-making process

27.1. See Personal Statement.

Q.28 Restructuring of blood services and creation of the National Blood Authority

28.1. This Annex provides a chronological outline from the documentary records of the position on the restructuring of blood services from when Sir Kenneth took up the post of CMO for England until the launch of the NBA on 1 April 1993.

Principle administrative Civil Servants and Ministers involved in the restructuring

28.2. The documentary records demonstrate that Mr Malone-Lee (NHS Management Executive), Mr Scofield (Grade 5, HC(4)A), Mr Dobson (Assistant Secretary) and Mr Canavan were the administrative Civil Servants principally involved in the restructuring of blood services and the creation of the NBA in April 1993.

28.3. At Ministerial level, the records show that the restructuring was principally handled by the relevant Parliamentary Under-Secretaries of State with blood policy in their portfolio. That was Baroness Hooper prior to the 1992 general election, and Mr Sackville after that election. The Secretaries of State, Mr Waldegrave and Mrs Bottomley respectively, were also involved particularly at the stages where key strategic decisions had to be made.

Position on the restructuring of blood services as at September 1991

28.4. The impetus towards the creation of a new authority for blood services had already formed prior to Sir Kenneth's appointment as CMO for England in September 1991. The chronological outline below is derived from the documentary records to September 1991 and summarises the position on the restructuring of blood services when Sir Kenneth took up the post of CMO for England:

a) The CBLA had commissioned a report by Touche Ross to review the future strategy and options for the organisation. This report was referenced, for example, in the Ministerial submissions to Baroness Hooper of 5 and 8 March 1991 [DHSC0002534_034; WITN3430101].

b) DH officials then worked on future options for 'uncoupling' the BPL from CBLA. The proposal was that BPL would concentrate on the efficiency of the fractionation of plasma and on making better economic use of the existing plant, whereas the CBLA would be responsible for creating and regulating the market (see for example Mr Dobson's minute of 23 May 1991 [DHSC0002534_029]).

c) In May 1991, Ernst & Young provided a report to the NBTS entitled *"Structural Review of the National Blood Transfusion Service"*

[NHBT0001799]. Their report suggested the need for a central body in the NBTS, considered a number of organisational options, and recommended a body which merged the present functions of the National Directorate of the NBTS and the CBLA and to act as the contracting body for supplies of blood and blood products. This in turn led the National Directorate of the NBTS to put restructuring proposals to the Department in June 1991: [NHBT0002194].

d) There was a 'brainstorming' meeting involving DH and interested bodies on 8 July 1991 (see, for example, [NHBT0002191]) and relevant discussions at the CBLA annual accountability review chaired by Baroness Hooper on 10 July 1991 [DHSC0004369_010].

e) On 12 July 1991, Mr Dobson put a submission to Baroness Hooper and Mr Waldegrave [DHSC0004245_017]. That submission unreservedly recommended the setting up of a National Blood Authority and uncoupling BPL from CBLA. The third proposal, the privatisation of BPL, was assessed to be in the interest of the NHS, but it was noted that it would be politically sensitive. A consultation exercise was recommended by Mr Dobson.

f) On 16 July 1991, Baroness Hooper provided a note to Mr Waldegrave on the proposals [DHSC0004245_004], indicating that she saw no difficulty with the creation of the NBA. On the potential privatisation of BPL, she noted, *"… though it also offers clear benefits to patients, [it] could be politically controversial. It would be tempting to postpone a decision on this aspect but officials advise that this would be a particularly good moment to attract a suitable commercial partner and that the opportunity to do so may not last indefinitely. My judgement is that we should accept both proposals and, by announcing them simultaneously, seek to emphasise the overall benefits to NHS patients of the combined change but I would welcome your views"*.

g) On 17 July 1991, Mr Waldegrave's Private Office replied to Baroness Hooper's Private Office indicating that the Secretary of State was, *"… content to combine the functions of the NBTS National Directorate and the CBLA into a new national blood authority but does not wish to go*

any further in pursuing options (ii) and (iii). If your Minister wishes to pursue the proposal to decouple BPL from CBLA with the Secretary of State please let me know and we shall arrange a meeting. Secretary of State is not at all attracted to the possible privatisation of BPL" [DHSC0004245_003].

h) On the same day, 17 July 1991, Dr Metters responded to Mr Dobson's submission. Dr Metters made clear his expectation that if Ministers agreed to the proposals for a NBA, they would still wish to retain the ACVSB to advise on the quality specifications, rather than pass that responsibility to the new NBA [DHSC0014938_079]. Mr Dobson later assured Dr Metters that he did not see the NBA's role as being the originator of advice on safety and quality standards (2 August 1991, [WITN3430102]) and see also 7 August 1991 minute from Mr Scofield [DHSC0006179_011]).

i) On 26 July 1991, Mr Dobson put a further submission to Baroness Hooper concerning more limited changes to the relationship between the CBLA and BPL in light of the Secretary of State's view against moves towards de-coupling BPL from CBLA with a view to the privatisation of BPL [DHSC0014938_067]. This matter was also discussed at a meeting between Baroness Hooper and Mr Wing, Chairman of the CBLA, on 5 August 1991 [DHSC0004369_018].

j) In August – Mid September 1991, the Department moved towards publication of a consultation document on the proposed changes. See for example,

   (a) The submission from Mr Canavan to Baroness Hooper on 12 August 1991 enclosing a draft consultation paper [DHSC0004369_031; DHSC0004369_032; DHSC0004369_033] and a further submission of 28 August 1991 enclosing a draft letter to Mr Wing noting that the *"…next step will be to consult NHS management and the professional interests about the proposals to combine the CBLA and NBTS Directorate into a National Blood Authority"* [DHSC0014938_004;

DHSC0014938_005]. This letter was sent from Baroness Hooper to Mr Wing on 2 September 1991 [WITN3430103];

(b) Mr Wing's response to Baroness Hooper on 4 September 1991, noting that *"… the Consultative Document is clear and being prepared for circulation this week"* [DHSC0006835_109; DHSC0014938_043];

(c) The response from Baroness Hooper's Private Office on 6 September 1991 confirming Baroness Hooper's approval of the draft consultation document and the commencement of the consultation process [DHSC0006835_103];

(d) The meeting between DH officials (Mr Dobson, Dr Rejman and Mr Rutherford) and Dr Sheila Adam (who at that time was with NW Thames RHA) and Dr Contreras and colleagues (North London RTC). The NW Thames/North London attendees agreed with a central co-ordinating body but did not think that the proposed NBA was suitable [DHSC0020713_030]; and

(e) The publication of the consultation document on 19 September 1991. For the medical recipients, the consultation document was circulated by Dr Walford [HSOC0004153], and Dr Rejman indicated to her that the letters being sent to RTCs included a section to address a concern raised by Professor Donaldson [DHSC0006835_043]. The relevant paragraph in the letter requested that the RTC's proposals should reflect discussions with the Consultant Haematologists in their regions with responsibility for hospital blood banks, as well as the discussion with their own RTC staff.

Post-September 1991 milestones leading to the establishment of the NBA

28.5. This section of the Annex provides further information on the events and milestones leading to the establishment of the NBA in April 1993 from the documentary records available after Sir Kenneth Calman's appointment as CMO for England in September 1991.

28.6. During the consultation period, in October 1991, Dr Gunson and Dr Moore of the NBTS put forward early proposals for the NBA in a paper entitled, *"National Blood Authority: Proposals for a planning guideline"* [NHBT0001840].

28.7. On 22 October 1991, Professor Cash wrote to Sir Kenneth on the NBA proposals. This correspondence is discussed further in Sir Kenneth's statement. In a minute from Dr Rejman to Dr Hugh Nicholas (Sir Kenneth's Private Secretary) dated 22 November 1991 [DHSC0006858_047], Dr Rejman advised against agreeing to a meeting with Professor Cash for a number of reasons including that:

(a) the consultation period had by this stage closed (see further below) and the Secretary of State – in light of some of the reservations expressed – wanted further discussions within the Department before a working group was established, but this was not yet public knowledge; and

(b) the consultation responses had included one from the Scottish Office who had consulted the Scottish NBTS, which was presumed to have included an opportunity for Professor Cash to give his views. There had also been responses from, and meetings with, the English RTCs.

28.8. Dr Rejman's minute enclosed a suggested draft letter responding to Professor Cash, which was sent from Sir Kenneth Calman to Professor Cash on 28 November 1991.

28.9. A large number of responses in the consultation exercise were received before and slightly after the end of the consultation period of 31 October 1991. The consultation responses were subsequently analysed and summarised by Mr Canavan and Mr Rutherford, and then raised in a minute from Mr Dobson to Mr Malone-Lee dated 8 November 1991 [DHSC0004743_025]. Referring to the analysis of responses, Mr Dobson noted as follows,

"1. … The main points seem to me to be:

(i) Harold Gunson has clearly underestimated the extent of opposition among RTC Directors (the group whose support is most crucial to implementing change) to the detail of the proposals, especially on the role of the NBA as a central contracting authority. On the other hand, the overall concept of an NBA with greater leadership and influence than the present Directorate seems to be accepted.

(ii) Ron Wing has given the unfortunate impression that members of the existing CBLA will take all the key roles in the new NBA. As a result we think he has ruled himself out as an acceptable chairman for the NBA.

(iii) Of other groups, Chairmen are worried at the politics and proposed speed of implementation (and want to raise with SofS at the meeting on 20 November); RGMs have not formed a collective view; only Regional Directors of public health are opposed on principle to the basic ideas in the paper.

2. Given this response, I think it would be wrong to press ahead with the original proposals unamended and timescale (implementation by 1 April [1992]*). Instead I suggest we should, subject to Ministers' agreement;*

(i) set up a working group with Dr Gunson, representative RTC directors, and perhaps one regional DPH to review the <u>detailed</u> mechanisms proposed in our paper while retaining the concept of an influential NBA;

(ii) make clear to Chairmen and others that implementation will be shelved until this group has reported, and is unlikely now to be before 1 September 1992;

(iii) convey tactfully to Ron Wing the message that, even if the concept of the NBA survives, he is unlikely to be its first chairman."

28.10. On 13 November 1991, Mr Rutherford wrote to Mr Malone-Lee attaching a list of the respondents in the consultation exercise and the key areas of concern raised [DHSC0006858_073, DHSC0006858_074].

28.11. On 14 November 1991, Mr Canavan then put a submission to Baroness Hooper and Mr Waldegrave [DHSC0006858_081]. This sought:

> *"… Ministers' agreement that we should take forward the proposal for a National Blood Authority (NBA) through further discussion with the NHS interests and to a timescale which would meet the detailed concerns of the RHA Chairman and others."*

28.12. The recommendation to Ministers was:

> *"(i) to set up a working group with the National Directorate, representative RTC Directors and perhaps a Regional Director of Public Health to review the detailed mechanisms proposed in the consultation paper while retaining an influential role for the NBA;*
>
> *(ii) to inform the RHA Chairmen and others that implementation would be delayed until this group had reported and that implementation of a NBA would be unlikely to be before 1 September 1992. A low key announcement of the intention to set up the NBA could be made some months earlier and the body could operate in shadow form from say April 1992."*

28.13. On 20 November 2001, Mr Phillips, Mr Waldegrave's Principal Private Secretary, conveyed Mr Waldegrave's views on this submission [DHSC0006858_056]:

> *"I* [Mr Phillips] *have … spoken to both Dr Metters and Dr Walford and we have taken the view that, given his* [Mr Waldegrave's] *reservations,*

there is no urgent need for a letter to go in advance of the RHA Chairmen's meeting.

Essentially the Secretary of State is concerned that if RDPH and RTC Directors are not on board, this is a substantial group who are opposed to the principle. Given that position, he prefers to talk this through a little more with officials before agreeing to set up the suggested working group. I will ask Miss Whitehead to set up a meeting as soon as possible.

At the Chairmen's meeting today therefore, he will take the line that following comments on consultation, he will give the matter further consideration, listen to any additional comments they may have and then form a view."

28.14. The next day, 21 November 1991, a minute from Mr Malone-Lee conveyed that, at the meeting of Mr Waldegrave and Baroness Hooper with RHA Chairmen the previous day, the RHA Chairmen had adopted a much more supportive frame of mind towards a National Blood Authority than their previous response to the consultation exercise had suggested [DHSC0006858_055]. It was noted that Mr Waldegrave had agreed that the proposals should be looked at in slower time and should not be launched until he was satisfied about the 'political sensitivities'.

28.15. In late November and December 1991, meetings and submissions involving Baroness Hooper and the relevant officials took place in which it was agreed that plans to form the NBA should proceed, but on the slower track suggested by Mr Waldegrave, and with the details to be worked on by a technical working group. See for example: (i) the minute from Baroness Hooper's Office of 25 November 1991 [DHSC0006858_045]; (ii) the minute of from Mr Malone-Lee to Mr Dobson of 6 December 1991 [DHSC0006858_020]; (iii) the meeting of Baroness Hooper with Mr Dobson, Mr Canavan and Dr Reed on 16 December 1991 [DHSC0006858_019]; and (iv) the submission from Mr

Canavan to Baroness Hooper on 17 December 1991 with a draft note for her to provide to Mr Waldegrave [DHSC0006858_010].

28.16. In Mr Wing's (Chair of the CBLA) letter to Mr Malone-Lee of 2 January 1992, he made reference to: (i) further discussions with Mr Wing regarding the fact that he would be unlikely to be the NBA Chairman because of the desirability of this being someone from outside the CBLA; and (ii) the need for the 'de-coupling' of BPL from CBLA and that BPL did not need to be privatised in order to achieve this [DHSC0041286_037].

28.17. On 21 January 1992, Baroness Hooper then wrote her own submission to Mr Waldegrave with the amended proposal to set up an NBA [DHSC0004082_085]. She sought the Secretary of State's agreement to ask officials to,

> *"- inform those consulted that Ministers have welcomed the support from those consulted over the setting up of the NBA and have accepted this basic idea. That a Technical Working Group is to be set up to consider the concerns over the operational mechanisms of the new body;*
> *- proceed to set up the Working Group.*
> [and that] *While the Working Group is doing its work, officials should try to identify suitable candidates for the Chairmanship of the new NBA, who should be independent of the interests of either the NBTS or CBLA, so that he/she can present an impartial view."*

28.18. Mr Waldegrave's Private Secretary responded on 29 January 1992 [WITN3430104]. He stated:

> "*The Secretary of State has seen your Minister's submission of 21 January. His recollection is that the Regional Chairmen were happy with the policy but were sensitive about timing in that they did not want to push on with it now. He would be grateful if Mr Malone-Lee would check with Sir Michael Carlisle as lead Chairman for his view on timing*

and if he would ask him to sound out his colleagues for their views. He would like this pursued quietly."

28.19. On 3 February 1992, Mr Scofield sent a minute to Mr Canavan updating him on the discussions which Mr Malone-Lee had held in response to the Secretary of State's views [WITN3430105]. This was followed by Mr Malone-Lee providing a minute to Mr Waldegrave's Private Office on 4 February 1992 [WITN3430106] in which he gave re-assurance to the Secretary of State that the RHA Chairmen were not opposed to moving towards an NBA but that the slower timescales were preferred. He explained:

"I discussed the proposal to establish an NBA with Sir Colin Walker and Dr Burgess last month. I have also spoken to Sir Michael Carlisle since receiving your minute.

The position of RHA Chairmen is that they are content with the decision to establish a National Blood Authority for which there is now a wide measure of support. They believe that it should not be established until later in the year, the other side of a general election. That is the intention.

The current plan is that a technical working group should now be formed to sort out some of the detailed issues before the NBA's role and responsibilities can be finally determined. The Authority itself would not be established until October. RHA Chairmen are content with this pace."

28.20. In light of this, on 11 February 1992, Mr Waldegrave's private office conveyed to Mr Malone-Lee the Secretary of State's final agreement to proceed as set out in Baroness Hooper's submission of 21 January 1992 [WITN3430107].

28.21. The next stage in the process was for DH to communicate to those involved in the consultation concerning the technical working group, and for that group to be given terms of reference and for membership nominations. See in this regard:

(1) Mr Scofield's minute to Mr Malone-Lee of 5 February 1992 [WITN3430108];

(2) Mr Canavan's submission to Baroness Hooper on 10 February 1992, and her agreement to proceed [WITN3430109; WITN3430110];

(3) The letter to consultees of 17 February 1992, an example of which is at [NHBT0000499_001]; and

(4) Dr Gunson's letter of 18 February 1992 to all Regional Transfusion directors [SBTS0000663_051].

28.22. Baroness Hooper was briefed on a visit to BPL on 6 March 1992 and the briefing for that visit included the following [DHSC0003591_067]:

> *"PS(L) will recall that last year CBLA put forward proposals for uncoupling CBLA and BPL, and Minister's decision in September against uncoupling and changing the status of BPL. Approval was given to proceed with plans to separate the BPL and CBLA accounting arrangements, as a management tool to enable BPL to be more clearly accountable for its performance within the organisation; this was implemented from 1 October 1991.*
>
> *In correspondence with officials in February, Mr Wing has again referred to decoupling in the context of BPL's ability to compete with other suppliers, both in UK and in Europe. Mr Wing may raise the issue again at the visit, but we assume that Ministers would not want to reopen the issue close to the election."*

28.23. Following this visit, Mr Wing wrote a follow up letter to Baroness Hooper dated 12 March 1992 [DHSC0002939_010]. Mr Wing further pressed the case for 'de-coupling' BPL from CBLA. Baroness Hooper replied on 31 March 1992 [WITN3430111].

28.24. Just ahead of the 9 April 1992 election, on 3 April 1992, the technical working group held their first meeting [WITN3430112]. Mr Scofield chaired the group; Dr Rejman was the DH medical officer member, and DH also provided the

Secretariat (Mr Canavan and Mr Rutherford). Agreed action points from the first meeting were provided and dated 6 April 1992 [DHSC0004743_039].

28.25. After the 9 April 1992 election, Mr Sackville took over responsibility for the NBA reforms from Baroness Hooper and Mrs Bottomley succeeded Mr Waldegrave as Secretary of State.

28.26. On 24 April 1992, Dr Rejman provided Dr Metters with a suggested reply to correspondence received from Dr Alderslade, the Regional Director of Public Health for the Trent RHA [DHSC0002411_012]. Dr Alderslade was concerned about the price paid for plasma provided by his RTC to BPL. Dr Metters responded to Dr Alderslade on 27 April 1992 [DHSC0002411_011].

28.27. The work of the technical working group from April 1992 – July 1992 is summarised below:

(1) The second meeting of the technical working group was held on 28 April 1992 [NHBT0000488_003 and associated papers: DHSC0004251_032; DHSC0004743_008; NHBT0000488_006; NHBT0000488_005; NHBT0000488_009].

(2) Mr Scofield sent a minute to Mr Malone-Lee outlining a progress update the next day, 29 April 1992 [DHSC0004251_034].

(3) On 6 May 1992, a minute from Mr Canavan to Mr Scofield provided ideas on the management structure for the NBA [DHSC0004251_030; DHSC0004251_031].

(4) On 11 May 1992, a paper by Dr Gunson and Dr Moore entitled *"National Blood Authority: Proposed Organisational Structure"* addressed the same subject [NHBT0000491_005].

(5) The third meeting of the technical working group was held on 26 May 1992 [NHBT0000488_002 and associated papers: DHSC0004251_008; DHSC0004251_009; NHBT0000491_003; NHBT0000488_009; NHBT0000492_009].

(6) In June 1992, the CBLA published a paper entitled *"Bio Products Laboratory: Proposal for a Trading Fund"* addressing BPL's status. Mr Wing as Chairman of CBLA advocated the advantages of BPL being

able to act as an accountable Executive Agency Trading Fund within the NHS [WITN3430113].

(7) The fourth meeting of the technical working group was held on 10 June 1992 [NHBT0000488_001 with associated papers: DHSC0041257_145; NHBT0000491_012].

(8) Mr Scofield sent a further update to Mr Malone-Lee in a minute dated 23 June 1992, noting that the working party's draft report had been circulated to its members for final comment [DHSC0004254_068].

(9) Mr Malone-Lee replied to Mr Scofield on 1 July 1992 [DHSC0004254_054]. Mr Malone-Lee requested further discussion because of what he described as *"an extraordinarily complicated set of accountabilities"* proposed between the NBA/RTCs, and the failure of the draft submission to Ministers, which was in preparation, to recognise the strength of the argument against BPL remaining in the public sector. Mr Malone-Lee expressed concern that he was "*…not at all sure that the NBA that is emerging from discussions will have the clout or authority to do what is required of it*" (see further below, in relation to Mr Malone-Lee's involvement in the change of direction towards the NBA having direct management responsibility for the RTCs).

28.28. The final report of the technical working group was completed on or around 22 July 1992. The report was entitled *"Report of the Technical Working Group on Operational Aspects of the National Blood Authority"* and made the following recommendations (in summary):

"Section 2 - Role of the NBA

- *The NBA should be given the authority and means to achieve the national objectives for the blood supply …*
- *The proposed role of the NBA as a central contractor should not be pursued …*
- *The NBA should operate as a strategic authority to plan and implement a national strategy for the blood services …*

- *The NBA should approve key aspects of the RTCs' business plans and monitor their output …*
- *The NBA should control the transfer of plasma to BPL for contract fractionation at agreed quantities, quality and handling charges …*

…

Section 3 - NBA relationships

- *The NBA should build good working relationships through dialogue with the RTCs …*
- *There should be procedures for resolving disputes between the NBA and RTCs; recourse to them should be the exception …*
- *The NBA should have the flexibility to respond to any changes in the RHAs' network …*
- *BPL should be given the maximum operational freedom consistent with the NBA' s statutory responsibility for it …*
- *The NBA should decide on the form of its relationship with BPL and be prepared to review it in the light of developments …*
- *The RTCs and BPL should not be considered for NHS Trust status until the NBA has developed its strategy for the blood services …*

Section 4 – Capital

- *The NBA should have maximum influence over strategic capital investment in the RTCs preferably through direct control of the capital budget. The NBA should also control maintenance capital …*

Section 5 - Composition of the NBA

- *The executive members of the NBA should comprise the Chief Executive, the Medical Director, the Director of Finance and Corporate Planning, the Director of Operations (NBTS) and the Director of BPL …*
- *There should also be a part-time Chairman and five non-executive members*

- *While it is possible to indicate the backgrounds from which non-executive members may be drawn, the composition of the NBA should not be unnecessarily constrained by regulations …*
- *The Chairman should promote the interests of donors on the new Authority.*
- *The NBA should have the power to appoint necessary committees and specifically should create a BPL Board …*

Section 6 - Europe

- *The NBA should develop flexible systems in the blood services to enable them to respond to developments and opportunities in the EC and within the Council of Europe …*

Section 7 - Future work

- *The NBA should be set up and key management appointed as soon as possible to take forward the issues in this report …"*

[SBTS0000466_008]

28.29. Concurrent with the final stages of the work of the technical working party and the issuing of its final report were two further developments relevant to the establishment of the NBA.

28.30. First, Mr Sackville visited the CBLA in Elstree on 6 July 1992 (see the background brief at [DHSC0003591_023]). Following this visit, Mr Sackville's Private Office minuted Mr Canavan on 8 July 1992, noting that there were two issues which Mr Sackville wished to follow up on:

"*<u>NBA</u>*

PS(H) supports the creation of a National Blood Authority (NBA) and believes that this is something officials should be working to achieve in the near future. However, he has some concerns that the NBA is planned to be simply a policy orientated authority rather than having direct responsibility for the management and delivery of blood services (i.e., the regional transfusion centres and BPL). PS(H) would wish to

have a paper setting out officials thinking on the NBA, how it proposes to work, its relations with RTCs/RHAs and the proposed relationship with BPL.

Future Management of BPL

PS(H) is interested in moving BPL towards a more commercial relationship in competing for business in England and Europe. He is not however, convinced that the time is right for a complete move away from public control, especially as they have yet to demonstrate financial viability. PS(H) would wish officials to pursue suggestions that BPL could become a trust or an Agency (in time moving towards trading fund status): as well as the option of BPL staying within the control of the NBA. PS(H) is more struck by Agency status than becoming a trust in that it will ensure management and the Board of BPL taking a hard-headed look at their business and the actions they need to take to ensure financial viability. He believes Agency status is a better mechanism by which to make them consider these options.

One issue which was of particular concern to PS(H), and on which he wishes to have more information, is the funding formula agreed between the CBLA and RTCs for providing plasma to BPL. PS(H) is concerned that this is loaded against BPL and wishes to see a rationale of the current costing. The Minister would also like more information on various charges made by each RTC in providing plasma to BPL and how this differs from the "spot market" price for plasma. If plasma was not provided to BPL would there be savings for the RTCs or would the cost occurring to RTCs in obtaining blood remain the same?" [WITN3430114]

28.31. Second, and following the above, the documentary records show that a meeting involving Mr Malone-Lee, Mr Scofield and Mr Canavan took place on 13 July 1992 at which the way forward in respect of the NBA was discussed. It was noted, amongst other things, that changes should be made to the draft submission to Ministers. It was discussed that the draft submission would now

make clear that while it had been one of the "givens" for the technical working party that the RTCs would continue to be managed by their respective RHAs, the position now was that direct management had been raised and,

> *"…[it] had not been rejected by the representatives of the RTCs. Indeed they could see the "writing on the wall" and were beginning to bring their own thoughts in line with the prospect of change. The management chain which was being recommended by the Working Group really left the RHAs out on the sidelines. To some extent their role would be redundant or alternatively they could feel obliged to flex their muscles and come into conflict with the NBA. Moreover developments on the future of the RHAs suggested that the kind of role of looking after the local RTC was incompatible with their future duties. For all these reasons we strongly favoured direct management of the RTCs by the NBA. This would also give the NBA more "teeth" and contribute significantly to the successful outcome of the exercise".* [DHSC0004320_042]

28.32. Therefore, although the technical working group had worked and reported on the basis that RHAs would continue to manage the RTCs once the NBA was formed, the contemporaneous documents demonstrate that the impetus was now towards the NBA holding direct management responsibility for the RTCs.

28.33. This was reflected in Mr Scofield's subsequent submission to Mr Sackville on 24 July 1992 [DHSC0006379_085]. This submission reported on the technical working group report but also considered, *"… the case for going beyond the Working Group's recommendations and establishing the NBA as the managing Authority for the Regional Transfusion Centres …".* The decisions required / conclusion section of the submission recommended the following,

"

- *that the National Blood Authority should be established …*
- *… agreement to setting up the NBA along the lines recommended by the Technical Working Group in the first instance but with a firm commitment to move to direct management of the RTCs as soon as*

possible and no later than twelve months after the NBA is formally established …

- *that BPL should be an integral part of the NBA …*
- *that subject to the results of a cost appraisal the NBA should be located at a neutral site…*
- *that the NBA should be set up as a Special Health Authority …*
- *that the target date for establishing the NBA as an operational unit should be 1 April 1993"*

In a follow-up note dated 24 July 1992, Mr Canavan provided Mr Sackville with further information concerning the issue of plasma pricing, which the Minister had raised in his minute of 8 July 1992 [WITN3430115].

28.34. On 30 July 1992, Mr Sackville's Private Office conveyed the Minister's response [WITN3430116]. Mr Sackville broadly approved the recommendations and future actions recommended in Mr Scofield's submission. Mr Sackville had some comments on specific points in the submission, conveyed in the following terms:

> *"PS(H) is very strongly in favour of NBA having direct management of the RTCs. However he is unsure whether it is necessary for a specific joint DH/NBA planning and implementation group.*
> *With regard to BPL's role within the NBA … PS(H) has commented:*
>
> > *" I prefer independent status, so long as we have agreement on BPL being charged for plasma; perhaps world spot (price?) – what effect would this have for the rest of the NHS?"*
>
> *PS(H) does recognise that independent status for BPL will be some years off: in the meantime, he would wish to encourage CBLA to seek agency status in the not too distant future."*

In the same correspondence, Mr Sackville commented further on: (i) the proposed location for the NBA; (ii) wishing to be kept informed of the interest

being shown by the OFT into BPL; and (iii) the need to obtain initial thoughts from the departmental solicitors over the possible legal implications of an OFT investigation.

28.35. On the same day, 30 July 1992, Dr Metters responded to Mr Scofield on the technical working group's report. Dr Metters again raised the desirability of separating the NBA's responsibility for quality service provision from policy advice on blood screening that needed to come from an expert scientific advisory committee and was the current function of the ACVSB [DHSC0006980_010]. Dr Metters asked if this separation was what Mr Scofield had in mind, noting that *"It will be helpful to know at this stage as CMO has it in mind to reconstitute ACVSB with a widened remit to advise on the screening of donors of tissues and organs, as well as blood and blood products."* Dr Metters' minute was not copied to Sir Kenneth's Private Office. Mr Scofield responded to Dr Metters on 7 August 1992, making clear that there would be distinct and separated roles for the ACVSB and the NBA. Mr Scofield noted that while *"…the NBA may wish to propose changes in standards…the final decisions will remain with Ministers on the advice of the ACVSB and with the licensing authorities"* [DHSC0006179_011].

28.36. In August and early September 1992, there were various exchanges concerning the plan for the NBA to have direct management responsibilities for the RTCs, including:

a) A letter from Sir Colin Walker (who later became Chair of the NBA and had been a member of the technical working group) to Mr Malone-Lee dated 6 August 1992. Sir Colin Walker noted that the working group had done a good job under Mr Scofield's chairmanship but had "…*felt considerably hemmed in"* by the previous Minister's guidance [DHSC0006379_084].

b) A minute from Mr Scofield to Mr Canavan of 10 August 1992, noting that, *"The key new feature compared to the Working Group's report is that PS(H) has given firm backing for the NBA to take direct management control of the RTCs"* [WITN3430117].

c) A letter from Mr Wing, Chairman of the CBLA, to Mr Sackville of 13 August 1992 commenting that, "*I have been confidentially informed of your bold and welcome decision concerning the establishment of a National Blood Authority and a nationally managed service. I know my Authority will be most pleased about this decision though I shall defer informing them until I am appropriately advised. I can assure you that CBLA will give every support to ensure success of this initiative*" [DHSC0041084_063].

d) A minute from Mr Scofield to Mr Malone-Lee, dated 21 August 1992, commenting on Mr Sackville's directions and stating that "*From our point of view this represents a very satisfactory outcome*" [DHSC0041084_055]. Mr Scofield went on to address next steps in the minute and also enclosed a draft paper for the meeting between the NHS Management Executive and Regional General Managers on 10 September 1992 [DHSC0041084_065].

e) An update from Mr Scofield to Mr Malone-Lee dated 25 August 1992, which followed Mr Scofield and Mr Canavan's meeting with Catherine Hawkins, the lead Regional General Manager on Blood Services [DHSC0006379_025].

f) A minute from Dr Walford to Mr Canavan on 2 September 1992 in which Dr Walford cautioned that it was her impression that the Regional Transfusion Centres were *"…likely to be very unhappy with"* the direct management proposal, although Dr Walford caveated this statement with the fact that *"It had been some time since I had any involvement in the discussions concerning the development of a National Blood Authority"* [DHSC0006474_019]. Mr Canavan responded to Dr Walford on 7 September 1992 [DHSC0020825_065], noting that Catherine Hawkins as lead Regional General Manager on Blood Services was in favour of the proposals and that Regional Transfusion Directors had been copied to the paper ahead of the meeting between the NHS Management Executive and Regional General Managers on 10 September 1992.

28.37. On 2 September 1992 Dr Gunson, as Director of the NBTS, wrote to all Regional Transfusion Directors concerning the NBA ahead of the meeting between the NHS Management Executive and Regional General Managers on 10 September 1992 and provided them with the DH paper, thereby informing the Regional Transfusion Directors of the plan for the NBA to take on direct management responsibility for the RTCs [SBTS0000025_021]. He commented, "*You will be as surprised as I was to learn that the Department has decided that the National Blood Authority should directly manage RTCs.*" Dr Gunson stressed to the Regional Transfusion Directors *"…that no changes in the RTC network are expected or proposed for 1993/94"* because the NBA would not assume full responsibility for the RTCs until 1994. Dr Gunson also pointed to the fact that detailed management was expected to be delegated by the NBA to BPL and the RTCs respectively. Dr Gunson made reference to the different views held about direct management adding, *"Personally, I am convinced that the decision taken by the Department of Health will be in the long term interests of the NBTS. Indeed as long ago as January 1991 Roger Moore and I concluded in a paper we wrote to the Department, 'National accountability will support devolved local management to ensure that the benefits of better quality, improved supply and greater cost-effectiveness are available to the NHS'.*"

28.38. At the NHS Management Executive meeting with Regional General Managers on 10 September 1992, the Action Notes on NBA were that:

> *"**9 NATIONAL BLOOD AUTHORITY** which it was proposed would be established as an SHA, ultimately taking over full responsibility for RTCs; of which RGMs were broadly supportive.*
>
> ***AGREED** that opportunity should be sought to debate the option of ultimately administering the 'harvesting' and distribution of blood through Trusts.*
>
> ***ACTION MIKE MALONE-LEE to pursue dialogue with Tom Sackville.***
>
> ***[REVISED SUBMISSION TO MINISTER]**"*

[WITN3430118]

28.39. On 11 September 1992, Mr Scofield minuted Mr Malone-Lee outlining Mr Scofield's detailed impressions of the NHS Management Executive meeting with Regional General Managers [DHSC0020825_043]. Mr Scofield commented in particular on the possible future Trust status of RTCs and towards the end of his minute, Mr Scofield noted that:

> *"6. A number of RGMs - certainly the most vocal - were basically representing the ambitions of their respective RTCs to become self- governing Trusts. Catherine Hawkins had foreseen that this would be the tack.*
>
> *7. In the general the RGMs addressed the issue from the perspective of the local RBA/RTC. They didn't tackle the question of improving the service at national level nor of optimising the functions of the NBTS and CBLA including all the complex problems of pricing. Discussion of the internal market was superficial and not enough weight was given to the sensitive nature of the service.*
>
> *8. In my view the blood service does not lend itself to a free market with RTCs fighting each other for donors and sales to local hospitals, nor would most donors accept such handling of their free gift. The rationalisation of the service needs to be managed rather than left to market forces. The position is analogous to the London question where it is generally accepted that special circumstances apply and powerful interested parties are involved.*
>
> *9. I believe that it would be possible to set up the NBA as proposed in the paper but with the agreement that once the rationalisation of National blood services has been completed and a healthy and efficient service has been produced, further consideration will be given to launching the remaining RTCs in*

the form of NHS Trusts. This decision would be made in the light of experience of purchaser/provider relationships in general and any developments in making other support organisations into Trusts. This commitment to giving the NBTS units as much freedom as possible would parallel the corresponding ministerial commitment that BPL should move to independence as quickly as possible.

10. I have spoken to Richard Armstrong PS/PS(H) who had asked for a feedback from the meeting and he felt that Minister was likely to go along with this proposal providing he could be sure that the radical changes had been made first and that Ministers could be satisfied at the time that the Trust solution would maintain and improve the overall service.

<u>Handling:</u>

11. You will wish to consider whether to report back to PS (H) immediately and offer this compromise solution and then seek to sell it at the meeting with RHA Chairman 23 September, or to await that meeting and then report back when the overall consensus between RGMs and Chairmen has become clear."

28.40. Following a meeting with Mr Canavan, Mr Scofield prepared a detailed file note dated 15 September 1992, which provided a picture of the situation reached and next tasks requiring action at working level towards the formation of the NBA [DHSC0020825_051]. Mr Scofield prepared a further file note on 15 September 1992 following a discussion with Mr Malone-Lee [DHSC0020825_059].

28.41. A further ministerial submission was issued from Mr Scofield to Mr Sackville, dated 18 September 1992 [DHSC0006379_006]. Mr Sackville was invited to indicate whether he was prepared to

a) consider Trust status for RTCs at some later date; and

b) accept the formula set out in detail in the submission as a "compromise solution". This was for,

> *"…the RTCs to be directly managed by the NBA while the national strategic plan was being drawn up and implemented, but for the NBA to be tasked with identifying alternative delegated management models for the RTCs, including Trust status, once a satisfactory rationalised National Blood Service has been established. This would parallel the action that the NBA would be required to undertake in preparing BPL for early independence. The timetable and form for the delegated authority would be spelled out in the strategic plan which the NBA would need to draw up as one of its priority tasks."*

28.42. Mr Sackville's Private Office replied to Mr Scofield on 23 September 1992, conveying Mr Sackville's views. The Minister was:

> *"2. …content for the NBA to take direct control of the RTCs. On the question of Trust status, he feels that this should be noted as a vague possibility for the future, but should not be offered as an excuse for the NBA taking direct control, which he feels is absolutely necessary to improve efficiency and to get costs down. His one concern about this approach is that RTCs should not lose their regional flavour and thus threaten their donor base.*
>
> *3. PS(H) is unsure whether RTCs are really suitable to become trusts. He would like to know the average income of each RTC and what the Trust Unit's view is."*
> [DHSC0006379_005]

28.43. On 2 October 1992, Mr Alf Jackson provided a follow-up submission for Mr Sackville giving the Trust Unit's view on Trust status for RTCs. [WITN3430119]. Mr Jackson's recommendation / conclusion was that:

> " … *SofS reaffirms that Trust status is not the correct management model for Blood Transfusion Services at present. The National Blood Authority does not become operational until the 1 April 1994 and it would not be appropriate for us to consider RTCs for Trust status until after the NBA had wrought changes to the blood transfusion/supply service (at the very earliest by September 1994 or 6th wave). It is suggested that this matter is reconsidered then."* (original emphasis)

28.44. Thereafter, the documentary records demonstrate that the Department moved towards a formal announcement of the creation of the NBA. The internal communications and developments included:

a) A handling brief for Mr Sackville for the Annual Accountability Review of the CBLA on 15 October 1992 [WITN3430120];

b) A submission to Mr Sackville's Private Office from Mr Canavan dated 23 October 1992 on the variable performance among the RTCs [WITN3430121];

c) A submission to Mr Sackville from Mr Canavan dated 26 October 1992 regarding announcing the creation of the NBA [DHSC0041257_098];

d) A request from Mr Sackville's Private Office dated 29 October 1992 for a meeting with Mr Malone-Smith and Mr Canavan to discuss a chairman for the NBA [DHSC0041257_097];

e) A meeting on 3 November 1992 between Mr Sackville and Mr Malone-Lee at which Sir Colin Walker was discussed as Chairman of the NBA (see the follow-up minute from Mr Sackville's Office of 5 November 1992, by which time Mr Sackville had spoken to Sir Colin and he had indicated agreement to being Chairman, subject to being able to continue in his existing role) [DHSC0041257_096];

f) A draft note dated 5 November 1992 for Mr Sackville to send to Mrs Bottomley in respect of developments in relation to the NBA [WITN3430122; WITN3430123];

g) A further meeting with Mr Sackville, Mr Malone-Lee and Mr Canavan on 12 November 1992, where the importance of the role of the Chief

Executive of the NBA was discussed and in which Mr Sackville also raised whether the RTCs could be brought under the control of the NBA sooner than the envisaged 1994 timescale [WITN3430124];

h) A revised draft inspired Parliamentary Question and press release dated 16 November 1992 [WITN3430125; WITN3430126]; and

i) A minute from Mr Scofield to Mr Malone-Lee dated 25 November 1992 on the timing and arrangements for the announcement of the NBA, as well as a list of issues to be discussed with the NBA Chairman, Sir Colin Walker, in a meeting with him the next day [WITN3430127; DHSC0046902_035].

28.45. The formal announcement of the decision to create the NBA was made on 27 November 1992 in answer to an inspired Parliamentary Question, with an associated press release [WITN3430128; NHBT0006432]. In the announcement, Mr Sackville noted that *"From 1 April 1993 it* [the NBA] *will replace the existing Central Blood Laboratories Authority and the National Directorate of the National Blood Transfusion Service; and subsequently will assume responsibility for managing the Regional Transfusion Centres at the earliest opportunity."*

<u>Events between 27 November 1992 and formal beginning of the NBA on 1 April 1993</u>

28.46. This section of the Annex provides an outline of the events between the formal announcement of the decision to create the NBA on 27 November 1992 and its beginning on 1 April 1993 from the documentary records available.

28.47. A National Blood Authority Planning Group was established with Sir Colin Walker as its Chair, and with membership including Dr Gunson, Mr Savery (CBLA, later Director of Finance for the NBA) and, from DH, Mr Canavan and Mr Rutherford. The National Blood Authority Planning Group held the following meetings in late 1992 and early 1993:

- 10 December 1992 (first meeting [DHSC0046902_002; DHSC0046902_007; DHSC0046902_008]);
- 13 January 1993 (second meeting [DHSC0006359_040; DHSC0006359_046]);
- 10 February 1993 (third meeting [DHSC0006359_031]);
- 18 March 1993 (fourth meeting [DHSC0006359_006]); and
- 7 April 1993 (fifth meeting [DHSC0006359_004]).

28.48. Mr Sackville's query concerning whether the date for the NBA assuming direct management responsibility for the RTCs could be brought forward from April 1994, raised at the meeting between Mr Sackville, Mr Malone-Lee and Mr Canavan on 12 November 1992, was addressed in a further submission to him on 15 December 1992 [WITN3430129]. Following consultation with Sir Colin Walker, the planned date of April 1994 was retained [WITN3430130; DHSC0041257_048; DHSC0046977_148; DHSC0046977_147].

28.49. As the preparations for the launch of the NBA were continuing, an allied development was further consideration given to the status of BPL. Ahead of the launch of the NBA in April 1993, the communications and consideration concerning BPL's status included the following:

(1) Mr Sackville met with Sir Colin Walker on 15 December 1992 to discuss BPL and Medeva PLC, who had made an approach to the Department. Mr Sackville had told Medeva that the privatisation option for BPL was not available but had invited the company to make proposals for collaboration with BPL (see briefing to Mr Sackville from Mr Canavan on 14 December 1992 [WITN3430131]). On BPL and the NBA, the briefing note provides that:

> *"It is intended that BPL should be part of the NBA but should be given the maximum operational freedom consistent with the NBA's statutory responsibility for the plant. At the CBLA Accountability Review PS (H) indicated that a more independent status for BPL eg. as a Trust, could be considered in future but*

that the aim in the short term was to make BPL self -financing and sort out production problems.

The advantage of having BPL and the RTCs within the same organisation for a time is that the difficulties over plasma pricing and the size of the plasma programme can be tackled by a body (the NBA) which has responsibilities to both cellular and plasma product users. Hitherto BPL and the RTCs blamed each other for the problems and each considered its interest were being sold out to the other side.

Sir Colin may share the views of the CBLA Chairman (Ron Wing) that from the business viewpoint, BPL would operate better outside the NHS. It could exploit a wider range of products and markets and attract additional capital for equipment and research. However, the political difficulties of hiving off BPL are recognised. The aim therefore, would be to make BPL as efficient as possible within those constraints and this may include some form of collaboration with companies such as Medeva."

(2) In a letter from Mr Sackville to Sir Colin Walker dated 22 December 1992 [DHSC0006792_038], Mr Sackville noted the following:

"*Up to now, BPL has not been "for sale". However, given that it is a classic non-core activity of the NHS, and the fact that attitudes within Government to involvement with the private sector are changing fast, this is the moment to review the position. In other words, if a respectable buyer comes forward with proposals which fulfil our criteria (e.g. buying NBA plasma) we should look seriously at them and not dismiss them out of hand. Another possibility would be to explore forms of collaboration with the private sector which do not involve a change of ownership or status for the BPL.*

> *In terms of time scale, my view was that the longer we wait to consider our options, the more difficult it will become to implement them. If action is to be taken, it should be within the next eighteen months. I will be happy to look at any proposals you wish to put to me, but I must stress the need for caution. First to ensure that nothing undermines either our principle of voluntary donation or the quality of UK blood products. Second, to consider carefully at what stage such a policy shift becomes known more widely: we will have to ensure our position and its presentation are very well thought out by that time."*

(3) On 20 January 1993, Mr Sackville then wrote to Medeva PLC [DHSC0006792_021], with a copy of this correspondence sent to Sir Colin Walker "on a personal basis" on the same date [DHSC0006792_020], commenting that,

> *"When we met last November I reiterated our policy that BPL was not for sale. However, since then attitudes within Government to collaboration between the public and private sectors have been changing and I think this is an opportune time to review all the options in respect of BPL. If there were proposals to buy BPL, whether from yourselves or other interests, I would wish to consider them seriously and not dismiss them out of hand; I would also be willing to consider other forms of collaboration. You will appreciate that we would need to examine very carefully any proposals in respect of the blood services in view of the particular sensitivities surrounding them. We would need to be satisfied that new arrangements protect our system of voluntary, unpaid donations and the continued supply to the NHS of blood products made from those donations."*

28.50. The status of BPL was also referred to in a briefing note for Mrs Bottomley's meeting with the Treasury on privatisation issues – see the minute from Mr Canavan to Sarah Bateman dated 3 March 1993 [DHSC0006578_052; DHSC0041151_004]. The recommended 'line to take' with the Treasury outlined in the briefing note to Mrs Bottomley was:

> *"- Recognise the operational advantages to BPL if it were put into the private sector. However, we must also take account of the possible repercussions for our system of voluntary, unpaid blood donation and our national and EC policies of seeking self-sufficiency in blood products made from unpaid donations for both ethical and health reasons.*
>
> *- Those wider concerns caused us to reject privatisation of BPL in the past. In view of the increasing emphasis on core activities and greater collaboration between the NHS and the private· sector, the NBA has been asked to review all the options for BPL. We shall consider proposals seriously but at this stage cannot be committed to change. We would need to be satisfied that any new arrangements protected our wider interests in the blood services."*

28.51. On 11 March 1993, this was then supplemented by a further briefing from Mr Scofield again ahead of Mrs Bottomley's bi-lateral meeting with the Treasury [DHSC0006579_095; DHSC0006579_096; DHSC0038505_025]. Mr Scofield's briefing set out arguments in favour and against the privatisation of BPL as follows:

> *"Arguments in favour*
>
> - *its work is almost exclusively the fractionation of blood plasma which is a classic pharmaceutical manufacturing process*
> - *its management and efficiency are not up to best industrial standards and its plant at Elstree has significant surplus capacity*
> - *it currently requires a Government subsidy of about £6 million per annum (11% of revenue)*

- *the OFT are investigating this subsidy and may refer the case to the MMC.*
- *it is undercut by commercial competitors and would be unable to survive a "cut throat" sales drive by a determined commercial contractor. BPL does not have the range of products or access to capital to compete on level terms with commercial pharmaceutical companies.*
- *BPL lacks a comprehensive sales and distribution organisation, especially for overseas marketing. It would benefit from teaming up with a private pharmaceutical company. One such company has declared an interest and discussions are in hand about various possible relationships.*

Arguments against

- *"blood " is politically very sensitive.*
- *there is concern that blood donors would object to part of their "free donation" being traded commercially*
- *presentationally there is strength in the case for Government having direct control over blood fractionation in the wake of the problems over HIV infection*
- *there would be no likelihood of recovering any significant part of the £80 million invested in the Elstree facility*

Conclusion

On balance it would be inappropriate to privatise BPL now. However

- *we have established the NBA (wef 1 April 93) to take over management of CBLA (including BPL) and the NBTS (wef 1 April 1994)*
- *this will significantly strengthen the management of blood services in general"*

28.52. On 17 March 1993, Mr Shaw, Director, Corporate Affairs NHS Management Executive sent a letter to all Regional General Managers and NHS Trusts

Chief Executives, copied to all District General Managers and Unit Managers, giving information about the NBA [NHBT0083596_002].

28.53. The NBA was launched on 1 April 1993 (see Mr Sackville's press release of that day [NHBT0003960]). The NBA held its first meeting on 22 April 1993 [WITN3430132].

Q.29 Differences in organisations and structures responsible for blood in Scotland and England

29.1. See Personal Statement.

Section 4: Anonymous HIV Sero-surveillance

30.1. See Personal Statement.

Section 5: Knowledge of, and response to, risk of viruses from blood products

31.1. See Personal Statement.

32.1. See Personal Statement.

33.1. See Personal Statement.

34.1. See Personal Statement.

Section 6: Screening for Hepatitis C

35.1. See Personal Statement.

36.1. See Personal Statement.

Section 7: HCV Lookback

Q.37 'Lookback' and the introduction of HCV screening of blood donations, from 1 September 1991

37.1. This section summarises documents sent bearing on the issue of discussion of any 'lookback' exercise, as part of the introduction of HCV screening of blood donations, from 1 September 1991. It has been prepared as an aid to assist Sir Kenneth and does not purport to be a complete summary of the records on this topic.

37.2. It is apparent that the issue was considered as part of the planning in both England and Wales and Scotland that took place for the introduction of HCV screening tests. However, the documents summarised below do not necessarily make a coherent whole and access to SSHD documents has not been obtained to date. At times, the Penrose Report (Chapter 35) has been referenced where it contains a useful summary.

37.3. The Penrose Report, Chapter 35, sets out the history of lookback prior to 1991 and, in particular, the influence of the HIV lookback exercise that was introduced in 1984. The Report notes at paragraph 35.11 that *"following the introduction of an HIV test in late 1984, it was agreed across the UK that donor testing for HIV would be accompanied by targeted look-back, when donors tested positive on screening, from the outset.*" It explains the impact that this experience had upon Dr Gillon of the South East Scotland Transfusion Service, as well as the attempts made to 'lookback' for Hepatitis C before the introduction of an effective screening test in 1991, attempts that were often inconclusive (see paragraphs 35.16, 35.34).

37.4. The Report notes the difference between 'reverse look-back' (tracing donors when a report of HCV infection in blood or blood components has been received; the process is focussed on the identification of infected donors) and 'targeted look-back'. In the second, the process starts when a donor is found to be infected; the donation history is then tracked back with a view to tracing possible recipients of the infected product. *"In contrast to targeted look-back, reverse look-back is not dependent on the availability of a screening test for*

the virus and its antibodies" (para 35.4). It is generally the targeted look-back which the Inquiry's look-back questions are focussed on, but at times the papers supplied relate to possible reverse look-back.

37.5. Consideration was given to introducing a 'lookback' element to the introduction of HCV screening, in 1990. See for example:

(1) On 1 May 1990, a letter was sent from Professor John Cash (SNBTS) to Dr Harold Gunson (National Director, NBTS), suggesting doing anti-HCV testing on donations to locate infected donors in the "twilight period", prior to the implementation of full anti-HCV screening [PRSE0000218]. This is a reference to reverse look-back, focussing on infected donors (see Penrose at paragraph 35.37).

(2) On 14 May 1990, a letter was sent by Dr Ruthven Mitchell (Director of Glasgow and West Scotland Blood Transfusion service) to Professor Cash asking whether the BTS should have a look-back policy to identify possible HCV transmission from donors, in cases where alleged non-A, non-B transmission had occurred and had been notified to the RTCs. It suggested that the service could be considered negligent if they did not have a policy on the potential future use of donor blood (in such circumstances). The author noted that he had raised the topic at the meeting of the ACVSB on 24 April 1990, but that at this stage look-back was not supported by blood transfusion service policy [NHBT0000189_131].

(3) On 21 May 1990, Dr Gunson replied to Professor Cash. He wrote: *"I am not sure that our RTCs will have access to anti-HCV test material. I think that it may be worthwhile to carry out the usual investigations when a transfusion-associated NANBH case is reported and to ensure that a library sample of serum is retained from each donor seen."* He suggested further discussion on June 27 [PRSE0004033]. According to Penrose, paragraph 35.38, "the usual investigations" referred to reverse look-back. According to Professor Cash's evidence, Dr Gunson was "pretty unenthusiastic" about look-back for a very long period of time, because of the scale of the task.

(4) The IBI has already noted, in its presentation on Dr Gunson, that it was agreed at the 27 June 1990 meeting of the NBTS/SNBTS Liaison Committee that *"whilst tests are and policies are evolving it would not be appropriate to establish a lookback policy and that ACVSB would take a view in due course"* (see IBI's Dr Gunson presentation paragraph 340, referencing [NHBT0000189_173]).

(5) A letter dated 9 July 1990 from Professor Cash to named colleagues recorded that in his discussions with Dr Harold Gunson they had agreed that it would not be appropriate to run a HCV lookback programme after screening for HCV had been introduced. It would however be appropriate to investigate the status of donors implicated in cases of post-transfusion hepatitis [PRSE0001133]. So: *"a preliminary decision had been reached at UK level not to begin a programme of targeted lock-back when donor testing for HCV commenced."* (Penrose, paragraph 35.45). See also the minutes of the ACVSB meeting of 2 July 1990 [PRSE0000976].

(6) However, according to Penrose at paragraph 35.21, on 21 June 1990, Professor Cash wrote to Dr Gillon, asking him to chair a Working Party to draft operational guidelines for SNBTS, on counselling donors confirmed to be HCV positive. Dr Gillon's Working Party *"came to an unanimous decision that there should be a look-back following identification of donors found to be HCV-positive"*. This, a recommendation for a targeted look-back, was recommended in its report which went to SNBTS Directors for discussion (paragraph 35.34; see 35.48 for further detail). Lord Penrose notes that the recommendation was inconsistent with discussions that had been progressing at UK level.

37.6. Dr Gillon's Working Party's recommendations were discussed on 6 November 1990 at the meeting of the SNBTS Scientific Committee. The Minutes record that it was agreed that Professor Cash should write to the Chairman of the ACVSB asking that careful consideration be given to the matter of HCV lookback for recipients of previous donations [PRSE0000348]. It is apparent

that the Committee had considered the draft policy from Dr Gillon on the management and counselling of donors identified as being HCV positive (see the draft dated 23 November 1990 at [PRSE0000515]). On 23 November 1990, a letter was duly sent by John Cash to Dr Metters, asking that the ACVSB consider a lookback policy in anticipation of the commencement of HCV testing for donations [PRSE0001573]. Professor Cash told the Penrose Inquiry that he regarded the 'Metters Committee' as the route for Ministerial approval (paragraph 35.61).

37.7. When the ACVSB met on 21 November 1990, it was agreed that the issue of counselling (which included the issue of lookback) should be referred to the UK's Advisory Committee on Transfusion Transmitted Diseases ("the ACTTD") [ARCH0003390[8]].

37.8. The ACTTD met on 8 January 1991 [NHBT0000073_028; NHBT0000042_067]. It was chaired by Dr Gunson; Professor Cash, Dr Mitchell and Dr Gillon were among the attendees. Dr Gillon's paper on counselling donors was discussed. At 4.11, the minutes state that *"It was agreed that there may be an ethical obligation to inform patients who may have received transfusions in the past from anti-HCV positive donations. This will involve considerable additional work including testing of library samples and will have to be funded. Extension of this to epidemiological investigations should be the subject of separate research studies."*

37.9. The Minutes of the SNBTS Medical & Scientific Committee of 19 January 1991 noted that the national date of implementation for HCV testing in RTCs was 1 July 1991. Professor Cash had written to Dr Metters on 'lookback' and the response was that Dr Metters' committee (presumably, the ACVSB) would consider this issue [PRSE0003568].

37.10. A further meeting of the SNBTS Medical & Scientific Committee, chaired by Professor Cash, was held on 19 February 1991. It discussed Dr Gillon's final draft document. At paragraph 3.4 – the minutes recorded that: *"in the light of*

[8] See also paragraph 341 of the IBI's presentation on Dr Gunson, which references Dr Gunson's communication of this referral.

national events, it was agreed that no "Look Back" should be introduced at present" [PRSE0003568].

37.11. The Penrose Report noted that *"The Inquiry has not uncovered any record of 'national events' leading to an agreement that look-back should not be introduced at that stage"* (paragraph 35.63). There is extensive discussion of the Gulf War, and its impact on rolling out screening for HCV in early 1991, in Chapter 31 (see paragraph 31.265) but that is not linked by Lord Penrose to this discussion of look-back. At paragraphs 35.96-97 of the Penrose Report, there is a summary of the measures being taken in Scotland for the Gulf War, but the report notes that the Gulf War conflict ended on 28 February 1991. The report continues: *"At most it [i.e., the War] would have had an indirect, and reducing, impact on the capacity of the SNBTS to handle testing or look-back thereafter. Dr Gillon's alternative explanation, that the expression in Professor Cash's letter related to English reluctance to embark upon the programme in consequence of their resource difficulties, is more cogent."*

37.12. The 9th meeting of the ACVSB was held on 25 February 1991. The minutes also record that a look-back exercise was not to be undertaken:

> *"The Committee discussed the problems of look-back and recommended that it should not be undertaken as a service, leaving the option for those carrying out research. However, all cases of post-transfusion hepatitis should continue to be investigated."*[9]

37.13. The decision of the UK Advisory Committee on Transfusion Transmitted Diseases ("the ACTTD") which met on 25 March 1991 was consistent with this:

> *"It was agreed that testing of blood and plasma donations would commence on a specified date. There would not be retrospective tests carried [out] on donations collected prior to that date"* [NHBT0000073_063, paragraph 4.14]

[9] http://www.penroseinquiry.org.uk/finalreport/pdf/SNB0018934.PDF

37.14. On 10 July 1991, Mr A. McIntyre (SHHD) sent a minute to Mr Panton (Scottish Office, NHS Management Executive) about the SNBTS "*Recommendation for Counselling of HCV Seropositive donors informing the donor*". He noted that Mr Panton had agreed to discuss the recommendations with colleagues in DOH. Mr McIntyre raised the issue of the recommendation in favour of 'lookback', in the case of regular donors, in accordance with SNBTS policy. He asked what the purpose was to be served by going back to recipients of previous donations, given that "*In the present state of knowledge, donors who are only HCV seropositive donors without evidence of antigen may not be infectious."* There was a risk of causing unnecessary worry and possible distress. It could also give rise to litigation in certain circumstances [SCGV0000163_043]. A handwritten note on the document suggested that further clarification of the SNBTS policy was needed.

37.15. The minute also recorded a discussion on the guidance to be given in respect of sexual intercourse. It was noted that Dr Tedder "*has published a paper stating that spread in this manner is a definite possibility.*" Mr McIntyre noted that he had already written to Dr Metters on this topic.

37.16. This minute is discussed in the Penrose Report at paragraphs 35.72, 35.73, where Scottish evidence is recorded that concerns about possible litigation were not recalled as an issue; rather, feasibility and logistics had been the concern.

37.17. Lord Penrose continues:

> *"35.74 So far as the evidence available to the Inquiry discloses, the SHHD position around mid-1991 was that targeted look-back had been advised against by the ACVSB/MSBT. There was no evidence that it was a 'live issue' for administrators in advising Ministers."*

Decision-Making in England

37.18. The quotation above refers to the ACVSB/MSBT and therefore to the position in England. It has proved difficult to date, however, to confirm the exact nature of the decision-making exercise from the documents available. There is clear reference in the ACVSB and ACTTD minutes of February/March 1991 to a decision not to undertake a targeted look-back exercise, but there was

some discussion thereafter which has been difficult to follow to a conclusion, again to date.

37.19. Thus, on 13 August 1991, the UK Advisory Committee on Transfusion Transmitted Diseases (ACTTD) held its ninth Meeting. The topics discussed included the issue of a lookback. The Committee noted that the issue had been considered but not determined, whether by ACTTD or by ACVSB. It might have legal implications; the Committee saw a recent article on (7 August 1991) from the Independent suggesting that patients were likely to bring litigation based on delays in testing blood donations for HCV. It was felt that the matter should be considered. It was agreed that an ad hoc group should be set up to consider the implications of the article. Its membership was to consist of Drs Gunson, Cash, Contreras, Mitchell and Professor Tedder or Dr Mortimer.

37.20. A document entitled "*Extract from the Minutes of an Ad Hoc Meeting of the NBTS UK TTD*" – 13.9.1991 [NHBT0000075_086] suggests that a further meeting took place of the ACTTD on that date, i.e. 13 September. However, the document itself is merely a record of steps leading up to the introduction of testing in September 1991, rather than a record of discussions of any current issues. (It appears that the extract was shared by Dr Gunson with the ACVSB at its meeting on 21 February 1992; see [NHBT0000079_025], ACVSB 12/2; but not the full minutes of the meeting which are at [NHBT0000075_054]).

37.21. The Eleventh Meeting of the ACVSB (not the ACTTD) was subsequently held on 29 October 1991. The minutes record a discussion of the Compendium of Recommendations made by the UK ACTTD - circulated as ACVSB 11/2 [copy at NHBT0002876]. The Compendium discussed, in detail, subjects such as confirmatory tests for donors who screened positive, and the counselling of such donors and handling of their donations, including on such matters as sexual partners). On this, it noted that others may be at risk through a variety of situations including *"probably sexual contact, though it may not be logical to take any additional precautions with a long-standing partner. A condom should be advised with new sexual partners, while the necessary precautions*

for longstanding partners should be talked through. There is no evidence of risk associated with ordinary daily contacts within the same household."

37.22. Relevantly, the Compendium suggested that donors should be told that *"The recipients of previous donations will be traced and their Consultants or GPs informed"*. (p11).

37.23. According to the Minutes, Dr Gunson said that the results of the first HCV test trials were reported in the Compendium. The results of the extended trial had been sent to Manchester PHLS, where Dr Craske had produced a report, with recommendations relating to the steps to be taken in respect of (inter alia) donors whose donations repeatedly tested positive. *"Dr Gunson said that no decision had been taken as to a look-back study".* Dr Craske's report was to be circulated to members and their views invited [NHBT0000079_004].

37.24. A further meeting of the ACVSB was held on 21 February 1992. However, the minutes of the meetings held across 1992 - 1993 do not include reference to a look-back exercise. The further consideration of this topic is further addressed under the heading of the next question.

Reasons for the decision not to introduce 'Lookback' in 1991

37.25. Looking at the reasons given retrospectively, documents include the following. (It is to be stressed that these are accounts taken from documents written in 1994 or 1995 and may not be comprehensive, etc).

37.26. A subsequent paper written by Professor Cash in 1994 entitled "Recommendations of the Standing Advisory Committee on Transfusion-Transmitted Infection [i.e., the ACTTD] to the Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation (the MSBT) concerning the merits of adopting an HCV "look-back" policy" set out the reasons for the policy decision in 1991 thus:

> *"When anti-HCV screening of blood donations was introduced in September 1991, a look-back programme was not recommended. Doubts about the long-term effects of hepatitis C infection, coupled with*

> *the lack of an effective therapy for individuals so affected, appear to be the main reasons behind this recommendation. Furthermore, secondary infection of HCV to sexual partners and offspring appears to occur rarely. This is in contrast to HIV, where secondary transmission is more likely and effective counselling can reduce the likelihood of such transmission."* [PRSE0001236]

37.27. The evidence of Dr Young (Deputy Chief Medical Officer, Scottish Home and Health Department) to the Penrose Inquiry was that "*The reasons why the lookback exercise was not launched at the same time as anti-HCV testing was because there were gaps in the scientific and medical knowledge; for example the natural history of the disease was not fully known; there was no cure available; and no feasibility study had been completed.*" [PRSE0002894].

37.28. Added to this might be the observation recorded in the Penrose Report at paragraph 35.101 from Dr Gillon (SEBTS), although the extent to which this applied outside Scotland is not apparent from this source:

> "*35.101 Between March 1991 and a symposium in Edinburgh on HCV in October 1993 [See Chapter 35.120 - 125], the debate about targeted look-back was ongoing in the blood transfusion community. Dr Gillon thought that the debate probably took a back seat to some extent because the introduction of universal HCV testing of blood donations was a major preoccupation: the work of getting it in place, developing confirmatory procedures, dealing with false positives and counselling the patients who had tested positive would have kept people 'pretty busy'."*

37.29. When Dr Metters announced the national Look-Back Exercise on 11 January 1995, his briefing for supplementary questions stated:

> "*…until recently it was considered that look back to identify recipients of blood transfusion who are at risk would be technically difficult; and as there was no effective treatment, to inform people they were at risk, when there was nothing that could be done about it, would increase distress without any benefit. The long term effects of the disease were also unclear and it was not easily transmitted. This position is now*

clearer and a means of treatment has become available. There is now some confidence that many, but not all, recipients of blood infected with Hepatitis C can be identified and Interferon alpha has been licensed for the treatment of chronic hepatitis C. This may be of help to some people…" [NHBT0005855]

37.30. Dr Metters' views are also set out in:

(1) His letter to Dr Nicholas dated 17 March 1994 [DHSC0002546_019], discussing the topic of screening for asymptomatic HCV more generally. He noted that the total number of asymptomatic hepatitis C in the population *"would appear considerable"* but that the point of a screening programme depended on having an effective treatment to offer: *"There would be little point introducing a screening programme if there is no effective treatment"*; and

(2) His letter of 27 February 1995 to Dr Sheila Adam, Public Health Director, North Thame RHA [DHSC0003512_007]. This gave a detailed account of the history of the LBE in response to concerns that it had been *"jumped on you without warning"*. Dr Metters noted that the MSBT had been following the issue of Hepatitis C through blood transfusion for a number of years. *"Until recently"* it was considered that lookback would be technically difficult; and as there was no effective treatment, to inform people that they were at risk when there was nothing effective that could be done would increase distress without any benefit. *"The long-term effects of the disease were also unclear and it was not easily transmitted."* The position had changed with the licensing of Alpha Interferon, in particular and he referred to the recommendation of the MSBT decision of 15 December 1994.

Q.38 Consideration of lookback - September 1991 to December 1994

38.1. Records traced relating to this issue are to date limited. In particular, minutes of the meetings of the ACVSB/MSBT (the latter from October 1993) in 1992 – 1993 do not reveal any discussion of the issue of a look-back exercise.

There is some further material in the IBI's Dr Gunson presentation, paragraph 344.

38.2. The most comprehensive source identified to date is the Penrose Report, Chapter 35. In very brief summary only, this explains how:

(1) Despite the UK-wide decision not to introduce a targeted look-back scheme, Dr Gillon of the SEBTS did introduce one in his region (Lothian, the Borders and Fife), when HCV screening was introduced, assisted by the availability of the more accurate second generation ELISA tests. The exercise took place between 1 September 1991 and 29 February 1992;

(2) Scotland had a technological advantage in this regard: "*In using second-generation tests with ready availability of PCR testing, the SEBTS had exceptional technology, possibly unique in the UK, available to undertake look-back from the outset of donor testing in September 1991*." (paragraph 35.92);

(3) Knowledge of the SEBTS initiative (subsequently termed a "pilot scheme") was limited in Scotland, but a paper on the experience by Dr Yasmin Ayob, who had been working with Dr Gillon, was sent for publication in November 1993 and accepted for publication on 21 July 1994: see Transfusion Medicine 1994, pp269-272.[10] Based on this study (which resulted in finding 9 infected recipients who were still alive), the paper stated that *"... we estimate that around 3,000 patients may be alive and infected with HCV as a result of transfusion in the UK, based on the prevalence of HCV in Scottish blood donors and excluding haemophiliacs*." It spoke of the identification of these patients as a "*daunting task*" but one that there was a "*clear ethical responsibility*" to undertake, given the availability of "*potentially efficacious treatment*" in the form of alpha-interferon. It also noted that "*No recipient was alive and traceable more than 5 years after transfusion*".

[10] https://www.penroseinquiry.org.uk/finalreport/pdf/LIT0013802.PDF

(4) The issue of look-back received some attention at a HCV symposium held in Edinburgh in October 1993, where Dr Gillon gave a presentation. One of the speakers was Dr Dusheiko of the Royal Free Hospital, London, who gave a positive talk about the latest treatment for HCV. It is possible (although not certain) that Dr Gunson (Medical Director of the NBA) also attended.

(5) The issue of a LBE was then placed on the agenda for discussion at the SNBTS's Medical and Scientific Committee on 9 – 10 November 1993, although no definite decisions were reached and the logistical challenges were thought to be greater in areas of Scotland outside of the SEBTS.

(6) The outcome of these events was a letter from Professor Cash to Dr Gunson on 18 November 1993, copied to others who sat on the MSBT. It encouraged the issue of lookback to be considered by the MSBT. Furthermore, discussions about the introduction of a look-back exercise in Scotland, including within SHHD, began.

(7) Chapter 35 contains detailed accounts of the discussion within SHHD, including with regards to the desire to consult with DH in order to create UK-wide policy. The minutes of the meeting of the MSBT, chaired by Dr Metters, of 29 September 1994, record a discussion of the issue of a look-back exercise. They record that Mr Tucker (SSHD) stated *"approaches to institute HCV look-back in Scotland had been resisted, and it was important that a UK wide approach was adopted"*. Mr Tucker told Lord Penrose that it was not accurate to say that SHHD was "resisting" attempts to introduce a HCV look-back, but it appears that there was a desire for a UK-wide approach to be agreed.

38.3. Whilst full details in respect of Scottish decisions are contained in the Penrose Report's Chapter 25, the issue of consideration of a Look-Back exercise by DH in 1994 onwards (by which time the issue was receiving substantive consideration) is considered further in answer to Question 40, below.

Q.39 Screening for women who had received Anti-D immunoglobulin

Background to the Irish decision

39.1. The documents show that on 21 February 1994, the Irish Blood Transfusion Service Board ("BTSB") established a national screening programme for Hepatitis C in women with Rh Negative blood type who had received Anti-D from 1970 [DHSC0002546_036; DHSC0003550_092].

39.2. The decision of the Irish health department followed research by the BTSB, which in January 1994 revealed that a disproportionate number of Rh negative female donors had antibodies for Hepatitis C. It was suspected that Hepatitis C could have been contracted through the Anti-D product, in particular, via batches of the product produced in 1977 [DHSC0003550_092].

The DH's response

39.3. After the Irish situation came to light Dr Rejman was tasked with producing a background Note and Line to Take. He circulated a draft minute on 23 February 1994 [DHSC0003550_085].

39.4. Dr Nicholas responded on behalf of HP(A) and HP(M). He raised three matters. First, he identified the need to reassure those mothers in the UK who had received Anti-D between the 1970s and 1980s on the basis that they would have received intramuscularly administered Anti-D. Secondly, he appears to have recognised that there would have been Rh negative mothers residing in the UK who had babies in Ireland during the period in question. Thirdly, he queried if any of the 1977 batches of Anti-D had been imported for use in the UK [DHSC0003550_085].

39.5. In respect of Dr Nicholas' third query, it appears that on 22 February 1994, the Department had been informed by the NBA that none of the Anti-D manufactured in the Republic of Ireland had been imported to England [DHSC0002546_034].

39.6. The final version of Dr Rejman's Note was sent to the CMO's Private Office on 25 February 1994. The Note indicated that it must have later transpired

that a very small number of patients in the UK had been given Irish intravenous Anti-D for reasons unconnected with pregnancy. The content of Dr Rejman's Note is set out in more detail in Sir Kenneth's statement.

39.7. Dr Rejman's Note was concerned also with an issue that had come to light in relation to a separate immunoglobulin product, called 'Gammagard'. This product was recalled by the manufacturer, Baxter, in early 1994 after it was linked with hepatitis C infections in Spain and Sweden.

39.8. Dr Nicholas commented on Dr Rejman's Note within a Minute dated 25 February 1994 [DHSC0002501_083]. He identified the following two categories of enquiry:

(1) from women who had received Anti-D in the UK; and

(2) from women living in the UK who gave birth in Ireland after 1969.

39.9. In respect of the first category of enquiry, it was determined that GPs would be advised to reassure their patients that they were highly unlikely to have received the Irish product and on the safety of intramuscularly administered Anti-D. On 4 March 1994, Dr Nicholas prepared a 'Draft Note for GPs' [DHSC0002546_023].

Testing Rh negative women who had given birth in Ireland

39.10. In respect of the second category of enquiry, Dr Nicholas commented:

> *"it would be difficult to suggest that where a risk has been identified, rhesus negative women in England and Wales who gave birth to a baby in Eire should not have the same opportunity to be tested as those in Eire, and as currently publicity on this issue in England has been little requests may be limited, and if news is passed on by word of mouth protracted".*

39.11. Dr Walford issued advice to PHLS' directors in favour of testing where a request was made by GPs which fitted certain criteria. This advice was set out by Dr Diana Walford in a letter addressed to PHLS directors dated 25 February 1994 [WITN3430133].

39.12. On 7 April 1994, in a letter sent by Dr Metters to Dr Tedder (UCL Medical School), it was said that women who received the Irish Anti-D and presented for testing, would be tested [WITN3430134]:

> *"It is reasonable that any rhesus negative woman who was given intravenous anti-D in Eire, who presents for testing in the UK should indeed be tested, and PHLS Directors have been informed accordingly. We have not heard that local transfusion centres in the UK have been inundated with such requests".*

Publicising the issue to Rh negative women who gave birth in Ireland

39.13. On 3rd March 1994, a Line to Take was circulated within DH, which said as follows [WITN3430135]:

> *"We have informed our Public Health Laboratory Service Laboratories (52 in number) of the problem. [If pressed, M(H) should avoid discussion as far as possible. The Republic is asking for further steps, which we would at present not be keen to take; the latest requests are very recent and need to be examined by medical colleagues. If we wrote to GPs with more information, as the Republic seems to want, the letter could be used by women in litigation against the Irish Government. The more public debate occurs, the more our public line will embarrass the Republic's Government since absolute reassurance must be given to British women. M (H) could say in private, if essential :-] We will consider thoroughly any requests the Irish Republic makes for further action. However, we all need to appreciate that publicity will make the position worse for the Republic's government".*

Q.40 Initiation of the Look Back exercise in 1994

40.1. As summarised in response to Question 38 above, a look-back exercise, termed a "pilot exercise" was carried out in Scotland [DHSC0003555_173], by the East of Scotland BTS, and was discussed more widely from November 1993 onwards. The outcome of this pilot, as reported in a Minute of 9

December 1994 (see below) was a SNBTS estimate that some 300 or more patients were estimated to have been infected with HCV through blood transfusions in Scotland; about 150 or so would still be alive (as about 50% of transfusion patients would die within 2 – 3 years of the transfusion as a result of the illness or event that necessitated the transfusion). In addition, there were some 5,000 or so HCV positive patients in Scotland, infected due to other causes (mainly drug use).

40.2. On 10 February 1994, the MSBT met for the second time [DHSC00020691_169]. There is no obvious mention of the issue of lookbacks in the Minutes. According to the Penrose Report at paragraph 35.162: "*The minutes of that meeting have not been recovered. But it is clear that look-back was referred to an advisory committee, the Standing Advisory Committee on Transfusion-Transmitted Infection to the MSBT (SACTTI). The SACTTI reported to the ACVSB/MSBT on 29 September 1994 when Dr Robinson presented their paper.*" Members of the SACTTI included Professor Cash and Dr Gillon.

40.3. Before that, on 21 June 1994, an Editorial Review article from the International Journal of STD & AIDS on sexual transmission of HCV was published, looking at the risk to sexual partners. This concluded that most at risk were sexual partners of HCV-infected individuals. The lifetime risk was small but the subsequent risk of serious liver disease was high (20% lifetime risk of cirrhosis when infected with HCV). Regular testing of partners should be undertaken.

40.4. On 5 August 1994, following the referral to the SACTTI, an ad-hoc assembly of experts met to discuss the feasibility of initiating a look-back policy to identify, test, counsel and if necessary refer surviving past recipients of blood components from donors later found to be anti-HCV seropositive after testing was introduced in September 1991. A large number of medical experts and attendees from the national blood authorities, including Dr Robinson, attended.

40.5. A subsequent paper from Professor Cash entitled "Recommendations of the Standing Advisory Committee on Transfusion-Transmitted Infection [i.e., the

UK SACTTI] to the MSBT concerning the merits of adopting an HCV "look-back" policy" set out its deliberations, including knowledge of the disease, its progression and treatment options. The comments on the decision not to undertake a LBE in 1991 have already been set out above under Q37.24. The paper referred to evidence from pilot studies in Edinburgh in discussion of whether there should be time limits on the look-back exercise. It stated that "*Making a number of assumptions, it is probable that implementation of a look-back programme for England and Wales will involve a caseload of approximately 3,000 for England and Wales.*" The overall recommendation was that there was a *"serious case for considering a look-back policy for HCV"*. The group recommended that the matter be considered further by the Hepatitis Advisory Group and the MSBT as soon as possible.

40.6. A SNBTS document dated 23 September 1994 [PRSE0002454] outlined the potential shape of a Look-Back Exercise in Scotland. The pilot studies continued in Scotland, assessing the impact for SNBTS. DOH was involved in discussions, and it was hoped to have an agreed position for a UK wide exercise by the end of the year, it was stated.

40.7. The matter was considered in England and Wales in September by the MSBT. The minutes of the meeting held on 29 September 1994 record discussions of a LBE exercise and its pros and cons, including reservations on the effectiveness of Interferon. There was a request for comments to be submitted by members in the next three weeks and key clinicians (Drs Zuckerman, Robinson and Gorst) were to form the core of a sub-group to consider these in time for the next meeting [PRSE0003670].

40.8. The UK SASCTTI met on 19 October 1994 [NHBT0010970]. The minutes show that the committee had *"several reservations"* about the recommendation of the ad-hoc group. It noted that MSBT was to set up a sub-group to consider the issue, *"with special regard to younger patients"*. The minutes continue:

> *"Considerable discussion followed concerning the actual likely therapeutic benefits for those patients identified as infected and the cost-benefit vs the need for 'openness', the lack of which engendered*

much criticism with regard to HIV, i.e., do the medical authorities have the right to decide whether patients should or should not know they have been infected, regardless of cost-benefit consideration, potential efficacy of therapy or age of recipients? A 'duty of care' was also perceived."

40.9. The minutes also record the need for further research on a number of issues, including sexual transmission of HCV.

40.10. On 17 October 1994, Dr Gorst (Consultant Haematologist, Lancaster) wrote to Dr Robinson (Medical Director, NBA) about the topic of a LBE [NHBT0005864]. He had read the *"SNBTS and the SACTTI papers"* and commented that he was *"rather on the side of doing this"*, asking whether he was right to think that the MSBT was *"rather lukewarm"*. He commented on the logistical challenges, which were *"large but not outfacing"*. Treatment was difficult – he noted that Interferon was *"unlicensed, not without side effects, expensive and of unproven efficacy in this situation."* He queried whether treatment could be set up as a trial but felt that this was unlikely to be viable.

40.11. A letter from Dr Follett (Microbiology Reference Unit, Glasgow) to Dr Robinson (Medical Director, NBA) dated 31 October 1994 discussed this letter from Dr Gorst [NHBT0005862_003]. Dr Follett discussed the treatment that would need to be offered if individuals were to be contacted who did not know they had a serious medical issue; they needed to have access to *"the best and, most importantly, the same treatment throughout the UK. At present, this does not happen with donors who are found HCV positive on screening.*" He raised issues about the detailed information that he felt should be made available to those identified by the exercise.

40.12. On or about 1 November 1994, Alpha Interferon was licensed for use in treating HCV, with an approximately 25% success rate [DHSC0003971_008 ; date is from WITN4486087].

40.13. A few days later (3 November), the MSBT subcommittee met to discuss the merits of an HCV LBE policy. Attendees included Professor Zuckerman, Dr Angela Robinson and Dr Gorst. The overall view of its merits was positive, but the group noted the importance of ensuring a co-ordinated approach and the

ethical issues relating to contacting those whose mental wellbeing might be compromised and who might not benefit from treatment. The Committee noted the uncertain prospects and low success rates of treatment with Interferon. Its members were concerned by the ethical implications of identifying those who might not benefit from treatment: *"i.e., in our efforts to identify infected recipients who may or may not benefit from treatment the mental wellbeing and quality of life of all such recipients infected or uninfected could be seriously compromised*" [see the Draft report of the sub-committee at WITN3430136].

40.14. Comments were received from clinicians such as Dr McMaster [NHBT0005868_002].

40.15. On 9 November 1994, Professor Cash (SNBTS) wrote to Professor Petrie (Professor of Clinical Pharmacology, Aberdeen) [DHSC0003555_236], referring to the outcome of a special meeting of the SNBTS on 8 November 1994 that Professor Cash had convened. He noted that the SNBTS anticipated developing a lookback programme for 1995. At the meeting, colleagues had been unanimous in supporting this but felt that guidelines were needed to harmonise the clinical approach to patients throughout Scotland and Northern Ireland. Although these would be targeted towards LBE patients they would, of course, also be relevant to the large group of patients with HCV related liver disease, not related to blood transfusion. Professor Cash outlined the potential members of a group to produce such guidelines.

40.16. On 16 November 1994, a briefing on Hepatitis C was sent to the Secretary of State (Mrs Virginia Bottomley). It had a wide list of copyees including the CMO's Private Office [DHSC0041152_216; DHSC0041152_217; DHSC0041152_218; DHSC0002548_159]. It included a short paper on the disease of HCV from Dr Nicholas, as well as a paper from Dr Rejman commenting on the settlement of the HIV litigation. The submission set out information on the current call for financial support or compensation for HCV sufferers. It noted the introduction of routine screening of donated blood for the presence of Hepatitis C, from 1 September 1991. Discussing the numbers

of those possibly affected, it noted that the MSBT had asked a small group of its members to examine claims made by the Independent newspaper on 16 November 1994 and to report back. *"This will enable a view to be established on the viability and desirability of a 'look back' exercise to trace, treat and counsel those who may be affected."* There was no request for ministerial action.

40.17. On 6 December 1994, Dr Nicholas sent a note about a programme which Panorama was preparing on the topic of Hepatitis C. He was not clear whether a LBE would be covered by the programme [WITN3430137].

40.18. On 7 December 1994, a draft of a submission to Scottish Ministers was sent to the DOH for comment; the issue for Ministers was whether they would wish to maintain a UK-wide approach [WITN3430138]. Mr Kelly responded on behalf of DOH to the SHHD the next day and stressed that the only way that the issues could be approached was on a UK-wide basis. He noted that a decision should be taken after the MSBT meeting of 15 December 1994. A covering note from Dr Metters noted that the NBA was looking into the logistics of a LBE and that if they advised one on 15 December, *"we can get Ministers to agree quickly thereafter"* [WITN3430139].

40.19. The Submission from Mr Tucker (Assistant Principal, Scottish Office[11]) was sent on 9 December to the Private Office of the Secretary of State for Scotland (the Rt. Hon Ian Lang) and the Minister of State for Health and Home Affairs (Lord Fraser). The latter appears to have been the substantive decision-maker. The submission [DHSC0003555_173] was further copied extensively, including to Dr Metters and other DH officials. It informed Scottish Ministers that a Panorama programme would be critical not only of the timing of the HCV screening programme in 1991 but also of the failure to conduct a lookback exercise to trace patients who might have been infected before testing was introduced. It set out the Scottish appetite to start a look-back exercise as soon as possible in order to minimise future legal challenges on

[11] Mr Tucker gave a statement to Lord Penrose [PRSE0001266] explaining that he was the administrative head of the Division (in the Scottish Office) with responsibility for formulating and coordinating policy advice to Ministers based on the view of the professional experts.

action not taken. There had been agreement that Health Departments should wait for the recommendation of the MSBT sub-group and act on a UK basis. But the paper asked the Minister whether *"in the light of advice from SNBTS and Departmental medical and legal advisors he wishes to give agreement to the look-back exercise proceeding in Scotland in advance of the rest of the UK."* It noted that SNBTS had advised the exercise was practicable, and that the legal advice was that if so, the Secretary of State had a duty to undertake that exercise as soon as possible; failure or delay might lead to legal liability. A handwritten note on the document records that as of 19 December there had been no response from Lord Fraser (Secretary of State for Scotland).

40.20. On 15 December 1994, the MSBT formally recommended to Ministers that there should be a Look-Back exercise for blood transfusion recipients infected with HCV prior to Sept 1991. The minutes record that although the meeting was chaired by Dr Metters, the CMO attended for the discussion of the Look-Back (or possibly "part" of it – the note is ambiguous).

40.21. It was noted that the feasibility of a LBE had been demonstrated by a study in Scotland (East of Scotland Blood Transfusion Service) and Alpha-Interferon was now licenced in the UK. It was proposed that a Working-Party should be set up, to determine the processes to be followed. A duty of care was owed to those infected through NHS treatment, so procedures should be put in place to identify those at risk. Whatever was done should be done equally and uniformly throughout the UK. The minutes[12] record detailed debate on how a LBE would be conducted, but the CMO stated: "*The CMO said that in the public interest an urgent decision on a UK wide basis was needed on the matters of principle. The detail was important, but less urgent".*

40.22. In the wake of this recommendation, a submission drafted by Mr Scofield went up to the relevant Minister with responsibility for blood policy (Mr Sackville, the Parliamentary Under Secretary of State) on 22 December 1994, recommending that a LBE should be undertaken. The Ministerial and other responses to the MSBT recommendation are set out in greater detail under Question 41, below.

[12] [PRSE0003635]

40.23. The place of the Panorama Programme in this history was subsequently set out thus by Dr Metters in his letter to Dr Sheila Adam of 27 February 1995 [DHSC00031512_007]:

> *"Ministers agreed to this [ie the MSBT recommendation] in early January but it was necessary to get all four Territorial Health Departments on board in order to mount a UK-wide exercise.*
>
> *We were also being hounded by the Panorama programme that had got wind of what was being discussed and was seeking to put pressure on us publicly to go down this road. It was essential that we announced the exercise to Parliament and this was done by means of a Parliamentary Question 13 January … "*

40.24. The view that Dr Metters took of the programme that ultimately aired on 16 January 1995 can be seen in a letter sent by him to the Editor of the Panorama Programme "Bad Blood" that same night. Dr Metters stated that the allegations made would have needlessly alarmed many thousands of people who had received blood transfusions that carried no risk of Hepatitis C whatsoever. About 1 in 2000 blood donors had been found to have Hepatitis C since screening began in 1991 and the best estimate was that some 3000 transfusion recipients now alive in the UK may have been affected, giving a risk that was substantially less than the programme implied. The letter set out the reasons for past actions or decisions, stating that until Interferon alpha 2 was licensed in the UK there was no treatment available; to have informed people that they were at risk but nothing could be done about it would have increased anxiety without benefit. The letter set out the LBE decision and that no other country has yet committed itself to such a specific exercise on Hepatitis C [NHBT0005797].

40.25. A copy of the letter to Panorama was sent to Dr Calman's Private Office, amongst other copyees [DHSC0032203_086].

Q.41 The establishment of the HCV lookback exercise

41.1. The Inquiry has asked for chronological account of how the HCV lookback exercise was established from the decision to undertake the exercise in

December 1994 to the announcement on 11 January 1995, identifying each individual decision maker involved.

41.2. Copious documentation dating from late December 1994 – January 1995, evidence the establishment of the LBE and its announcement on 13 January 1995. Not every document will be referenced as a result.

41.3. A submission to Ministers (and specifically to the Minister of State for Health) was drafted by Mr Scofield in the wake of the MSBT recommendation of 15 December 1994. The records show the involvement of Dr Metters as leading on the medical aspects of the submission, although overall decision-making rested with Ministers. Dr Metters provided comments on the draft submission on 21 December 1994 (copying in the CMO's Private Secretary, Dr Harvey). [DHSC00032203_154]. Further comments were provided on 22 December by Mr Shaw [DHSC00032203_151], including a concern that the Department was unprepared to face the public campaign against it; and by Mr Paley [DHSC0032208_154]. The need to identify the costs of the steps to be taken, including their implications for treatment costs, was noted. Dr Nicholas provided detailed comments on the medical aspects of the submission, including infection and clearance rates [DHSC00032203_153].

41.4. The amended submission (following receipt of comments) drafted by Mr Scofield went up to the relevant Minister with responsibility for blood policy (Mr Sackville, the Parliamentary Under Secretary of State, or PS(H)) on 22 December 1994, recommending that a LBE should be undertaken. The submission was copied to the CMO's office, amongst others. ([DHSC00032203_153] (submission and copy list); [DHSC0002501_116] (Annex A); [DHSC0003555_228] (Annex B); [DHSC0032208_161] (Annex C)). The submission set out the proposals for the LBE. It noted the timetable for the Panorama programme (a Ministerial statement was planned) and that writs claiming compensation for HCV infection had been taken out against a former RTC. The government's view was that although patients had been infected, there had been no negligence and there were no plans to introduce a financial support scheme.

41.5. Meanwhile Scotland was pressing ahead, without waiting for a formal decision in London upon a LBE in England and Wales. Lord Fraser (Minister of Home Affairs and Health, the Scottish Office) wrote to Mr Sackville to this effect on 22 December 1994 [PRSE0001781], stressing that Scotland had a duty to press ahead if it had the capability to do so.

41.6. On 4 January 1995, a letter was sent by Mr Sackville to Lord Fraser, setting out the Ministerial approval of the MSBT recommendation for a LBE. Dr Metters as DCMO would chair a Working Party to determine the process to be adopted. Mr Sackville hoped that Scottish experts would contribute and that the LBE could proceed on a UK wide basis [DHSC0032208_136]. Lord Fraser responded positively by a letter dated 9 January 1995 [DHSC0002551_110], discussing the co-ordination of efforts that should take place, although he noted that the SNBTS was already under instruction to proceed. He was content for the announcement to be made by means of an inspired PQ on 11 January 1995.

41.7. Also under discussion was a Ministerial contribution to the Panorama programme. See:

(1) Minute dated 20 December 1994 from Mr Scofield [DHSC0003544_064] noting that PS(H) had decided not to appear on the Panorama programme (9 January 1995) but to submit a written statement answering the three points raised by the programme makers, and asking for notes to assist on this.

(2) Response from Dr Rejman dated 22 December, enclosing a note on decisions about the timing of screening of blood for HCV and a background note ([DHSC0002548_061]; covering note, enclosing summary accounts of the background to the introduction to screening at [DHSC0002551_217] and [DHSC0003555_224]).

(3) A statement from PS(H) was faxed to Panorama on 23 December 1994 [DHSC0003555_220: minute] and [DHSC0003555_087] (statement from Mr Sackville, Parliamentary Secretary for Health). The statement included brief reference to the recommendations of the MSBT and the need for follow-up on a UK-wide basis. In his minute, Mr Hollebon

(Private Office, Mr Sackville) noted to Mr Kelly that PS(H) had made some minor amendments to the statement and it had been faxed to Panorama. If Ministers agreed to the package of measures set out in Mr Scofield's submission of 22 December, the statement could be strengthened to include any new material [DHSC0003555_220].

41.8. Following Ministerial approval of the recommendation for a Look Back Exercise, various administrative matters were put in motion. To summarise the documents:

Date	Action
3.1.1995	Minute from Mr Scofield to PS(H)'s Private Office (copied widely including to the CMO's Private Office) [DHSC0003555_084, misdated 1994]: Mr Scofield noted that his understanding that PS(H) had agreed to the submission on the LBE and there is therefore no question of any delay by the DH or any justification for the Scots *"going it alone"*.
3.1.1995	Minute from R. Scofield to Dr Metters on the steps needed to be taken [DHSC0003555_083, mis-dated 3 January 1994]. This sought to set out why Scotland should follow a UK-wide approach.
4.1.1995	Minute from Mr Sackville's Private Office to Mr Mogford, PS to the Secretary of State (Mrs Bottomley), copied to Dr Calman's Private Office: informing the Secretary of State that PS(H) has agreed that there should be a LBE as recommended in Mr Scofield's submission of 22 December. An announcement that there should be a UK-wide exercise will be made on 11 January. The pressure from the Panorama programme has eased as it has been rescheduled for a later date. But it was important to seize the initiative by making an announcement as soon as possible. PS(H) has agreed that a helpline should be set up, a letter sent to GPs, there should be an inspired PQ and that the CMO and Dr Robinson (NBA Medical Director) should front a press briefing [DHSC00032203_133].
4.1.1995	Letter from Mr Sackville to Lord Fraser (Minister of Home Affairs and Health, the Scottish Office) announced the Ministerial approval of MSBT recommendation for a LBE. Dr Metters as DCMO will chair a Working Party to develop the arrangements. Mr Sackville hopes that Scottish experts will contribute and that it can proceed on a UK wide basis, and avoid piecemeal approach by Scotland moving more quickly [DHSC0032208_136].
4.1.1995	Comments on the R. Scofield Minute from Mr J. Shaw

	(NHSME), suggesting that a Lookback announcement could be included in the statement to be given to the Panorama programme. Noting the need to make adequate arrangements handling for viewers' queries following the Panorama programme [DHSC0003555_197].
4.1.1995	Minute from Dr Rejman to Dr Metters enclosing early drafts of the Q & A for the public helpline and the draft leaflet for GPs [DHSC0003555_190].
4.1.1995	Meetings with Mr Sackville and the NBA, attended by Mr Scofield. An 'Action Plan' was drawn up [DHSC0003555_062]. The Action Plan (see [DHSC0003555_087], version dated 6.1.95) set out such matters as the membership of the ad hoc Working Party, drawn from members of the MSBT and ACH to draw up guidance and procedures for the LBE and counselling and options for treatment, together with any other action which should be taken to satisfy Ministers' duty of care. The full membership is set out at [DHSC0003555_090].
4.1.1995	Invitations sent out to the proposed Working Party members, eg: Dr Angela Robinson [NHBT0005851_002]: Dr Howard Thomas [DHSC0002551_168].
4.1.1995	Briefing from DH to the Treasury, informing it of the Department's response to the issue of HCV infection, in advance of the Panorama programme scheduled for 9 January [DHSC0002422_114]. Notes that a campaign is being mounted, DH intends to take Counsel's advice on whether a case in negligence exists. Attempts to quantify the treatment costs.
5.1.1995	Minute from Mr Scofield to Mr Keith Paley (DH) commenting on the funding for and costs of the LBE Action Plan. NBA will expect further funding for their part in the exercise and *"we should not begrudge them"*. Costs are smaller than the much greater costs of running out of blood if donors become scared [DHSC0032208_129]. A further note from Mr Scofield to Mr Jim Furniss (P3, DH) sends the Action Plan, commenting that *"Your friends at Roche are probably behind the huge pressure that is building to get Interferon prescribed for everyone who is HCV positive"* [DHSC0003555_119].
5.1.1995	Further Planning Note from Schofield to Dr Metters and wide copyee list [DHSC0032203_128, dated 5/1/1994, but must be 1995]. Enclosed a detailed 'Action Plan'. All efforts would be made to ensure that the Scots joined the UK-wide programme but irrespective of their decision, the exercise would be announced on 11 January.
5.1.1995	Minute from Mr Scofield to Dr Rejman, commenting on the latter's first draft of the PG leaflet and Q&As for those

	staffing a switchboard to answer questions from members of the public [DHSC0002551_187].
5.1.1995	'Action Plan' sent by Mr Scofield to George Tucker (Scottish Office): planning for co-ordination with Scotland; copied to Wales and NI as well.
5.1.1995	Comments sent by Mr T. Kelly on the Q & A Briefing for the Helpline prepared by Dr Rejman [DHSC0003555_189].
5.1.1995	Comments sent by Dr Nicholas on the Q & A Briefing for the Helpline prepared by Dr Rejman [DHSC0002551_192]. Includes comments on the risk of sexual transmission to partners: a real albeit small risk; serological studies of sexual contacts of patients with chronic hepatitis C infection have found evidence of infection in 0 – 30% of patients' sexual partners or spouses.
6.1.1995	Mr R. Scofield prepares a *revised "Action Plan" setting out the steps to be taken by all parties [DHSC0003555_155]. He sends the first draft of a Press Statement to Dr Metters (DCMO) – press briefing will be for media and medical correspondents. Briefing Pack being prepared. [DHSC0003555_068].
6.1.1995	Minute from Dr Metters to Dr Rejman enclosing a redraft of the letter to GPs [DHSC0003555_068]
6.1.1995	Minute from Mr Paley to Mr Scofield, discussing a conversation between the two of them on whether there was *"scope to duck the issue – and preserve our PES position – over the undertaking to 'treat' those infected with Hepatitis C through blood transfusions…"*. Mr Paley notes Mr Scofield's understanding that there is a 'duty of care' to do what can reasonably be done, including a duty to treat (albeit as appropriate and within available resources and with a view to other priorities). As a result, the undertaking to treat had been included in the inspired PQ and draft press notice. Mr Paley notes the consequences: the DH will not be able to mount a PES case to recoup the costs of treating 6000 or so affected individuals and it will have to be met as a burden on existing regional allocations [DHSC0002422_122].
6.1.1995	Letter from the Welsh Office CMO (D.J. Hine) sets out Welsh agreement to the LBE and proposed Welsh participation in the Working Party [DHSC0003555_088].
9.1.1995	Comments from a Scottish perspective (Mr McIntosh) on the GP letter, notes, draft Press Release and PQ [DHSC0003555_113]. Notes, in relation to the GP letter, that it is important not to give the impression that all recipients – it will only be possible to take all reasonable steps to do so, but as a result of the length of time, the hospital records will not be adequate to achieve 100% success in tracing patients [DHSC0003555_113, also fax

	cover sheet at DHSC0003555_112 sending the comments on to Mr Scofield]
10.1.1995	Note from Mr Scofield to Dr Rejman, Dr Nicholas and Mr Kelly on final preparations for the press conference and also further consequential issues, including help for haemophiliacs with HCV and other groups infected by routes other than blood transfusions [DHSC0003555_076]. The Chair of the Haemophilia Society is to be briefed on the LBE.
10.1.1995	Policy note from Mr Scofield to Dr Metters enclosing messages to be sent to GPs and some consultants on the LBE announcement. It suggests that a CMO letter to 140,000 medical practitioners would be overkill for the time being and poorly targeted [DHSC0003555_104]. Mr Scofield notes that a HSG *"is usually employed only when we have an instruction to give the Field. This is more passing on information"*. It would be better timed when the Ad-Hoc WP has put out its guidance.

41.9. The announcement of the LBE was made via an inspired Parliamentary Question on 11 January 1995 [NHBT0005796]. This noted that the planning for the process was in hand; the actual exercise would follow once that was completed.

41.10. The PQ was immediately followed by a Press Conference with a wide list of invitees [DHSC0002502_016] at which Dr Metters (DCMO) and Dr Robinson (Medical Director NBA). In particular, the papers show how Dr Metters was sent [see DHSC0002551_002] a series of documents including:-

(1) A copy of the Press Release [NHBT0005792];

(2) The "Lines to Take" [DHSC0003555_130] and notes for supplementary questions [NHBT0005855];

(3) Note on the administrative arrangements [DHSC0003555_003; WITN3430140 (briefing arrangements)];

(4) There is a copy of the additional information for GPs at [DHSC0003555_014] and the script for the Helpline at [DHSC0041441_149];

(5) A draft of the Opening Statement from Dr Metters [NHBT0005856].

41.11. An announcement of the decision was then sent to all Directors of Public Health by Dr Rejman, from the CMO's Office (with a letter from Dr Metters, Additional Information for GPs and Helpline Questions and Answers). The Directors were asked to cascade the information to (a) all GPs; and (b) appropriate hospital consultants including: haematologists, consultants in haemophilia centres, general physicians, general surgeons, gynaecologists, hepatologists, gastro-enterologists and consultants in infectious diseases [HHFT0000002_002].

Q.42 My involvement in the Lookback Exercise

42.1. The Inquiry has asked where the figure of 3000 potentially infected patients derives from. As to this, see:

(1) The published report of the look-back exercise carried out in 1991/92 in South East Scotland (see the Penrose Report, Chapter 35);

(2) Professor Cash's report from the ad-hoc meeting of the UK SCTTI in August 1994, which estimated the likely numbers involved at 3,000; see Question 37 above;

(3) The Draft report from the MSBT Sub-Committee: "*Based on previous experience of implementing an HIV Look-Back programme and on the SNBTS pilot study of an HCV Look-Back programme, the best estimate is that up to 3,000 recipients in England and Wales could have been exposed to HCV antibody positive blood and are therefore at risk of contracting transfusion transmitted HCV liver disease. Current evidence suggests that the likelihood of transmission by HCV infected blood is high.*" The document went on to discuss post-transmission 5 year survival rates, which could mean that not all those patients would have survived, but the higher figure of 3000 potentially affected patients appears to be consistent with the overall numbers of those who it was estimated might have been at risk of infection from transfusions.

(4) The report upon the implementation of the LBE drafted by Dr Metters, on 5 February 1996, below at Question 56. The report suggests that the estimate of 3000 proved to be broadly accurate.

Wording of the PQ:

42.2. The Inspired PQ of 11 January 1995 ultimately read:

> *"The Government has accepted the recommendation of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation with a look back exercise should be undertaken with a view to tracing, counselling and treating those who may have inadvertently been infected with Hepatitis C through blood transfusions given in this country …"* [DHSC0002551_030]

42.3. In relation the intention with respect to those who might have been infected via blood transfusions, the PQ said that the exercise was being *"undertaken with a view to tracing, counselling and treating…"* those infected.

42.4. Documents relating to its drafting include comments from Mr McIntosh (SNBTS, General Manager) on the press release and accompanying documents: [DHSC0003555_113]. The writer was concerned that the public and GPs etc would not be given a misleading impression that all patients would necessarily be contacted. There is a note from Mr Kelly to Mr Sackville's office confirming that Lord Fraser had asked for changes to be made to the PQ – the Scottish Office had asked that it should not say "undertaken to trace", but that "rather it would be more accurate to say 'undertaken with a view to tracing ….' etc." Mr Kelly explained that there were no objections and that the changes would be made [see DHSC0002551_030]. The changes to the PQ that Lord Fraser/Mr McIntosh had recommended were duly made.

42.5. The letter to GPs and also the Supplementaries for the briefing for the Press Conference addressed the issue of whether the tracing exercise might not be 100% successful. The latter stated: *"... Not all patients at risk will be picked up. Some will not be picked up because infected donors have not given blood since September 1991. In others it may be because of difficulty in tracing hospital records"* [NHBT0005855].

Q.43 Concerns raised after the announcement of the lookback exercise

43.1. The Inquiry has asked what concerns were raised with the DOH about the LBE, and what steps were taken to address them.

43.2. The issues that were raised, or the challenges faced, can be divided into a number of areas:

a. Patient / public concerns;

b. Funding, both for the LBE itself and the related effects including the costs of treatment;

c. Practical arrangements, including the speed of implementation; and

d. Any other issues arising.

43.3. The documents relating to these issues are addressed briefly below.

Patient / Public Concerns

43.4. The announcement of the LBE and its implementation had the potential to affect and to worry those who had received blood transfusions before September 1991 and became worried by the risk of infection. Thus the meeting of the LBE WP on 24 February 1995 [WITN3430141] noted that there had been well over 12,000 calls to the Help Line, although they were now tailing off.

43.5. Advice was given on 13 January 1995 by the PHLS (Colindale) to PHL Directors that anti-HCV testing was an appropriate response to patients with a history of a blood transfusion prior to September 1991 and abnormal liver function tests; GPs should try to establish these things [NHBT0002757]. This advice was later corrected, normal LFTs being no assurance of lack of HCV infection (see the letter from Dr Hewitt dated 26 January, [NHBT0019915]).

43.6. A further letter was apparently sent by Dr Walford (Director of the PHLS) on 20 January although no copy has been traced. But on 23 January 1995, Dr Metters replied to Dr Walford. He noted that PHLS laboratories were now

receiving requests for Hepatitis tests from individuals who were concerned that they might have been infected from a previous transfusion and discussed how the results of such tests could be linked to the information held by a transfusion centre, with patient consent, so as to enable 'matching' with the results of the LBE [NHBT0036689]. Further information about the steps to co-ordinate the two processes is set out in a letter from Dr Hewitt (Colindale North London Blood Transfusion Centre) dated 26 January 1995 [NHBT0019915].

43.7. It is apparent that the PHLS conducted tests for such individuals as a result of these patient/GP requests, with numbers increasing: see the letter of 3 March 1995 from Dr Walford (then its Director) [DHSC0003536_099], concerning the funding of additional testing by the NHS.

43.8. According to a minute dated 19 January 1995 from Dr Nicholas to Dr Metters, Mr Scofield and Dr Rejman, it was not merely the announcement of the LBE that had caused anxiety, but the Panorama programme screened on 16 January, which had generated considerable anxiety [DHSC0041441_173, first page only attached]. Its own helpline appeared to be difficult to get through to and had now stopped. When members of the public who were worried could not get through, they turned to their GPs and were requesting a HCV test. GPs were responding inconsistently and questions were being asked by hospital consultants and PHLS about who was going to pay for such tests. Patients were also seeking guidance from doctors other than their GPs, which suggested that future DOH guidance might require a wider circulation. An impression had been created following the Panorama programme that archived samples would be tested and people were worried about being missed out [DHSC0041441_173].

43.9. Information had been given to GPs on 11 January. This did not address the question of whether or not worried patients should be offered tests, but dealt with the medical background and risks more generally. It advised GPs to consult other local specialists (such as the regional transfusion centre) if further information was needed, and stated that *"guidance on the management of these patients is currently being prepared"* [NIBS0001097].

43.10. The draft paper from Dr Gillon discussed at the LBE WP meeting on 24 February 1995 set out counselling guidelines, including on the risk of infection and noted that all anti-HCV positive patients should be referred to a specialist with an interest in the condition for further assessment; that would usually involve a period of observation and, in most cases, a liver biopsy. Patients considered to be at risk of progressive liver disease *"may be offered treatment with interferon"* [WITN3430142]. The paper did not address issues of psychological support, but rather counselling on the implications of the test result. At the meeting on 24 February, it was agreed that this paper should be merged into another piece of work, on treatment options. The final outcome was Annex B in the CMO letter.

43.11. This more detailed guidance was released on 3 April. GPs were advised not only about the LBE generally but on the advice they should give to patients. In relation to counselling, the guidance indicated that patients confirmed to be anti-HCV positive should be counselled on the implications of the test result. This included the prospect of developing liver damage without symptoms, cirrhosis, hepatocellular carcinoma and the possibility of a complete recovery. Furthermore, the guidance provided an outline of counselling in relation to avoiding infecting others. This included asking HCV positive recipients whether they had ever donated blood or a tissue. Practical advice on issues such as not sharing toothbrushes and razors should be given by GPs. When seeking medical or dental care, patients should be advised to inform those responsible for their care of their anti-HCV status. They should also be advised to forewarn and practise safe sex with new partners. Lastly, all anti-HCV positive patients should be referred to a specialist with an interest in the condition for a further assessment. Further counselling would be given at specialist centres, where treatment options could be discussed in more detail.

43.12. It is apparent that concerns were expressed about the availability of counselling, including the ability of GPs to handle giving appropriate information to patients. The matter was raised by the British Liver Trust, which in meetings with Dr Metters in 1995 raised this topic (amongst others). For example, the BLT met with Dr Metters on 16 June 1995, sending suggested 'action points' to the DH in advance of the meeting which included requests

for DH funding for a hepatitis C co-ordinator/trainer and *"an appropriate regional liaison structure of nurses/counsellors"* [see DHSC0003552_147].

43.13. In a minute dated 2 October 1995 from Mrs Phillips, discussing HCV prevalence and treatment across the population as a whole (not merely as a result of the LBE), she wrote:

> "*15. Another resource question that will have to be addressed is the question of who is to counsel the different categories of patients who are found to have HCV. BLT [the British Liver Trust] wished to undertake the work themselves given appropriate funding. This is not a practicable option and counselling is currently been undertaken by a variety of health care professionals. Guidance issued to the NHS in April (CMO letter) said that patients confirmed to be anti-HCV positive should be counselled on the implication of the test result and referred for a specialist opinion. We are under some pressure to provide additional resources specifically for this.*" [DHSC0003552_018]

43.14. The availability of counselling continued to be an issue; see the discussion of the Interim Report to Mr John Horam in February 1996, below at Question 50.

Infected Donors

43.15. The Inquiry has asked what steps were taken to address the situation where donors who had been identified as HCV positive did not respond to attempts to contact them. This was not a situation addressed by the CMO's letter of 3 April 1995. The Look Back Exercise was focussed on recipients of infected blood, not the donors.

Resources

43.16. The written records reveal discussions and questions about the funding of the LBE, with requests for reimbursement, from a wide variety of agents involved, for the additional work done. This included complaints from GPs about additional work (see, e.g., [DHSC0002556_379; DHSC0003595_201], a letter answered by Dr Rejman, who pointed out that the exercise had been designed so that no GP was likely to face significant additional work), as well

as questions from hospitals, the NBA and the PHLS about the funding of the work involved.

43.17. The overall message was that it was reasonable to expect local NHS structures to fund the work from existing allocations. See for example the minute from Mr Paley to Mr Scofield dated 16 February 1995 [DHSC0032208_063]. The NBA in particular was considered to be well-resourced at the time.

43.18. A further line of correspondence related not to the additional work of testing and counselling as a result of the LBE, but paying for the costs of treatment required, i.e., (at that time) courses of Interferon. For example, on 6 April 1995, the CMO received a letter from Dr GD Bell, a Consultant Gastroenterologist, who asked who was responsible for paying for the treatment advised as a result of being identified as HCV positive. [DHSC0003595_023].

43.19. A complex issue was the capacity of the health service to counsel and to treat those identified as a result of the LBE, or for Hepatitis C more generally (given that by far the greatest number of those infected were infected as a result of sharing needles or other equipment as a result of drugs misuse). These issues of capacity are discussed in answer to Question 50 and Section 8 more broadly.

Practical Difficulties and Other Issues Arising

43.20. Certain specific questions were raised, e.g., by Dr Robinson with Dr Metters, on particular categories of people, such as patients living abroad. See Question 50 below. But from the Interim Reports that started to be drafted in September 1995, it appears that the most serious problems identified related to the speed of implementation of the exercise, and with bottlenecks relating to matters such the availability of medical records that would have allowed the recipients of potentially infected transfusions to be identified. See further below at Question 56, on the interim report.

43.21. Other miscellaneous issues arose. There is discussion of specific queries under the headings below.

Q.44 Tracing donors who did not return to a Transfusion Centre

44.1. The Inquiry has asked what consideration was given to tracing the recipients of blood from a donor who had given blood prior to September 1991, but had not come back to a Transfusion Centre since that date.

44.2. The minutes of the first LBE WP of 20 January 1995 [NHBT0009715] record that the LBE would concentrate "in the first instance" on donors who had given blood before September 1991 and had been found to be HCV positive on a subsequent visit. It was said that the "*work involved*" in tracing donors who had not returned since then would be "*disproportionate to the benefit*".

44.3. There were further discussions about the practicalities of identifying which of the donors who gave blood prior to September 1991 (but never returned thereafter) might have been infected. The method discussed was the testing of stored samples, presumably as these represented the only source of information about infection in such donors.

44.4. The issue was discussed at the LBE WP meeting held on 14 March 1995, when it was agreed that there was a need for a cost benefit analysis of the options [WITN4461155]. The NBA together with the SNBTS would prepare a paper on the options for stored samples, including why stored samples were not tested earlier. Samples were held mainly in North London RTC and Scotland.

44.5. Further information about the testing of stored samples was then sent in, in April and May 1995, by Dr Gillon (Edinburgh and SE Scotland Blood Transfusion Service, SNBTS) and Dr Robinson (NBA). It noted that only North London and Scotland held substantial numbers of stored samples. Dr Gillon (6 April, [DHSC0003595_040, DHSC0002555_010]) noted that it would not be possible to separate out the samples from those donors who had returned to give blood after September 1991 (and who should therefore be caught by the LBE) and those who had not. As a result, it would be necessary to test all the samples, at an estimated cost (in 1995) of c£1 million. According to Dr Gillon, the cost of £1 million (in Scotland) might lead ("I would

guess") to the detection of around 60- 70 living recipients who received HCV infected blood. The letter from Dr Robinson (4 May 1995, [DHSC0003595_040]) stated that it would be impractical to find the appropriate information (about samples held from Jan 1989 – End August 1991) from the paper records that had been kept and as a result all the archived samples from January 1990 – end August 1991 would have to be tested. The cost would be in the region of £920,000 and might detect a further 40 – 50 living recipients of HCV infected blood.

44.6. The Chairman's brief for the next LBE meeting recorded a concern that these two letters provided a very poor basis on which to make decisions. It also noted that Scottish Office lawyers were taking a "cautious line" implying that everything should be done almost irrespective of cost [WITN3430024].

44.7. When this issue was discussed in the meeting of 25 May 1995 of the LBE WP, the minutes record concerns that testing would not be on a "*level playing field*" (as there were samples for only parts of the country) and about the costs. However, there was also an expectation that lawyers' position (SHHD and DOH) was or would be that it would be "*difficult*" not to go back and test the samples, despite the costs involved. The Chairman felt that it would be necessary for the WP to offer an alternative way forward to Ministers, taking account of the alternative uses for the estimated £2m it would cost. It was agreed to discuss this item further when more experience of the Look Back was available [DHSC0002557_097].

44.8. The minutes also record consideration of whether "HCV screening might be offered to anyone who has a transfusion." It was thought that to announce this would be *"very costly for the diagnostic services, although many of those who are concerned may already have gone to their GP and their GP may have done a test."*

44.9. The matter was reconsidered in the meeting held on 13 October 1995, which is discussed further in Sir Kenneth's statement.

Q.45 & Q.46 The Meeting of the Health Select Committee in February 1995

45.1. See Personal Statement.

Q.47 The erroneous National Blood Service letter of 21 March 1995

47.1. See Personal Statement.

Q.48 Issue of the CMO Letter of 3 April 1995

48.1. See Personal Statement.

Q.49 The provision of psychological support

49.1. See Personal Statement.

Q.50 Infected recipients living outside of the United Kingdom

50.1. The Inquiry has asked whether consideration was given as to how to trace the recipients of infected blood who lived outside of the UK. The account below is from the documents identified.

50.2. It is apparent from the minute of 18 April 1995 from Anne Hackett to Mr Brown [DHSC0032052_062] that at that date no consideration had been given to the procedure to be followed if a recipient of infected blood should live outside the UK. The handwritten note canvassed whether this should be considered further or left to be dealt with when a case arises. The handwritten note, probably from Mr Brown, appears to ask Ms Hackett to note the issue as one to raise with policy colleagues when there was next a round up on blood issues.

50.3. A more formal response has not been traced, but the issue was picked up in correspondence with Dr Robinson of the NBA. By a letter dated 20 June 1995 to Dr Rejman, Dr Robinson asked for advice on the information that should be given with regards to foreign nationals who were private patients, who had now been identified as recipients of infected blood from HCV donors. (She noted that patients in a similar position had been contacted under previous HIV lookback exercises) [WITN3430143]. Dr Rejman's minute about this to Mr Pudlo (6 July 1995, [DHSC0003538_239; DHSC0003538_240]) stated that his understanding was that the DOH had already advised Dr Robinson to tell clinicians abroad about an individual who had received a unit of blood from a

donor subsequently found to be HCV positive. He did not see that the position was any different if private patients were involved. Dr Rejman attached a draft response.

50.4. The response was sent on behalf of Dr Metters on 12 July 1995, when he wrote to Dr Robinson:

> "*I recall that you asked previously about whether to tell a medical institute abroad about a unit of blood which they had been sent from the UK which had been collected from a donor subsequently shown to be HCV positive. On that occasion, it was suggested that it was appropriate to tell the clinician at the institute about this. I would have thought that the situation in respect of foreign nationals who were treated in the UK as private patients is no different and that their overseas clinicians should be likewise informed.*" [DHSC0002557_239]

50.5. At the time of compiling this Annex, it has not been possible to find an earlier letter from Dr Metters (or Dr Rejman) to Dr Robinson, addressing the question of infected patients abroad. Looking at the terms of the reply from Dr Metters, it is possible that he was referring back to an oral conversation with Dr Robinson rather than a letter. The NHBT may be able to give further information about any follow up.

Q.51 Letter of May 1995 from Ken Clarke to Virginia Bottomley

51.1. The Inquiry has highlighted a letter sent by Mr Kenneth Clarke MP on behalf of his constituent, Dr Bywater. The documents show:

(1) Letter Mr Kenneth Clarke MP to Mrs Bottomley dated 24 May 1995, regarding correspondence from Dr Bywater, his constituent. According to Mr Clarke, the letter raised the issue of people infected before 1989; the constituent thought that there should be an advertising campaign to invite people to come forward for testing who were infected before 1989 [DHSC0003552_107].

(2) Copy letter to Mr Clarke from Dr Bywater, noting the Look Back exercise announced on 11 January 1995 but setting out his belief that

this was related only to those transfused from 1989, and querying why efforts were not being made in respect of any earlier dates. He asked, in particular, why tests were not being offered to those transfused prior to 1989 [DHSC0003552_108].

(3) Letter from Mr Levy to Dr Nicholas, 9 June 1995, asking for the latter's input into the draft reply [DHSC0002549_096] and draft reply for Dr Nicholas to consider [DHSC0002549_097]. The letter set out information about the LBE and was to come from Mrs Bottomley. It noted that the LBE would consider previous donations from any donor shown to be HCV positive since screening began. The previous donations in many cases would be before 1989 and so the lookback was not limited to 1989. The topic of donations made before the introduction of screening when no further donations had been made by the donors in question was complex. "*However, consideration is being given to whether sufficient information is available and what action may be appropriate*".

(4) Response from Dr Nicholas (12 June), commenting that Dr Bywater does not seem to have received the CMO's letter, perhaps as he was retired and appeared poorly informed. He commented further on the use and effects of interferon-alpha but not on the "1989 issue" [DHSC0003552_104].

(5) The reply sent by Mrs Bottomley to Mr Clarke on 15 June 1995 [DHSC0006947_138], giving information about the look-back exercise. It noted that the exercise was not limited 1989 but "*Donations made prior to the introduction of screening and where no further donations by those donors have been made since are more complex. However, consideration is being given to whether sufficient information is available and what information may be appropriate*."

(6) A further letter from Dr Bywater to the CMO dated 6 July 1995 [DHSC0003552_113] in which he asked why steps had not been taken to inform and test at-risk patients 4 years ago, from 1991. He suggested that Interferon had been in use in specialised centres for the

last 5 years. The handwritten comments note that Dr Rejman was asked to co-ordinate a reply ("*treat officially*").

(7) Letter from Dr Nicholas to Dr Rejman dated 25 July 1995, commenting on Dr Bywater's correspondence and asking whether the latter had seen all the information supplied about the exercise [DHSC0003552_103]. Dr Rejman drafted a reply which referred to the reasons why the LBE had not started earlier, including the absence of a licensed treatment until 1994. This was sent to Dr Bywater on 27 July 1995 [WITN3430144].

(8) The DHSC has traced further correspondence from Dr Bywater to Lord Ashley of Stoke and from there to Baroness Cumberlege (see draft letter at [DHSC0002556_372; DHSC0002556_171], 21 April 1995). That letter, as well as the PM's Briefing at [DHSC0002556_378], also noted that if someone was otherwise diagnosed as having hepatitis C, but it was found that they have had a transfusion in the past, a similar look back exercise would be undertaken to see if the transfusion was the cause of the infection.

Q.52 Correspondence about transfusion numbers

52.1. In May 1995, in a paper entitled "Hepatitis C virus Infection: Public Health Research Priorities" [DHSC0002556_039], Dr Adrian Renton of the Academic Department of Public Health, St Mary's Hospital School London, gave an "*estimate that there may be some 40,000 transfusion associated cases and perhaps comparable numbers of injecting-drug-use acquired cases currently in the UK population. In addition there may be several thousand community acquired cases*". The figures were given in the context of proposals for follow-up studies linked to the LBE.

52.2. Professor Thomas sent this paper, and another, to Dr Metters, who appears to have passed them to Dr Rejman for study and comment. In a minute from Dr Rejman in response (24 May 1995) [DHSC0003595_044], Dr Rejman immediately picked up the figure of 40,000 transfusion associated cases. He said that he had asked Professor Thomas to come to the next LBE WP meeting with a justification of the estimate. Dr Rejman noted that the paper

had reminded him again of the lack of knowledge held about precise numbers, and the impact which higher numbers could have on a possible HCV payments scheme. He noted that if higher figures, well in excess of the 3,000 that NBTS expected to identify, could be justified, then *"our advice to GPs about reassuring patients and advising them not to be tested for HCV may need to be reconsidered."*

52.3. The issue was then discussed at the next meeting of the LBE WP, on 25 May 1995, at which Professor Thomas was in attendance [DHSC0002557_097]. The minutes record that Dr Nicholas asked to see the basis on which the figures were calculated. Dr Thomas agreed to go back to the authors (of the paper) and ask for an explanation of the mathematical modelling used.

52.4. On 26 September 1995, Dr Rejman wrote to Dr Doyle [DHSC0003534_081], noting that the predicted numbers of live recipients of infected blood who were expected to be identified by the LBE was in the order of 3,000 (i.e., consistent with previous estimates). He continued:

> "*The total number of infected haemophiliacs, blood transfusion recipients, recipients of tissues and transplants, both alive and dead could be anything up to 40,000. This is the figure calculated on the basis of some mathematical modelling …. However, on the basis of guestimates, this figure is not totally unreasonable…*"

52.5. The context of these exchanges was planning work upon the likely demand for interferon treatment. See for example the paper from Mrs Phillips dated 2 October 1995, drawing attention to the fact that the main route for HCV infection was via contaminated needles and other injecting equipment used by intravenous drug users [DHSC0003552_018]. The overall numbers of those infected might be in the order of 100,000 – 200,000. The British Liver Trust had claimed that between 0.1- 1% of the population might be infected. This had not been substantiated but in the US the overall infection rate was in the order of 1.2%. Current DOH advice, published in 1991, was that drugs misusers should be tested, but "*this seems largely to have been ignored up to now*". Mrs Phillips set out the pressures and treatment challenges, including the low rate of success from alpha interferon and the fact that there were no

clear guidelines on its use. She noted that it would be regarded as unacceptable to discriminate between patients on the basis of how they contracted the disease.

52.6. The prevalence estimates were picked up at the next LBE WP meeting on 13 October 1995 [WITN3430014]. The minutes record:

> "*Number of infected recipients.*
>
> *9.1 Professor Thomas explained the figures for transmission rates he had cited at the last meeting … were based on estimates figures, for non-A non-B cases over the last 20 – 30 years. The look back group was looking at a more limited period; the incidence in the general population was likely to be much higher. A French study showed a 6% rate in all transfused patients. [The French were keen to other countries to carry out checks too.]. Professor Thomas would send a copy of the relevant papers to the Secretariat.*"

52.7. There is an undated note by an unknown author at [DHSC0003534_054; DHSC0004761_101; DHSC0003534_056] which explained further:

> *"The figure of 40,000 for prevalence among recipients of blood transfusions has gained some currency. In Dr Renton's model such an estimate is based on an annual mortality of about 10%. However, we know that half of transfusion recipients are dead within one to two years. This implies an annual mortality rate of 25% – 50%, a good way above the upper end of Dr Renton's range. The prevalence estimate is very sensitive to the annual mortality rate. A rate of 25%-50% leads to a prevalence estimate below 10,000. With these mortality rates and indeed with Dr Renton's rates of 10% and 20% prevalence at [sic] the starting data [sic] of 1975 is irrelevant because the vast majority will be long dead. The lookback figures may give a better starting point for an estimate than the apparently promising "crude actuarial model" approach followed by Dr Renton."*

52.8. Dr Rejman provided detailed commentary to Dr Metters on 1 November 1995 [DHSC0002550_143]. He commented on the number of variables and the limited data available.

52.9. Dr Metters replied on 6 November 1995 [DHSC0002550_137]. He wrote to Drs Nicholas and Rejman expressing the opinion that the only conclusion he could draw was that "*we really have no certainty*" about the numbers of patients with HCV "*as a result of transfusion or perhaps more importantly, the total numbers in the population who are HCV positive*." *"We could give all the data to the mathematical modellers and ask them to come up with better estimates, but given the numerous uncertainties about transmission via different groups during the last six 5-year periods, I doubt they will be able to give us any more robust figures!"* His view was that, rather than "*arguing*" over mathematical modelling etc, HP Division and CA-OPU2 should decide what additional information about prevalence was needed for policy purposes and build this into the research programme that RDD was constructing.

Q.53 Public health campaigns to raise awareness of Hepatitis C

53.1. The Inquiry has asked whether any consideration was given to a public health campaign to raise awareness of Hepatitis C, particularly amongst those infected who might not be identified by the LBE.

53.2. Two documents have been highlighted by the IBI. Their context is a meeting held between the Permanent Secretary (Sir Graham Hart) and the British Liver Trust in early January 1995. This was followed by a Minute from the Permanent Secretary to Dr Metters and others on 13 January 1995 [DHSC0002552_204].

53.3. The Permanent Secretary recorded that the thrust of the argument from the BLT at the meeting was that liver disease was under resourced and given too low a priority all round. He asked for briefings on a number of subjects, including on the priority given to liver disease in health promotion and treatment from Dr Metters, as well as on the proposal for research to develop an algorithm for the treatment of Hepatitis C with interferon.

53.4. In response to the request to Dr Metters, he received:

(1) A minute from Dr Metters to the Private Office of the Permanent Secretary dated 2 February 1995 [DHSC0041441_140]. Dr Metters noted that there was no simple answer to the questions about priority

asked, not least as viral liver disease was not the whole story. Although recent publicity had focussed on Hepatitis C caused blood transfusion, "*Most Hepatitis C in this country is due to intravenous drug misuse as a result of needle sharing. Thus the important public education message is the avoidance of needle sharing*." He noted that although there were many unanswered questions about the natural history of liver disease, "*… the recent publicity to Hepatitis C will undoubtedly move liver disease up the research and health education agenda*". Although there might be "political reasons" for allocating additional resources, "*... in terms of overall morbidity or mortality I am not sure that the time has come for liver disease to be given special priority …*"

(2) In response to the same Minute, Dr Rejman had noted that the licensing of Interferon would increase the priority given to liver disease irrespective of any central action by the Department [DHSC0041441_142]. He noted that the numbers of those suffering from cirrhosis or hepatocellular carcinoma caused by Hepatitis C every year could be "*quite considerable*."

53.5. This was correspondence on the general issue of the priority to be given to liver disease, in the context of HCV infection generally. There are comments on the issue of public awareness, as highlighted above.

53.6. There was comment on the possibility of wider HCV testing from Dr Rejman, in response to a letter in the BMJ in October 1995 [DHSC0002557_098]. He commented that the author appeared to be suggesting that all recipients of blood should be tested. "*This would be very expensive, cause much unnecessary anxiety and many people who are hepatitis C positive are asymptomatic for many years or even throughout their lives. It is unlikely that such people would benefit from being tested*." Testing by PCR was unfeasible.

53.7. The options for speeding up the LBE or achieving its objectives more quickly that were considered are addressed at Question 56 below.

53.8. More generally, a Ministerial briefing dated 4 October 1996, to the PS(H)'s Private Office, addressed the subject of what the Department was doing "about making doctors and particularly general practitioners aware of hepatitis C" thus: "*The education of doctors is not primarily the role of the Department of Health, but a matter for the professions. However the Chief Medical Officer wrote to all doctors in April 1995 in connexion with the hepatitis C blood lookback exercise, this letter contained a useful annex on hepatitis C and guidelines for counselling patients with hepatitis C. The British Medical Journal has published an informative article in their 'education and debate section' earlier this year and the British Medical Association have recently published a document 'A guide to hepatitis C.*'" [DHSC0004761_005]

Q.54 Letter of 16 June 1995 from Dr Rejman to Dr Robinson

54.1. The Inquiry has noted that on 6 June 1995 Dr Robinson had written to Dr Metters about "*the Bristol situation*", concerning patients who were already under the care of hepatologists, and in respect of whom a link with infected blood had now been found. Dr Robinson asked what information should be provided to the patients, in circumstances in which the patients knew that they had liver disease but a possible transfusion link "*has not formally been recognised at this point in time*". She noted that these two cases might be the tip of an iceberg and asked for guidance on what information should be provided to whom on these type of cases.

54.2. The draft reply from Dr Rejman is at [DHSC0003595_007; DHSC0003595_008]. He suggested that the hepatologist should be told of the link "*but we do not believe that there is any advantage in the patient being given this information at the present time, since it will not make any difference to his treatment.*" He continued: "*The letter to the consultant needs to be couched in careful terms so as not to commit the BTS to admitting that the hep C in the individual was indeed caused by the unit of blood, since the specific unit has not been tested and other causes of hep C may not have been entirely excluded. This would of course be very important if there were to be any system of payment in the future*."

54.3. The actual reply was sent by Dr Metters on 20 June 1995 (see [NHBT0020469]). This stated that the consultant hepatologist should be told about the possible link to infected blood. But *"it is important not to state that categorically that this was the cause of his hepatitis C, since the specific donation has not been tested and also we do not know whether the patient may be at risk of Hepatitis C from other causes*." In relation to information to the patient:

> "*The final decision on what to tell the patient must remain with the consultant hepatologist. However, I do not believe that there is any reason for the patient to be told that it is possible that their hepatitis C was acquired as a result of contaminated blood, as this would make no difference to their treatment by their consultant hepatologist*".

54.4. Whilst it is not apparent what, if any, guidance was sought by Dr Rejman or Dr Metters before drafting or sending this letter, legal advice was obtained shortly afterwards – see below.

54.5. Dr Robinson appears to have asked Dr Hewitt (the Acting Medical Director) to advise her on the letter that should be sent to Hepatologists. See the letter from Dr Hewitt to Dr Robinson dated 6 July 1995, attaching a draft response [NHBT0002727_002; NHBT0002727_003]. On 11 July [DHSC0003538_254] and again on 15 August [NHBT0010810], Dr Robinson wrote back to Dr Metters, seeking further guidance. The letter of 11 July attached the proposed response drafted by Dr Hewitt to Hepatologists.

54.6. On 30 August, Dr Rejman sought legal input from DOH legal advisors (Ms James), sending the draft reply supplied by Dr Hewitt for comment. On 31 August 1995, Ms James replied by way of handwritten comment on his minute: "*I have no comment to make on your draft. There is no legal barrier to telling patients about the presumed source of infection. Not telling them is the tricky point. I am happy that the decision is a matter of medical judgment. X can therefore stand as far as I am concerned*." [DHSC0002549_063].

54.7. Dr Rejman passed this information back to Dr Metters the same day: "*SOL have replied that they are content with the draft and the sentence marked X*." [DHSC0002549_058; DHSC0002557_165]. He attached a draft answer from

Dr Metters to Dr Robinson, which did not comment further on the issue of information to the patient but noted that the Hepatologist might not realise that the implicated donation would not actually have been tested and that it might be worth stressing this. This was sent out by Dr Metters on 1 September [NHBT0002725_002].

54.8. It is not entirely straightforward to identify what draft was being commented upon. However, the text of the final, approved letter from the Consultant Haematologist can be seen at [WITN3430145], with a letter from Dr Robinson dated 15 September 1995. The penultimate sentence read:

> *"I should make it plain that there is no objection to information being given to the patient about the presumed source of the HCV infection, if you think it appropriate."*

54.9. It appears from this that the suggested guidance that was being commented upon by Ms James, and the guidance that was 'approved' from RTCs to Hepatologists, was that there was no objection to patients being informed about the presumed source of their infection, if the clinician saw fit. It was not suggested that this was to be avoided.

Q.55 GP Knowledge of the CMO Letter

55.1. The Inquiry has asked about a briefing from Mr Pudlo to Mr Hollebon (Private Secretary to the Parliamentary Secretary for Health) dated 11 July 1995 [DHSC0003552_115]. It followed a request for a briefing on a pamphlet published by the British Liver Trust "C-Positive".

55.2. The documents show that:

(1) The pamphlet [DHSC0042937_098] criticised the LBE for the fact that it would not identify recipients of blood from a donor who had not returned to give blood after 1 September 1991. It advised those worried to contact BLT for advice, or their GP for a Hepatitis C test. It also stated: *"The Trust is now concerned that those who are identified are adequately counselled."* It reported on concerns about individuals newly diagnosed (not through the LBE exercise but more generally) not

receiving adequate information or support. The "C-positive" newsletter further carried an article from a Clinical Nurse Specialist which made the point that there was a general problem of a lack of awareness of HCV amongst healthcare workers, GPs, hospital doctors, nurses, etc.

(2) In the absence of Dr Rejman, Mr Pudlo replied [DHSC0003552_115] giving information about the BLT, stating that it was developing as a political pressure group and "*was critical of the lack of counselling for new HCV patients and poor GP awareness of the disease. Its concern ranges far wider than patients infected through blood / blood products. Its aim in this context is to raise awareness of HepC and to secure ring-fenced funding for HepC treatment".* Mr Pudlo provided "lines to take" on various issues, including the statement that: *"CMO letter alerting clinicians has been well-received and has heightened GP awareness of the condition".*

(3) The NBA produced a "Progress Report" on the LBE, tabled for the WP meeting on 25 May 1995 [DHSC0003595_036]. Amongst the detailed information contained in the report is a statement, under the heading "Counselling Guidelines": "*A straw poll of GPs in the South West zone suggests that these have not been digested, none could recall the CMO's letter on Look-Back*."

(4) The Inquiry has also supplied the Progress Reports from Northern Ireland, 23 May 1995 [NHBT0040501_004] and Scotland, 25 May 1995 [NHBT0088395]. These do not raise the issue of GP awareness or highlight problems in that regard. Scotland noted: *"Reluctance encountered on the part of consultant haematologists and GPs with respect to "seeing" patients";* that was with regards to follow-up counselling.

(5) The minutes of the discussion of these reports at the LBE WP meeting of 25 May 1995 [DHSC0002557_097] record both the feedback that "*some GPs in Bristol were not even aware of the CMOs' letter*" and that "*The feedback so far had generally indicated that GPs saw the CMO letter as helpful."*

Q.56 Interim Report on Lookback

56.1. The Inquiry has highlighted a draft report on the LBE exercise produced in September 1995 and its report on progress.

56.2. This Interim Report produced by John Nash on 4 September 1995 [DHSC0002557_157] was an early draft. It contains only a little information about progress. The report went through various iterations before, ultimately, an updating submission based on its contents went from Dr Metters to Ministers in early February 1996 [DHSC0004469_013]. The submission was addressed to the Private Office of the Parliamentary Under-Secretary of State for Health, the Minister responsible; by this time, Mr Horam. It was widely copied, including to the CMO's Private Office.

56.3. Before that submission and report went to Ministers, the progress of the LBE and options for more speedy progress had been discussed in a series of meetings or reports, as follows:

(1) The interim report written by Mr Nash went through various redrafts. See for example [WITN3430146], which is a version dated 9 October 1995. By this point a summary had been added to the initial version, stating that "*The Look Back so far has been slower in achieving its objectives than had been predicted. The Blood Transfusion Services are being encouraged to work better and faster on this project".*

(2) There was a request for updated progress reports from England, Wales, NI and Scotland to be tabled at the LBE WP, on 13 October 1995. At the meeting, progress was discussed, with varying reasons being given for any difficulties being experienced [WITN3430147]. This was the last meeting of the LBE WP and the Chairman said that a report would be made to Ministers.

(3) On 20 December 1995, Dr Rejman asked for comments on the draft; Dr Metters responded [WITN3430148].

(4) The MSBT met on 8 January 1996 [DHSC0020692_118]. This meeting considered the various challenges and bottlenecks, including on the tracing of records, and the options to respond. "*One option was to abandon the lookback and offer Hepatitis C tests to anyone who had been transfused. Members were not in favour of this as the lookback exercise was expected to produce important information about Hepatitis C. …. But simply sending out messages [on speeding up] from the centre seemed unlikely to produce action in the field.*" Hospital records and the shortage of suitably trained staff for counselling were identified as key bottlenecks. *"The Chairman [Dr Metters] emphasised the initial agreement that counselling must be done well; patients must not be misinformed. Dr Robinson said that counselling was being done effectively by transfusion staff, but they faced a heavy load because GPs were often unable or unwilling to undertake that role. Dr Rejman mentioned that for the CJD/hGH lookback counsellors trained in other fields had been used after being taught the necessary facts about CJD."*

(5) Officials proposed to put to Ministers the various options discussed. There was a discussion of the proposals, including whether if problems were dealt with at one stage it would merely lead to issues at a later stage; *"The Chairman agreed that the NHS could only deal with patients at a certain pace".* He intended to summarise the options for the members of the MSBT before a submission went to Ministers. He asked that the national blood services make contact with hospitals, on a personal basis, before April to enquire when the tracing might be completed.

(6) Dr Rejman followed this up on 12 January 1996, by sending a list of the various option that might be taken to the members of the MSBT and the LBE WP members who had attended the January MSBT meeting [NHBT0005808]. He asked for comments from

the various members, which were received (see the comments from Dr Robinson at [NHBT0009953_063] for example).

56.4. A Ministerial submission was drafted and sent to the Parliamentary Under-Secretary for Health (Mr Horam) on 5 February 1996 [DHSC0004469_013]. It set out the history of the LBE and the numbers identified up to that point. On this: there were 1727 donors for Hepatitis C who had given blood prior to 1991. 9048 donations had been identified, with 2808 recipients identified of whom 1631 had already died of unrelated causes (see Annex E at [DHSC0004469_025]). "*These figures suggest that the original estimate of identifying approximately 3000 recipients who are alive was realistic*".

56.5. The submission explained that the exercise had taken longer than expected. The bottlenecks were: (i) tracing medical records for recipients identified by hospital blood banks; and (ii) a shortage of counsellors to see patients prior to and after testing. But if these bottlenecks were overcome, hepatology services and, where appropriate, commencement of treatment, "*would probably not be able to cope*". The recommendation to Ministers (following the advice of the MSBT) was to continue 'as is', as slower identification of those affected across the rest of 1996 was unlikely to damage patients and risked creating subsequent bottlenecks.

56.6. Annex F [DHSC00044469_027] set out the alternative approaches to continuing as planned - including abandoning the LBE and offering Hepatitis C tests to anyone who has been transfused. There should be communications between the BTS and hospital where particular problems were identified, to enquire as to progress etc. Annex F recommended that the options of abandoning the Look-Back entirely and offering hepatitis C tests to anyone who has been transfused should not be followed as the LBE *"had been carefully designed to identify and offer counselling and treatment to recipients of blood transfusion units implicated in the Look-Back in a structured way that would maximise benefits to them. At the same time the Look-Back would obtain important information about the rate of transmission and natural history of Hepatitis C when acquired from transfusion that was currently not available."* It was said (relevantly to the possible offer of assistance to overcome

bottlenecks) that *"a delay in the identification process that might be extended for the rest of 1996 would not disadvantage patients as the evidence was of a 20-30 year time frame for significant liver damage to occur".*

56.7. Overall, the Minister was asked to note progress, with a meeting with officials for any further details to be discussed.

56.8. Mr Horam responded briefly on 12 February noting the progress and actions to date [DHSC0002533_119]. Further detail was provided on 4 March 1996, when his Private Secretary wrote on his behalf:

> "*… PS(H) has clarified his views. He agrees that central exhortation to speed up the Look-Back exercise would be unlikely to achieve much. He is content with the preferred option of continuing the current strategy, whilst improving communication between the BTS and hospitals where there are particular problems and offering assistance to overcome the bottlenecks.*
>
> *PS(H) does not feel that a meeting at this stage is necessary but looks forward to receiving a further report in the next 6 – 9 months.*" [DHSC0002533_152]

56.9. Other correspondence shows the pressures related to the potential wider demand for treatment for HCV and interferon in particular. See the letter from Dr Nicholas dated 16 January 1996 [DHSC0004469_052] to Ms Phillips and Ms Marsden, speaking about the difficulties of managing the potential demand from other groups. *"Such patients could compete with those infected by blood transfusion as available resources allocated to the treatment of hepatitis C by Health Authorities is likely to be limited."* This issue has been addressed further below.

56.10. On 5 March 1996, Dr Metters noted that the result was that *"a letter needs to go to BTS encouraging them to identify and explore problems with hospitals that have major backlogs"* [WITN3430149].

56.11. On 14 March 1996, Dr Robinson wrote, seeking to pursue various options that the DH figures felt had been discounted. Dr Rejman commented, in a minute to Mr Guinness dated 1 April 1996:

> "*One of the problems in this whole exercise has been that the NBA has promised a lot, but has not been able to deliver … The other aspect of the exercise where the BTS is particularly involved is that of counselling. Originally the NBA said they could do this with no difficulty, but it would appear that this is one of the problem areas at the present time*." [WITN3430150]

56.12. Dr Rejman reiterated the need for the BTS to identify where the hold-ups were and to report back to DH, whereupon the DH could consider what needed to be done. He reiterated that central exhortation was unlikely to be productive. Mr Guinness subsequently wrote to Dr Robinson asking for a report on the hold-ups, so that if necessary the issue could be aired at the MSBT meeting on 2 May 1996.

56.13. The LBE was discussed at the MSBT meeting on 2 May 1996 (see the minutes at [SBTS0000518]). *"The committee agreed that general guidance from DH would not be helpful when many hospitals had already made good progress. Each national blood services should identify particular problem hospitals and refers to the relevant health Department for action, eg in the case of England via the NHS Executive."* The plan was for the exercise to be completed by the end of 1996. It is apparent from documents such as [DHSC0041177_159] (Dr Metters' comments on the minutes of the meeting of the MSBT on 2 May 1996) that Dr Metters was trying to ensure that progress continued to be made.

56.14. A detailed paper on Hepatitis C was discussed at the NHS Executive Board on 13/14 June 1996 [WITN3430151]. The paper highlighted the conflict between "what may be desirable public health policy and the capacity of the NHS to deliver" (paragraph 2, covering letter from Dr Winyard). It identified the dilemma:

> "*From a public health point of view, there is an obligation to remind health professionals, and people who may have been infected, about HCV and the desirability of counselling and testing. We have so far avoided going down this route because of the resource implications for the NHS.* ***The identification of asymptomatic patients by testing,***

> ***though consistent with policy on HIV, will place increasing pressure on specialist services which are already fully-stretched*** *(some hepatologists have told us that hepatitis C represents 2/3 of their current workload).*" [emphasis in original].

56.15. The paper notes that faced with criticism of the slow progress of the LBE, Ministers decided not to speed up detection as the bottleneck would then transfer to hepatology clinics (paragraph 6). It argued that it would be contentious, and inappropriate, to distinguish between routes of infection when offering access to treatment (paragraph 8).

56.16. A copy of the paper for the NHS Executive Board was included in the CMOs' briefing pack, for a meeting of the CMOs on 4 – 5 July 1996.

56.17. A minute from Mrs Towner to Drs Metters and Rejman dated 13 September 1996 regarding the MSBT meeting of 18 November 1996 queried the ongoing role of the MSBT in supervising the completion of the LBE. It was suggested that it was a matter for the Blood Service, supervised by the NHS Executive, to ensure that it was carried through effectively [DHSC0004079_129]. Dr Rejman agreed, and also argued against a further update to Ministers [WITN3430152] but Dr Metters' view was that the oversight of external specialists, monitoring progress, remained necessary [WITN3430153].

56.18. The Minutes of the MSBT meeting held on 18 November 1996 show that the meeting considered the latest information about the exercise [NHBT0006005].

56.19. In February 1997 the latest figures on completion / progress were still those compiled in September 1996 [see WITN3430154]. However, updated figures were presented to the MSBT on 25 March 1997 [see Minutes at NHBT0006016 and paper at MSBT11/6]. It is apparent that there were still outstanding problems in completing the exercise: "*The Chairman felt that the Department needed to look at how best to pass "encouragement" down the management chain where authorities or Trusts did not appear to have done all they could, especially where there was either no funding or a disregard of Ministers' views"* (paragraph 3.4). Members had anxieties about the standard of record keeping in hospitals and whether this was contributing to the "*significant numbers of recipients who had not yet been identified or followed*

up". The Chair suggested that the Committee should re-examine the issue after some six months had elapsed.

56.20. Consistently with this, the topic of the LBE was put before the MSBT again on 27 October 1997. The Chair's briefing notes/Agenda [DHSC0004809_048] recorded that Dr Robinson had again provided an updated report on progress, although some of the figures still dated back to March 1997 and she might be able to update the position. DH (Dr McGovern) could be asked to speak to the follow up action that had been agreed at the March 1997 meeting; Dr Robinson had provided him with details of the authorities where there appeared to be hold-ups *"and he will be approaching them directly. If this fails further action will be considered."*[13] The information provided by Dr Robinson was in the form of a presentation from Dr Robinson dated 1/9/1997: see [NHBT0077689], specifically p10.

56.21. On 13 November 1997, a lengthy and detailed submission on HCV was sent to the CMO's Private Office and to the Private Offices of M(PH) (Ms Jowell) and MS(L) (Baroness Jay). The references to general issues concerning Hepatitis C are addressed below (Question 57). In relation to the LBE, it noted the existence of the LBE, and that it was continuing. *"There have been criticisms over the slow progress made in this exercise and the lack of commitment from some hospitals to tracing infected patients. The look back raised expectations that testing and treatment would be available for those infected through NHS treatment"* (paragraph 7). It noted that *"Specific commitments given in respect of those infected through NHS treatments, either through blood transfusion … or through blood products … are difficult to reconcile with the fact that some patients coming forward for treatment who were infected though other routes are being denied treatment."*

56.22. A series of recommendations were set out, including with regards to raising awareness of HCV. There was a suggestion that Ministers might find it helpful to have a seminar on hepatitis [DHSC0004457_107].

[13] They also record that Dr Rejman had now been replaced by Dr McGovern, as new member of the Secretariat; Gwen Skinner also replaced Ann Towner.

Q.57 The Hepatitis Seminar of 1998

57.1. The Inquiry has asked about a seminar that the CMO held for M(PH) and MS(L) (Ms Jowell and Baroness Jay) on hepatitis in 1998, by reference to a minute written on 3 December 1998, after Sir Kenneth Calman had stood down as CMO [DHSC0038649_079].

57.2. Documents relevant to the seminar that are available include:

(1) Ministerial Submission dated 13 November 1997, entitled 'Hepatitis C - Issues for the NHS.' This lengthy and detailed submission, sent to the CMO's Private Office and to the Private Offices of M(PH) and MS(L) referred to general issues concerning Hepatitis C. It noted *"the public health implications, the large numbers potentially involved – thought to be up to 300,000 in England – and the difficulty in treating this chronic blood borne virus".* It set out background information on the virus, its prevalence and effects. It discussed research efforts, the lack of availability of testing and the look-back exercise, noting criticism of slow progress. *"The look back raised expectations that testing and treatment would be available for those infected through NHS treatment."* The medical profession was being supported to produce clinical guidelines on prescribing practice. The issues discussed included both litigation involving HCV infections through blood transfusion and the Haemophilia Society's campaign for special payments for haemophiliacs infected with HCV. A series of recommendations were set out, including with regards to raising awareness of HCV. There was a suggestion that Ministers might find it helpful to have a seminar on hepatitis [DHSC0004457_107].

(2) Draft briefing dated 11 February 1998 for the Secretary of State for Health (Mr Frank Dobson) in respect of a question in Parliament about the steps taken to raise awareness of Hepatitis C [DHSC0004799_132]. Towards the end, the briefing states: "*In November 1997, officials provided Ministers with [a] submission addressing some of the implications of hepatitis C for the NHS. A presentation on hepatitis C is being arranged for M(PH) and MS(L) later this year to follow up the submission."*

(3) There is a letter from Dr Nicholas to the CMO's Private Office dated 1 April 1998 [DHSC0046979_029] which notes that the seminar has been fixed for 5 May and asked for the CMO's input on the objectives of the seminar.

(4) A reply was sent on the CMO's behalf on 3 April [DHSC0004457_065]: *"CMO has said that he would like a brief introduction about hepatitis in general, followed by a brief introduction about hepatitis C (all facets – biology, measurement, vaccines) and then go on to specific questions to be addressed with respect to Hepatitis C".*

(5) Details of the programme were sent to Minister and to the CMO's office on 1 May [DHSC0046979_021]. The papers attached included:

1. Summary Information on Hepatitis C infection in the UK [DHSC0038649_079]
2. Background Note on Hepatitis Infection in the UK [DHSC0038649_079]
3. Hepatitis C – Issues for the UK (submission of 13 November 1997 which went to Ministers on 17 November) [DHSC0004457_107]

57.3. The briefing letter dated 1 May 1998 attached the attendance list.

57.4. No note of the meeting has been traced. But on 3 December 1998, the Note to the Private Office of the new CMO stated:

> *"1. Earlier this year, the previous CMO, together with officials with policy interests in blood borne viruses, drug misuse, and the provision of services and treatment of liver disease, conducted a seminar for M(PF) and the then MS(L) on hepatitis C to apprise them of the public health issues and implications for the NHS. Raising public awareness through health promotion activities will inevitably lead to increased requests for testing and in referrals for assessment and treatment and will present an increased pressure for Health Authorities in the allocation of their resources. An important issue is therefore how pro-active the Department should be in raising awareness and expectations among individuals who may have been at risk.*

> 2. ***The outcome was that Ministers asked for a further meeting some time in the autumn to consider in a more focused manner possible ways forward on a number of issues.*** *This further meeting had has to be postponed, largely as officials in HSD2 have been involved in setting up the enquiry into cardiac surgery in Bristol, during which time Lady Hayman has replaced Baroness Jay, However there is a need to take this work forward, and we hope the meeting with Ministers can be re-scheduled for early in the new year."* ([DHSC0038649_079], emphasis added).

57.5. The views of the new CMO were sought on a further seminar.

Section 8: Treatment and support for Hepatitis C positive patients

Q.58 Counselling and Support, 1992

58.1. On 4 February 1992, Dr Mehtar, Chair of the North East Thames Microbiology Advisory Committee, wrote to the CMO requesting a separate allocation of funding to investigate and deal with the overall prevalence of HCV carriers and to advise them via "social support systems" [DHSC0002501_019]. He noted that three centres tested for Hepatitis C as a screening service, and also *"provide specialised supplemental and reference facilities for sero positive individuals".* He argued that factors such as the numbers of those being diagnosed and the serious consequences of infection meant that there needed to be a separate allocation of funding to enable advice *"to HCV carriers via social support systems – much the same as HIV positive patients and Hepatitis B positive patients."*

58.2. The documents that have been examined show the process by which this letter was considered in the Department.

58.3. The letter appears to have been passed to Dr Shanks and then to Dr Rejman to draft a response [MHRA0028927]. It appears from a note written by Dr Rejman dated 21 February 1992 [DHSC0003550_021] that the matter was considered by Dr Metters (DCMO). He advised Dr Rejman that he thought that it would be appropriate for "ME" division to respond.

58.4. Dr Rejman then sent a draft response to Mr Rogers of PMD, including some draft paragraphs for him to consider [see DHSC0003550_021 and DHSC0003550_022]. These referred to the fact that the initial screening tests for Hepatitis C were being performed by RTCs, with supplementary checking by Reference Centres. Initial counselling was arranged by a Medical Officer at the RTC. The further management of positive donors was by negotiation between the RTCs and the hospital clinical departments concerned. It was suggested that the funding was a matter for the Regional Health Authorities concerned.

58.5. On 10 March 1992, an official from PMD2A1 commented to Mr Wilton (amongst others) that this CMO correspondence had been sent to them by mistake. But a handwritten note on this minute from Mr Wilton, addressed to Dr Hilton (HP(M)1), noted that there had not been a separate allocation of funds for Hepatitis B, whether for health care workers or more generally. The chances of a separate HCV allocation were therefore "slight". The author felt that this was a question to be settled at Regional level but asked for Dr Hilton's views.

58.6. Dr Hilton responded on 18 March [DHSC0002501_017]. She noted that Dr Mehtar's letter had referred to dedicated funding for social support systems for HIV positive and Hepatitis B positive patients. She was not aware that there was any dedicated funding for Hepatitis B patients. *"The Department has not set aside any new funding for hepatitis C testing of blood donations and I think it unlikely that there would be any mechanism for funding this referral service centrally."* The lead with regards to hepatitis C lay with HC(M)2 and Dr Hilton suggested that this was the department which should be leading.

Q.59 The Views of the British Liver Trust, 1995

59.1. The IBI has referenced a briefing drafted by Paul Pudlo, CA-OPU2 for Andrew Hollebon PS/PS(H), for Mr Sackville [DHSC0003552_115] on 11 July 1995. It appears to have been a briefing written because the Minister or his office asked for a briefing on the British Liver Trust pamphlet "C Positive". Given that Mr Sackville made statements in an adjournment debate on the same date (see [HSOC0026481_010]), the briefing was, presumably, requested as part of the process of preparing Mr Sackville for the debate.

59.2. In his note, Mr Pudlo noted that the British Liver Trust were critical of the lack of counselling for new HCV patients and poor GP awareness of the disease. The contents of the briefing and Mr Pudlo's response have been addressed already in response to Question 55, above.

59.3. There had been previous contact between the Department and the BLT in 1995. Question 53 refers to the January meeting with Sir Graham Hart. This was followed by a letter to Dr Rogers sent by Sir Graham on 28 February 1995

[DHSC0003544_021], advising on the government's stance on liver disease treatment and how to access funding for the BLT's research proposals.

59.4. Some funding for the BLT was made available on 23 March 1995 [see WITN3430155]. The response from the BLT was that this was inadequate, and it made a bid to provide counselling as a result of HCV diagnosis in the LBE exercise [WITN3430156].

59.5. The CMO's letter of 3 April 1995 announcing the arrangements for the LBE exercise made reference to the expectations for counselling of those affected (see Section 7).

59.6. The IBI will be aware of an article in the Independent dated 18 April 1995, in which the British Liver Trust attacked the Government for what it described as the "*cheap and easy*" way in which it planned to tell "*thousands of unsuspecting people*" that they might have HCV [NHBT0005777]. It was critical of the design of the LBE and the absence of "unbiased" counselling arrangements.

59.7. It appears that Dr Rogers of the BLT wrote to the CMO on 20 April, after the Independent article referred to above, suggesting a meeting (the letter is reported in a minute at [WITN3430024]. There is an internal response from Mr Scofield [DHSC0002549_173; DHSC0002549_174] which records that the CMO was not keen to meet with the BLT, but the suggestion was that Dr Metters should meet them instead, with those involved in the LBE WP. A meeting was scheduled for 16 June, with discussion and briefings in the Department addressing topics such as the production of further public information for those at risk of HCV infection [DHSC0003539_107, note from Dr Nicholas] and the BLT's research agenda [DHSC0002549_120].

59.8. In advance of that, a meeting took place on 26 May between Dr Rogers and Mr Podger, in which the latter laid out the Department's position on a number of issues [WITN3430157] including on the ring-fencing of funding for treatment with Interferon. This was not something that the Department was prepared to support: see [DHSC0003595_026], which made a parallel with the prescribing of Beta Interferon for MS sufferers.

59.9. There is a note of the meeting held on 16 June with Dr Metters at [DHSC0002557_233], which sets out the BLT's concerns about counselling, amongst other issues. The BLT noted that for patients identified through the LBE, there could be three sources of counselling: the consultant under whom the patient had received the transfusion, the GP or the BLT. The BLT felt that it was the appropriate body to undertake counselling. There was discussion of whether the BLT could apply to the DH for further funding of its own work, but no agreement with regards to funding BLT to provide a Hepatitis C counsellor. Dr Metters wrote to Mr Paige of the BLT thereafter, sending the note of the meeting to the BLT. The Guidance in EL(94)72 that had been issued by the NHS Executive on prescribing and purchasing, including on the development of local strategies to manage the introduction of new drugs into the NHS was to be sent to the BLT.

59.10. The briefing from Mr Pudlo for Mr Sackville on 11 July 1995 stated:

> *"The Department has said that it would be open to suggestions from the BLT to improve counselling but officials believe that work has to be done to identify needs – in this respect the Haemophilia Society project should provide useful answers."*

59.11. See, on this project, Question 60 and Question 63 below.

59.12. There is further information about the funding that was ultimately supplied to the BLT under Question 64. It appears that by 1998, the DH was reporting that was providing the British Liver Trust with a three-year project grant of £38,250 years for a hepatitis awareness and assistance project, payable from 1997/98 to 1999/2000 inclusive, and two smaller project grants for the general publicity and a helpline (for all liver patients). See Question 64 below.

Q.60 Meeting with the Haemophilia Society, August 1995

60.1. In August 1995 a meeting was held between Mr Barker of the Haemophilia Society and Mr Pudlo, DH [DHSC0041361_051].

60.2. In the minute following this meeting from Mr Pudlo dated 9 August 1995 [DHSC0002467_049], Mr Pudlo reported back on the issues that had been

discussed. The main focus appears to have been on access to Alpha Interferon treatment but other issues including counselling were also raised. The minute was addressed to Dr Rejman but was copied to the CMO's Private Secretary, Dr Harvey, amongst others.

60.3. The Haemophilia Society was told that the prospect of ring-fencing funding for counselling initiatives (amongst others) was *"remote. However we are funding through s64 a Society Study into patient needs in terms of counselling."* Mr Barker had told Mr Pudlo that the Society was beginning to get results from its research and to identify areas for further work. He was urged to liaise closely with groups like the British Liver Trust and Mainliners to avoid duplicating efforts or arriving at inconsistent solutions.

60.4. According to a letter sent from Mr Sackville to Mr Haigh, Hospital Unit Business Director at Schering Plough House[14] [DHSC0041361_044] dated 28 November 1995, the study was into the best way to support haemophiliacs who were affected with hepatitis C; £91,000 pounds was being made available in 1995/1996, with a commitment to further funding in 1996/1997 and 1997/1998 for this purpose.

60.5. On 2 October 1995, a detailed paper on HCV treatment [DHSC0003552_018] was written by Mrs Phillips (HCD-SCS(A)2) with input from Drs Nicholas, Doyle and Mrs McIntyre. The topic of counselling was addressed:

> *"Another resource question that will have to be addressed is the question of who is to counsel the different categories of patients who are found to have HCV. BLT wish to undertake the work themselves given appropriate funding. This is not a practicable option and counselling is currently being undertaken by a variety of healthcare professionals. Guidance issued to the NHS in April (CMO letter) said that patients confirmed to be anti-HCV positive should be counselled on the implications of the test result and referred for a specialist opinion. We are under some pressure to provide additional resource is specifically for this."*

[14] Schering Plough was one of three companies involved in the production of Alpha Interferon: see [DHSC0004203_013].

60.6. There is further information under Question 63.

Q.61 Access to Alpha Interferon Treatment

Access by Haemophiliacs infected with HCV

61.1. The issue of access to interferon treatment was raised in an adjournment debate on 11 July 1995. Mr Sackville promised that the Department of Health would look into allegations of problems with the provision of Alpha Interferon for treatment of haemophiliacs infected with HCV [HSOC0026481_010].

61.2. On 9 August 1995, a meeting was held between Mr Pudlo (DH) and Mr Barker of the Haemophilia Society. The agenda for the meeting was set by a letter from Mr Barker to Mr Pudlo dated 18 July 1995 [DHSC0002474_007], in which he raised a number of issues including requests for specific, centralised funding for counselling, the PCR test for HCV and treatment with alpha interferon. He suggested that the Society had *"examples of haemophilia centres wishing to prescribe interferon but being told that they cannot because of lack of funds. This is unacceptable".*

61.3. The nature of the discussion and the issues raised are apparent from Mr Pudlo's subsequent minute to Dr Rejman, which was copied the CMO's office [DHSC0020838_160]. From this, it seems that Mr Barker stated that there were difficulties experienced by haemophiliacs in getting access to Interferon treatment.

61.4. In his Minute about the meeting, Mr Pudlo reported that the Society had only anecdotal evidence of treatment being withheld on financial grounds. Mr Pudlo had explained the difficulties which DOH had in responding without hard data on the nature and extent of the problem. He had agreed that the UKHCDO would be asked for further information. Mr Pudlo asked if Dr Rejman would contact Haemophilia Centre Directors to seek agreement in principle for a survey to be conducted. Dr Rejman responded [DHSC0003534_087], saying that he would ask that the matter be discussed at the next meeting of the Regional Haemophilia Centre Directors on 4 September.

61.5. The steps that were taken can be seen, for example, in the letter from Mr Pudlo to Mr Barker dated 16 November 1995, which was a belated response to the Society's letter of 18 July. Mr Pudlo reported that the issue was raised with the Directors of Haemophilia Centres at their meeting in late September. "*We have since received a handful of reports indicating difficulties, some of which have now been resolved.* We *are currently waiting for a response from Dr Brian Colvin*" [DHSC0041361_045]. Please also see paragraph 61.15 below, referencing this topic being raised at the LBE WP meeting on 13 October 1995, with a request for any further information about difficulties experienced.

61.6. The results of the investigation were subsequently reported back to the Haemophilia Society via a letter to Mr Barker dated 29 January 1996 from Mr Pudlo [HSOC0014304]. Mr Pudlo stated that, generally, the patients identified by the LBE were in no different a position to those represented by the Haemophilia Society. They should be counselled and referred for specialist opinion; the treatment offered would be determined locally. At the end of the letter, he added that the *"policy of not allocating resources for specific treatments is based on the principle that decisions about treatment provision are best made locally, taking account of the neds of the all the resident population."* General allocations took account of the need to fund new treatments and the best way of promoting them was to demonstrate their clinical effectiveness.

61.7. As for the issues reported about accessing treatment, they related to problems in three Health Authorities and in one Children's Trust (where the primary problem was in relation to securing ethical approval). The letter from Mr Pudlo reported that in all cases agreement had been reached that funding would follow a clinical decision that treatment was indicated. Mr Pudlo commented that the difficulties experienced seemed likely to have resulted from teething problems associated with the relatively recent licensing of alpha interferon for HCV treatment and asked to be kept informed if any further problems were brought to his attention.

Wider Patient Access to Interferon Treatment

61.8. Discussion of the broader issue of access to Interferon treatment generally can be seen in a large number of documents, including (but not limited to) the following discussed below.

61.9. It is apparent that the issue of HCV and treatment needs for wider groups including drug users were flagged up as one area of potential financial pressure, by spring 1995 at least: see for example Dr Nicholas's Note of 31 May 1995 [DHSC0002419_101]. But there were issues to be addressed as to how further NHS funding could be procured and how it was to be tackled in Public Expenditure Survey (PES) rounds, involving negotiations with the Treasury. Those involved in Treasury bids (Mr Urry) cautioned: "*However it currently stands as just one more new activity area among many others in the NHS. To run it as a PES pressure in future years it will be essential to have sound projected costings*" [DHSC0003552_158]. See too [WITN3430158] where Mrs Phillips commented that the Department "*could not countenance*" the ring-fencing of funding for interferon but "*as for Beta Interferon, it would not take too many additional patients to present a challenge to budgets. Mr Urry has commented on the PES implications of this as far as patients with HCV are concerned*". Later, in September 1995, Mrs Marsden commented that a "pressure" had been put forward in this year's PES for treatment for HCV in connection with the Lookback. But the only mechanism for addressing any resource issues was through PES and the earliest opportunity would arise in the 1996 PES [WITN3430159].

61.10. The wider challenges posed by HCV infection were noted by Mrs Phillips in a minute to Mr Waterhouse on 7 September 1995 [DHSC0003539_101]. She noted the issues that had been raised by the BLT at its meeting with Dr Metters in June 1995 and suggested that the issue needed to be raised with the NHS Executive. However, this copy is a draft and her final minute was probably not have been sent until 2 October 1995 (see below). In the meantime, Dr Peter Doyle asked for input about any information about HCV

prevalence arising from the LBE on 20 September [WITN3430160].[15] Dr Rejman replied shortly thereafter [WITN3430161] explaining that there were about 4000 infected haemophiliacs and it was thought that those identified by the LBE would be in the order of 3000; but better information should be available after the next WP meeting. He also referred to the estimate of 40,000 total infected from Dr Renton (discussed in Section 7).

61.11. On 25 September 1995, a letter was sent by the British Liver Trust [DHSC0041441_022] to Mr Stephen Dorrell, the Secretary of State for Health, about HCV. It was signed by Alison Rogers for the BLT and also by Mr Barker for the Haemophilia Society and Mr Williams, the Director of MAINLINERS. The letter stated that *"The key problem is that, because of the devolved nature of the purchaser/provider funding system, local commissioners are not providing services - not because there is no need for them, but because they are unaware of the extent of the problem."* The problem was exacerbated by lack of public information about the virus and ignorance about it amongst all but the most specialised medical practitioners. It was suggested that that there were problems in: getting access to up to date information, support and counselling on how to cope with living with the virus, diagnostic procedures and treatment with interferon or other drugs. A departmental task force was suggested.

61.12. Internal discussion by civil servants of this letter includes a commentary by Dr Rejman [DHSC0041441_018]. Dr Rejman noted that the majority of haemophiliacs at risk had been tested and that the issues of difficulties in accessing treatment were being investigated. There was also discussion of whether the Minister (Mr Sackville) might meet with the three organisations concerned [see WITN3430162] but there was a concern that the meeting would be embarrassing unless there was something definite to say. However, the need to reply to the charities' letter was overlooked due to "administrative error" [WITN3430163, minute of 12 February 1996]. A draft reply was finally

[15] See also [DHSC0003552_038], in which he stressed the importance of finding more information about minimum and maximum levels of prevalence in the population.

circulated by Dr Nicholas on that date and a reply ultimately sent on 3 April 1996 [DHSC0003539_007].

61.13. In the meantime, a full paper on HCV and the NHS dated 2 October 1995 [DHSC0003552_018] was written by Mrs Phillips (HCD-SCS(A)2) with input from Drs Nicholas, Doyle and Mrs McIntyre. It was addressed to Mr Waterhouse. It referred back to the meeting with the British Liver Trust and Dr Metters in June 1995. The Note set out the issues that the authors considered needed to be raised with the NHS Management Executive. *"Essentially, we are aware that there may be large numbers of people in the population infected by HCV many of whom will require assessment by a competent hepatologist and some of whom will need treatment with alpha interferon".* The note addressed the issue of likely prevalence in the population; the course of the disease; treatment needs and the disappointing record of Alpha Interferon (only 20-25% of patients with HCV experienced a sustained response). The 'lookback' was under way, and there was pressure for increased testing of potentially affected groups: current and ex-drug misusers. Further work on estimating prevalence was recommended, as well as on NHS capacity to manage the potential demand. The writers asked if guidance on the use of alpha interferon would be useful, although they noted that any proposal *"to discriminate between patients on the grounds of <u>how</u> they contracted the disease would not be acceptable here".* Further internal discussions were recommended, noting the tension between the need for a central initiative to deal with a potentially significant public health problem, and the aim of leaving the NHS to determine its own priorities based on assessment of local needs.

61.14. It is apparent that the suggestion that the NHS Executive Board should consider this topic was picked up and ultimately led to a paper being submitted for a meeting of the Executive on 13/14 June 1996. Please see Question 62 below. Dr Metters commented on 6 October [WITN3430164], noting the need for *"the development of a general framework for the introduction of high cost drugs across the primary / second care interface. To issue separate guidance every time a new product of this type comes on the market is inherently an unsatisfactory way to proceed."*

61.15. The topic of funding and access to treatment was discussed at the meeting of the LBE WP on 13 October 1995 [WITN3430147]. The Minutes record that Mr Pudlo reminded members of the Minister's promise about "doing everything possible" to ensure that those who contracted HCV through blood products got treatment. "*This had been in response to suggestions that some patients were not being given alpha interferon when this was appropriate. Officials were in touch with haemophilia centre directors seeking further information about the nature and extent of any problem. If the working group had any such information officials would welcome it.*" The members noted that "KVW" had agreed an algorithm of treatment with providers and had agreed an allocation of funding. Other purchasers were still considering the position. Given the competition for funds, it was suggested that NHS Executive action might be needed to ease the situation. Another member highlighted the expense of the treatment as a reason for difficulties. Dr Metters asked for any relevant information to be sent to him, "*to enable the Department to deliver on the undertaking that Ministers had given to the House.*"

61.16. The topic of central funding of HCV treatment was addressed in Mr Pudlo's letter to Mr Barker of the Haemophilia Society on 16 November 1995 [DHSC0041361_045]:

> *"As to funding, the Department does not hold back money centrally or allocate resources to support specific treatments for particular segments of the population. Resources are allocated directly to health authorities using a national formula, which is based on resident population projections and then weighted to take account of a number of factors, which include relative health and age. Purchasers are responsible for assessing the health needs of all their local residents, deciding which services to purchase and where to place contracts. These principles apply to the funding of treatment for Hepatitis C, appropriate counselling and PCR testing. Having said that, we do feed into the process of resource determination, anticipated pressures on health service expenditure and in that context Hepatitis C has been identified as a contributory factor. It is important that this is informed by*

evidence on the potential impact of the disease and relative benefits of available forms of treatment."

61.17. On 28 November 1995, a letter was sent from Mr Sackville to Mr Haigh, Hospital Business Unit Director[16] [DHSC0041361_044], in response to the latter's note of 1 November 1995. The Minister's reply referred to the ongoing investigation into allegations that haemophiliacs were having difficulties accessing treatment, but also discussed DH policy more generally. The DH generally adopted the policy of developing funding to local purchasers, based on a national formula. *"This is an arrangement that is unlikely to change in the near future, but we welcome other views especially when they contribute to a better understanding of an evolving subject."*[17]

61.18. An adjournment debate on "haemophiliacs" was held in the House of Commons on 13 December 1995 [WITN3430165]. The Minister, Mr John Horam, stated "*We have said all along that those people who could benefit from it should be able to receive alpha interferon."* He referred to the investigation of those cases where it had been said that haemophilia sufferers had not been to secure access to the drug, but "*So far there is little evidence of significant difficulties …"* The evaluation of the use of alpha interferon had been identified as a "top priority in the NHS" by the Standing Group on health technology.

61.19. In a minute written on the same date [DHSC0002533_058], Dr Nicholas expressed his concerns about the current situation. He had understood from the recent Departmental meeting that the Department was not in a position to treat Hepatitis C as a greater priority or allocate more funds to it, but he

[16] As previously noted, Mr Haigh's interest was as a manufacturer of Alpha Interferon.

[17] Mr Haigh followed this up with a further letter on 9 February 1996 to Mr Sackville's successor Mr Horam, arguing that health authorities needed to understand the case for treatment. He attached examples of cases where treatment had been denied and stated that they showed that at least one health authority had a formal policy of not providing the treatment; guidance was needed [DHSC0002533_074]. Mr Horam replied on 15 March 1996 [DHSC0002533_072]. He stated that there were a major programme of work to demonstrate the effectiveness of interferon, which would be the best way of ensuring that it was made available. He attributed problems of access, when the drug was clinically indicated, to teething problems but made it clear that the investigation conducted related to haemophiliacs with HCV.

acknowledged the risk that *"if it left entirely to purchasers, the allocation of resources for the treatment of hepatitis C may be very patchy across the country"*. The "line" would have to come from HCS_SCS and Finance. *"It is a problem to which there is no easy answer, and one about which I expect we shall receive frequent questions."*

61.20. In summary, the issue of the scale of HCV prevalence, the adequacy of funding for HCV treatment generally, and variations in approach across the country, had emerged as an issue of concern across 1995, with a commitment to bring the matter to the NHS Executive and/or Ministers for further consideration. The position in 1996 is addressed below.

Q.62 Discussions on HCV treatment and its funding, 1996

62.1. At Question 62, the IBI has asked about the discussions that took place "in 1996 concerning guidelines for treatment of HCV and its funding".

62.2. Please note that during this time, the further topics of whether guidelines needed to be issued about Hepatitis C infected health care workers, and of the infection risks to health care workers, were also under discussion, with consideration of guidance on these topics too. These matters do not appear to be the subject of the IBI's questions and so have not been addressed below, but they did form a part of discussion on HCV treatment guidance at the time.

62.3. It was noted above that a detailed paper on HCV and its implications, dated 2 October 1995 [DHSC0003552_018], was written by Mrs Phillips (HCD-SCS(A)2) with input from Drs Nicholas, Doyle and Mrs McIntyre. This suggested that a fuller paper be prepared for the NHS Executive and/or Ministers.

62.4. An undated draft of this further paper can be found at [DHSC0002419_015[18]]. There is an extensive copy list including the CMO's office and the "top of the

[18] [DHSC0002539_057] was also sent with the R9 but appears to be merely an earlier one-page draft of Annex B – those at high risk of infection. The iteration at [DHSC0002419_015] (p29) is a later draft. Equally, [DHSC0002539_059] appears to be an earlier draft of Annex D and does not add materially. [DHSC0003539_025] is

office generally", but it is assumed that this is the copy list for the paper once finalised. There are a number of documents showing the process of developing the draft and comments on the draft, including [at DHSC0002419_064], a record of meeting held by officials on 24 November 1995 to discuss the issues. This noted that the next opportunity to apply for funding would be in the 1996 PES, which implied that funds would be available until April 1997. This could be problematic, but any earlier announcement would *"mean we are deemed able to provide from within existing resources".* Mrs Phillips was to produce a paper for the "Top of the Office" and the NHS Board based on her paper of 2 October 1995.

62.5. Similarly [DHSC0003539_067] includes a minute dated 5 January 1995 (although January 1996 must have been intended) from Ms Marsden to Mrs Phillips. Ms Marsden noted the interest that the Home Office had in the subject. She commented on the need to avoid damaging the Public Expenditure Survey (PES) negotiations with the Treasury by signalling a change in policy at this stage. She suggested that more concrete actions needed to be offered to the Board and made detailed comments on the draft, frequently from the perspective of handling ongoing negotiations with the Treasury. It is apparent from [DHSC0004056_019] that on 24 April 1996, Mrs Phillips circulated a draft to a wide circle of officials, asking for comments.[19]

62.6. Meanwhile, on 16 January 1996, Dr Nicholas circulated a letter received from Dr Poulson, Consultant in Public Health Medicine, Avon Health [DHSC0004469_052]. Dr Nicholas noted that the scale of the problem of HCV in drug misusers had brought into focus by the LBE, which had raised expectations amongst other groups that treatment should be offered. He

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a copy of Annex C only and the text is the same as that contained in [DHSC0002419_015], so is not material. Equally, [DHSC0003539_027] is a copy of Annex E and the copy list, but also adds nothing to [DHSC0002419_015], so is not material.

[19] Comments on the draft received as a result include [DHSC0004056_014]: from Donna Sidonio (PC1 Presc) dated 2 May 1996. This made a link with the CMO submission on Clinical Gudelines for Major New Drugs, being co-ordinated by her branch. "The submission will be going to CMO this week to forward to M(H)". It was suggested that the Board might find it helpful to see. Further comments are at [DHSC0004056_016; DHSC0004056_017; DHSC0004056_018; and DHSC0004056_019]

suggested that screening could be recommended / justified if resources were available to manage any positive cases detected. At that time, any response would have to be "*guarded*". On the other hand, "*we cannot be seen to step backwards*."

62.7. There was continued pressure exerted by campaigning or charitable bodies. Thus on 16 February 1996, the BLT issued a press release reporting on a survey conducted in liver units across the UK. The headline message was that HCV "*patient numbers are increasing, but … treatment, counselling and support services are inadequate to deal with the growth"* [WITN3430166, page 1-3]. The press release was critical of the limited numbers of patients identified as having come through to liver units as a result of the LBE, suggesting that if 3,000 patients were being identified by this exercise, they were not getting through to specialist units. In addition, three-quarters of units were experiencing problems funding interferon treatment.

62.8. The same month (19 February 1996), the Haemophilia Society sent the final version of its detailed report on the experience of haemophilia sufferers with HCV to the Secretary of State for Health [HSOC0003748].

62.9. [WITN3430167] summarises its contents, in the context of briefing for a March 1996 Ministerial meeting with the Haemophilia Society. That briefing also summarised the steps that had been taken by the DH, including:

(1) Support for the study itself (a grant of over £90,000 in the current financial year and £117,000 in 1996/7, on top of core funding of £35,000 this year and £38,000 in 1996-7);

(2) The lookback exercise itself;

(3) Support for the BLT through the s64 grant scheme; this included a grant specifically to deal with the additional workload of advising patients infected with the virus;

(4) Establishment of the HCV Register;

(5) *"Research proposals are being sought on establishing the prevalence, transmission routes and Natural History of hepatitis C infection"*[20];

(6) *"a Ministerial commitment to investigate allegations of problems of access to alpha interferon. A few cases were identified by the Society, all of which have been resolved."*

62.10. On 26 March 1996, a further meeting with the Haemophilia Society took place with Mr Sackville. The Minister's briefing for the meeting [see WITN3430168] repeated that funding for both treatment and counselling were matters for local decision.

62.11. A further draft of the paper "Hepatitis C: issues for the NHS" was circulated to colleagues by Mrs Phillips on 17 April 1996 [WITN3430169; paper at WITN3430170]. There was further discussion of how to manage the relationship with the Treasury and financial pressures sent in response [WITN3430171].

62.12. The topic of Hepatitis C was "*briefly discussed*" at the CMO's Medical Group on 14th May 1996 [see DHSC0004056_013]. Dr Peter Bourdillon's minute to Mrs Phillips suggested that he gave information about the condition and its treatment, but queried the justification for offering the asymptomatic screening and treatment, "*the benefit of which is yet to be demonstrated*". Dr Metters noted that the MSBT had recommended to the Department that all those who might have acquired Hepatitis C should be offered testing and, if warranted, treatment. "*Dr Hangartner expressed concern that the medical workforce of hepatologists would be insufficient to meet the potential demand. Dr Metters said that earlier this year PS(H) had discouraged officials from speeding up the look-back process because of worries about the extra workload for hepatologists. CMO suggested that Dr Metters and Dr Bourdillon should discuss the matter further."* Noting that "*Cirrhosis can be lethal but it is treatable*," Dr Boudillon's view was that *"Some of the side-effects of alpha-interferon are life threatening. Better justification would seem to be indicated*

[20] See the further discussion of the research agenda in, say [DHSC0044525_303] (Dr Metters), stressing the need for prevalence studies. There is an evaluation of proposals at [WITN3430172]. Further work would be needed to document the exact progress of this work.

for the treatment of asymptomatic subjects with a drug with potentially life threatening side effects."

62.13. It is apparent that Dr Metters was unhappy about the views expressed in this Minute by Dr Bourdillon, regarding them as criticisms of the LBE. He set out his views in a response to Dr Bourdillon on 21 May 1996 [DHSC0004761_077], pointing out matters such as the co-ordination that had taken place to launch the LBE.

62.14. A response on the same day from Dr Peter Bourdillon (HCD-SCS) to Dr Metters clarified that he was querying not the LBE exercise, but "screening" of asymptomatic past or present intravenous drug users intravenous drug users for chronic hepatitis C. *"Where is the evidence that this is a clinically effective and cost-effective exercise?"* he wrote [DHSC0004056_012].[21]

62.15. A later document from Mrs Towner [22 May 1996, DHSC0004056_009] summarised the commitments that Ministers and other DH spokesmen had given regarding the availability of Alpha Interferon as a treatment for Hepatitis C: see the list at [DHSC0004056_010]. She stated that *"In summary, the commitment given has been to provide treatment where appropriate (or necessary). There has been no firm commitment to provide treatment - as distinct from referral for specialist opinion - in every case."* Dr Metters responded on 24 May 1996 with a short note copied to the CMO's Private Office [DHSC0004056_008]. He referred to Miss Towner's note as a *"useful summary*" of the statements. Most were in the context of the LBE, but *"some can be given a wider interpretation. Perhaps the most telling are in the debates on 11 July and 13 December 1995",* as well as paragraphs 18, 22 and 24 of the CMO's letter of 3 April 1995. He suggested ensuring that the paper referenced comments in the public domain.

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[21] In [DHSC0004056_018] he expressed the same concern to Mrs Phillips (30 April 1996). See also [WITN3430173], which is an article from the BMJ (Volume 312, 25 May 1996) which argued the case both for and against screening asymptomatic people at high risk of Hepatitis C (mostly drug users). Dr Metters commented on 3 June 1996 [DHSC0042289_052] that screening was not being proposed, with the exception of blood recipients amongst the LBE who were still alive – rather, it was a question of testing being available to those at risk who requested it.

62.16. From the Minute from Mrs Phillips (HCD-SCS(A)2) dated 17 April 1996, it appears that the intention was to submit the final version of the paper to the Board meeting in May 1996 [DHSC0003534_016[22]]. This Minute references a meeting to be held on 18 April 1996, to discuss the topic of "Hepatitis C: issues for the NHS". The copyee list included a number of civil servants including medical officers.

62.17. The final paper submitted was EB(96)42: Hepatitis C [DHSC0006348_083],[23] with a covering Note from Dr Winyward, who was to present it. The covering Note stated:

> *"It is clear that there is no obvious preferred way forward. The key dilemma that we and Ministers face is the conflict between what* ***may*** *be desirable public health policy and the capacity of the NHS to deliver. In this situation guidance recommending action which cannot in practice be undertaken could result in more embarrassment for us and Ministers than the current situation where we are criticised for not making such recommendations."*

62.18. The main paper noted that there were essentially two groups of patients. Some, including haemophiliacs and recipients of blood transfusions (minimum of 7000 cases) had been infected as a result of NHS treatment. The other group were current and past drug misusers who had shared equipment; this

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[22] [DHSC0003534_017] which follows is merely the cover page for the Paper; the substantive content is no included. There is a short draft Executive Summary (undated) at [DHSC0003539_017].

[23] Various drafts have been brought to the attention of the DHSC team by the IBI, but they appear to be earlier iterations of the final paper. There is a copy of the Executive Summary at [DHSC0003971_008]. There is a copy of Appendix 1 (Prevalence amongst IVDUs) at [DHSC0004761_101]. Appendix 2 is at [DHSC0004761_102] (Prevalence amongst Transfusion Recipients). This latter paper took issue with the figure of 40,000 for HCV prevalence amongst recipients of blood transfusions, derived from the work of Dr Renton. It provided data to suggest that *"The chance of contamination [via blood transfusion] is only about 0.125%. With 560,000 people exposed to a risk of 0.125%, 700 are likely to have acquired infection. With allowance for other groups, it appears that the demand for services may be in the region of 1500, provided that treatment is not offered to those unlikely to survive long enough to develop cirrhosis."* Those figures did not include any infected haemophiliacs. Appendix 3 [DHSC0004761_103] gave figures for the cost of various HCV related procedures, including a course of interferon treatment (£2000 - £5000). [DHSC0004761_107] contains a draft of Annex A.

group, unlike the first, was likely to grow. The current best estimate of those infected was 300,000.

62.19. The paper noted that, in respect of the first group, that Ministers had given commitments to help if haemophiliacs had experienced difficulties accessing HCV treatment; *"So far the few cases identified have been readily resolved".* Equally, a Ministerial assurance had been given that patients identified as a result of the Lookback Exercise would be tested and, if appropriate, treated. It is apparent that the real pressures stemmed from the numbers in the second group. But:

> *"Distinguishing between people infected through NHS treatment and through other routes such as drug misuse would be contentious. Ministers would be exposed to criticism if it appeared that the Department/NHS was operating a selective policy on testing and/or treatment depending in the mode of infection (shades of the "deserving" and "undeserving" poor). Pressure groups like the British Liver Trust would rapidly identify any evidence of a two tier approach if Ministers fail to follow the "Tackling Drugs Together" commitment. The only acceptable grounds for refusing treatment would be a medical contraindication. Similarly, appearing to withhold treatment on costs grounds would be politically unacceptable…"*[24]

62.20. The paper referred to a commitment to issue purchasing guidance on drug treatment services, but added that *"Clinical guidelines along the times of those issued by SMAC on Beta Interferon may also be useful…. Issuing any guidance, however, implies a new signal about the relative priority to be attached to treatment. Initial soundings of purchasers indicate that, particularly in the current climate of serious strain on the acute services, such guidance is unlikely to be welcome particularly if prescriptive."*

62.21. The Minutes and Action Notes of the NHS Executive Board meeting held on 13/14 June 1996 record [DHSC0044009_023], under the heading of Hepatitis C:

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[24] See, on the legal advice that underpinned this statement, [DHSC0042289_071] (30/05/1996) and [DHSC0016616].

> *"Graham Winyard introduced this paper which sought the Board's views prior to producing a submission for Ministers. The Board agreed that measures needed to be taken on the public health perspective, recognising the limits of current knowledge, and that further policy development would be affected by the views of professionals (including possibly SMAC), research findings and other information.*
>
> *ACTION: DR WINYARD TO TAKE FORWARD."*

62.22. The attendees are listed in the Minutes; they did not include the CMO.

62.23. Mrs Phillips recorded the outcome of the meeting in an undated note sent shortly afterwards [DHSC0004065_006].[25] She wrote to colleagues: "*As you know, the paper on hepatitis C was considered by the NHS Executive Board last week. There were no surprises and basically we should proceed as planned. None of these specific questions were answered although the preferred option was apparently two and a half! - in other words, somewhere between do nothing pending further advice/research and accepting the need to embark on measures to increase awareness."*

62.24. She set out the further work that she needed to do, including encouraging the profession to draw up clinical guidelines *("under consideration but I have started the ball rolling*"). She noted that *"there seems to be a general consensus out there that the guidance would be best coming from the profession if we can get them to agree, which would be no mean achievement."*

62.25. A comment from Donna Sidonio (PMD-PC) on this minute[26], sent on 21 June 1996, referred to speaking to Mrs Phillips and reminding her that *"Ministers/the Department needed to take a clearer position generally on the development of clinical and management guidance and new drugs, the role of COG [Clinical Outcomes Group] etc."* She referred to sending a submission to M(H) in early July.

62.26. A further minute dated 17 July 1996 from Donna Sidonio to Mr Dobson [DHSC0004056_005] refers to the outcome of the Executive Board meeting.

[25] This copy of the message is undated.
[26] Also to be found at [DHSC0004065_006] – the document contains both minutes.

She says that she had not seen a report of the meeting *"but understand that the Board took the view that, although there are public health implications which need to be addressed, the handling and dissemination of any advice from the centre should be low-key".* She noted that although there seemed to be an expectation that the Department (HCD SCS) would be developing guidelines for the management of HCV and use of Alpha Interferon *"In fact HCD SCS have already approached the profession (hepatologists) informally and asked them to develop clinical guidelines."* In the absence of a firm view on handling from the Board, a cautious approach seemed necessary. She added that "*last night, at a meeting with CMO and HCS SCS colleagues, Dr Winyard apparently put forward the same line."* She recorded:

> *"The upshot of the discussion was that HCS SCS/HP3 believe there is a strong case, on public health grounds, for at least developing clinical guidelines on the management of HCV, including the use of Alpha Interferon. However, in order to take account of last week's Board views, and to arrange for guidelines to be developed which are robust and likely to be commendable by COG, they expect such guidelines to be developed over a fairly slow time scale - taking up to about a year. They will seek input from professional and patient interest groups in developing the guidelines."*

62.27. She noted that Mrs Phillips would prepare a Ministerial submission asking for approval of this approach.

62.28. There is a draft Ministerial submission dated 19 November 1996 from Mrs Phillips [see DHSC0004203_031]. A note from the CMO's Assistant Private Secretary dated 22 November records *"CMO has seen this and commented: 'A very useful review'"* [WITN3430166 at page 4].

Ministerial Submission: December 1996

62.29. A Ministerial Submission "Hepatitis C: the Current Position" was sent on 23 December 1996, from Mrs Phillips to the Private Office of the PS(H), Mr

Horam [DHSC0004203_013]. It was copied widely including to the Secretary of State and the CMO's Private Offices.[27]

62.30. The Ministerial Submission *"informs Ministers of the issues raised by Hepatitis C and proposes a framework for handling the disease with options for taking this forward"* (para 1). There was information about the disease and its prevalence. The objectives for the Department and the NHS were said to be:

a) *"As with other transmissible diseases, to handle the public health aspects of hepatitis C;*

b) *to maintain public confidence; there has been criticism of the department stance on hepatitis C and unfavourable comparisons made with our handling of other related public health problems such as AIDS;*

c) *To set a framework which will enable the NHS to manage the disease locally (action needed includes both prevention and treatment)."*

62.31. On the first issue, the submission noted *"a strong case and mounting pressure for sending out clear public health information to encourage people at risk to come forward for testing".* It noted that *"we have resisted too proactive a public health stance eg: the sort of publicity campaign mounted for HIV/AIDS because of the resource implications for the NHS."* However, the Executive Board had *"confirmed the Department's responsibility for issuing clear public health advice despite the implications for NHS expenditure."* As a result, suitable opportunities were being taken to update the public health information available.

62.32. The recommendation to Ministers (paragraph 18) on this issue was to continue by updating public health advice, rather than to launch a public health campaign, since "*we do not wish to cause unnecessary concern or a surge in referrals which the NHS could not deal with, particularly given the currently limited options for treatment."*

62.33. As for the second issue:

[27] Although there seems to have been some re-writing and re-submission: see for example [WITN3430174], the exact details of which have not been tracked through.

> *"There is a perception which has some substance that the Department is trying to keep its response to the relatively new problem of hepatitis C low key, mainly because of the resource implications of raising public awareness. We are under pressure from the drugs misuse agencies, voluntary organisations, professionals and the drug companies to take a more proactive approach to both the detection and clinical management of HCV …. there are many people who do not know they are infected who will only [come forward] if advised specifically that they may be at risk. Some Health Authorities are unwilling to encourage them to come forward for testing since this will increase the demand for treatment. The Department and the NHS need to demonstrate that public health is given the highest priority in order to maintain public confidence in our handling of the illness and the NHS' ability to deal with it."*

62.34. With regards to public confidence, the recommendation (paragraph 20) was that *"we make it clear that we are taking a more proactive stance in relation to hepatitis C and that we are attempting to raise its profile responsibly and ensure that the NHS is prepared but without causing widespread alarm".*

62.35. The implications for the NHS were set out, noting the funding pressures arising from treatment costs. The case for treatment was not always straightforward, it was noted: "*To deny any individual patient, however infected, a trial of a drug that made delay or prevent the development of serious liver damage is contentious. Conversely, to encourage people to seek treatment at a time when they are asymptomatic, and may remain so for decades, during which time more effective treatments may be developed, is equally questionable, particularly as such trials of newer treatment regimens are already in progress and are expected to report in the next few years."*

62.36. The submission continued:

> *"Purchasers in some areas have made it clear that they are not willing to pay for treatment with Alpha Interferon: clinicians have been told that purchasers will not pay for treatment not covered by existing contracts. In other areas, patients with the same (or less severe) clinical condition*

may be offered treatment without restriction. Our policy on the availability of treatment is that Health Authorities should not rule out the purchasing of an intervention known to be clinically effective where appropriate. However, it is, in the first instance, a clinical decision as to whether it should be made available for any particular patient."

62.37. The submission noted that there was evidence of increased expenditure on Alpha Interferon but there had been no attempt centrally to advise the NHS about prescribing.

62.38. Further information and recommendations (paragraph 24) noted that research into the effectiveness of treatment with alpha interferon and drugs under development was currently being commissioned as part of the health technology assessment programme, although there were concerns that this would take too long and unfavourable comparisons with HIV research. The submission noted:

"In addition, we are supporting the profession in their plans to produce clinical guidelines on Alpha Interferon. This will be similar to the clinical advice issued to help the NHS manage the introduction of Beta Interferon …. A professional consensus conference was held in October involving organisations with an interest in HCV where the general principles on which guidelines could be based were agreed. If these are commended by COG they would be promulgated to the NHS. This initiative will be given financial support by the NHS Executive if appropriate.

Issuing any guidance to the NHS, even commending clinical guidance, gives an implicit signal to purchasers about the priority to be attached to a particular condition or treatment…. Any guidance …. should ensure that HAs do not put a blanket ban on the testing and treatment of HCV patients."

62.39. The recommendation was that purchasing guidelines should not be issued in addition to clinical guidelines, as it was thought that this would be unhelpful for purchasers. "*In parallel to this we may raise the cost of testing and treatment as a new pressure in PES97."*

1997

62.40. Responses to the Ministerial submission of December 1996 so far identified do not include any direct commentary from the CMO's Office. [DHSC0006855_010 and WITN3430175] suggests that Ministers were inclined to increase the research budget, and it appears that it was subsequently increased from £1m by a further £0.5m.[28]

62.41. There was a meeting on the topic of HCV, with PS(H) and the SoS meeting Claire Phillips, on 12 February 1997: see the note at [DHSC0004203_005, DHSC0004203_003]. This records that the Secretary of State's intention was that the framework for policy "*should be to develop appropriate research and planned health promotion without causing unnecessary health scares or swamping NHS services."* There should be a properly coordinated R&D programme on HCV. *"On health promotion, Ministers would not want to see a separate identifiable HCV prevention campaign which would unnecessarily raise its profile and thus public concern. It should continue to be addressed through the safer sex and drug misuse programmes."*

62.42. The note of the meeting continued:

> *"On clinical guidance, Secretary of State noted the plans to promulgate guidance produced by the RCP [Royal College of Physicians], following the meeting scheduled for June. He suggested that GPs should have a greater role in identifying, diagnosing, treating and referring HCV as appropriate, and that GP involvement should be secured before the June meeting. The most effective way to do this should be through a letter from CMO to the RCGP [ie Royal College of General Practitioners].*
>
> *It was agreed it would be very useful to have on record a statement of the Government's action on researching, preventing, diagnosing and treating HCV. If CMO was in agreement, a further CMO letter, this time to District Directors of Public Health, setting out all the elements of the policy should be sent out in the near future."*

[28] See [WITN3430176], paragraph 5 – Ministerial Submission.

62.43. It is apparent from [DHSC0004203_003], a memo from Dr Metters to Dr Shepherd (PS/CMO) that the CMO then asked Dr Metters to suggest how action on the last two paragraphs quoted above could be taken forward. Dr Metters set out proposals to ensure liaison between the RCGP and RCP, noting that "how" GPs might be further involved would not be clear until after the RCP conference in June. He was not supportive of the need for the CMO to write to the RCGP, suggesting that there was already contact between the two bodies and that discussions with their respective Presidents might be more effective. Dr Nicholas might put together a statement of government action on HCV so far. Dr Metters raised some concerns with regards that a profile that a letter to District Directors might have, advising that CMO might wish to suggest that a letter be deferred *"until at least we have advice from RCP".*

62.44. There was debate on the extent to which the SoS's aims on involving GPs in care were appropriate: see [DHSC0004203_004], in which Dr Clappison raised reservations. It is also apparent that the progress on guidelines raised concerns; a draft submission from Mrs Phillips to the new Secretary of State in July 1997 [DHSC0046979_112] recorded that the process of supporting the development of clinical guidelines *"is taking longer than anticipated but it is hoped that the guidelines will be available early next year."*

62.45. This submission noted that *"There are a number of children infected with HCV mainly as a result of (1) treatment with contaminated blood products before blood was screened for HCV and (2) transmission from current or one time drug misusing mothers…. Alpha interferon is not licenced for treating children but it is hoped to fund a trial into this to find out whether it is effective."*

Ministerial Submission, November 1997

62.46. The document referenced above was a draft only. It appears that a submission was not finalised and put up to Ministers until November 1997. The Ministerial Submission dated 13 November 1997 is entitled 'Hepatitis C - Issues for the NHS.' [WITN3430176]. This lengthy and detailed submission was sent to the CMO's Private Office (Dr Shepherd) and to the Private Offices of M(PH) and MS(L) (Ms Jowell and Baroness Jay). It referred to general

issues concerning Hepatitis C. It noted *"the public health implications, the large numbers potentially involved – thought to be up to 300,000 in England – and the difficulty in treating this chronic blood borne virus".* It set out background information on the virus, its prevalence and effects. It discussed research efforts, the lack of availability of testing and the look-back exercise, noting criticism of slow progress. *"The look back raised expectations that testing and treatment would be available for those infected through NHS treatment."* On access to treatment with alpha interferon, there were problems with regards to inconsistency or equity of access. The concerns appeared to centre around those who had been infected by routes other than blood or blood products: *"Specific commitments given in respect of those infected through NHS treatment, either through blood transfusion … or through blood products …. are difficult to reconcile with the fact that some patients coming forward for treatment who were infected through other routes are being denied treatment."*

62.47. On guidance for the use of alpha interferon, the submission stated that the medical profession was being supported to produce clinical guidelines on prescribing practice:

> *"In response to the variety of opinion and clinical and commissioning practice in the use of alpha interferon, we are supporting the medical profession financially and administratively in the production of clinical guidelines.*[29] *The intention is to bring about a more consistent approach to prescribing (for both clinicians and commissioners) and to maximise cost-effectiveness in the use of the drug. A workshop has been convened in December for representatives of the professions and patient groups involved to present papers on different aspects of diagnosis and treatment with alpha interferon. The clinical guidelines will be independently appraised under the existing arrangements (overseen at present by the Clinical Outcomes Group and in future by the External Reference Group to the new Executive Board sub-committee on quality). If the appraisal is favourable, which will depend*

[29] From [DHSC0006282_107], it is apparent that there was funding provided to the Royal College of Physicians for this purpose.

in part on whether the appropriate methodology has been followed, the NHS Executive would commend the guidelines to the NHS early next year."

62.48. With regards to health care workers, the submission notes that health care workers were *"at risk of acquiring hepatitis C infection as a result of occupational exposure to the blood or tissues of infected patients"*. The Department was currently revising *"Guidance for Clinical Healthcare Workers: Protection against Infection with Blood Borne Viruses*". On infected children, it noted that research proposals to the MRC and HTA had been turned down, but the Department hoped to find some mechanism for funding treatment and for evaluating its effectiveness.

62.49. A series of recommendations were set out, including with regards to raising awareness of HCV and reiteration of the fact that there should be no "blanket bans" on treatment. There was a suggestion that Ministers might find it helpful to have a seminar on hepatitis (see Question 56 for this issue).

Q.63 Dr Nicholas' note of 30 June 1997

63.1. See Personal Statement.

Q.64 Steps taken to address the stigma suffered by those who had been infected by blood or blood products

64.1. The Inquiry has asked about the stigma attached to HCV infection and about the steps taken to address the stigma suffered by those who had been infected by blood or blood products. See the Personal Statement.

64.2. The IBI may also note Dr Nicholas's response to a query about information provided, on 6 June 1996 [DHSC0003595_024]:

"… I am not certain that there is any obligation on Health Authorities to provide patient literature and information on individual diseases. Some will do so in particular instances and where they chose to do so will accurately reflect what is known about that disease. I know of one provider unit that provides patients with literature on hepatitis C and also has videos available. Mr [M] himself refers to a factual booklet produced by St James's Hospital in Leeds. The fact that literature of

this kind vanish is from hospitals has, in my experience, more to do with individuals anti-socially removing it for their own use than to do with any censorship by HAs or provider units."

Section 9: Retention of samples and consent

Q.65 Retention of tissue samples and patient consent

65.1. See Personal Statement.

Q.66 The HCV Register

66.1. This Annex sets out the background to developments in the HCV Registry during Sir Kenneth's time as CMO England, focussing particularly on consent and confidentiality. It has been drafted to assist Sir Kenneth with the preparation of his statement and to assist the Inquiry.

66.2. An early summary of the research proposal entitled, "National register of Transfusion Acquired HCV infection" was produced on 10 March 1995, by Dr Mary Ramsay (PHLS Communicable Disease Surveillance Centre) and Dr Philip Mortimer (Central Public Health Laboratory) [DHSC0006819_078]. The objectives were described as follows:

> *"Objectives*
>
> *1. To establish a central, national register of cases of presumed transfusion acquired HCV infections.*
>
> *2. To establish a central, national archive of sera from cases of presumed transfusion acquired HCV infections.*
>
> *This will facilitate the retrieval of important clinical and laboratory data in case of medico-legal, clinical and research purposes. It will not preclude proposals to follow up and investigate this cohort from other agencies."*

66.3. On 10 March 1995, Dr Angela Robinson (Medical Director, National Blood Authority), minuted DHs' Mr Scofield (CA, OPU [NHS Executive, Directorate of Corporate Affairs]) [DHSC0006819_078] with a copy of the research proposal which the authors hoped would be considered at the next MSBT meeting on 14 March. She commented to Mr Scofield that:

> *"Having spoken to Jeremy Metters, he suggested I send it to you for consideration and circulation to the internal MSBT team 'only' prior to 14th March. Neither Jeremy or I are against this proposal in principle but Jeremy has already flagged up the need for informed consent."*

66.4. On 28 September 1995, the proposal for a national register was discussed at a pre-Meet to a Clinical Directors Meeting [NHBT0009891_001]. The potential uses of a register were considered and it was noted that the formation of the registry had been recommended by the MSBT Ad hoc Committee on HCV Lookback. Dr Heptonstall suggested that it could be named, *"The Registry of Known Date Hepatitis C Infections"*. In relation to the issue of consent, Dr Heptonstall suggested that:

> *"clinicians be approached, rather than the patient, for consent for inclusion on the registry. However, it was felt that consent was not really an issue, although it was recognised that some information (such as HIV risk factors, alcohol intake etc) could be seen as sensitive. The use of Soundex coding was discussed. JH felt that as less than 20 hepatologists were probably involved it would be worth contacting them for their written approval".*

As *"further action"* it was suggested that Dr Heptonstall *"tidy up her proposal and forward it to AR* [Dr Angela Robinson] *week commencing 2nd October, in time for the discussion at the next MSBT Ad hoc Meeting on 13th October".*

66.5. By 10 October 1995, the proposal was in a more detailed draft stage labelled as "v.4" [WITN3430177]. More detail was provided on the background (section 2) and purpose (section 3) as well as the plan of investigation (section 4). Within that section, section 4.2 addressed what was proposed for patient registration and Appendix B addressed information to be acquired from the clinician responsible for initial assessment. At this stage of the draft proposal, this stated, "*Consent of clinician to inclusion on of case in register (? Consent of patient to inclusion in the register?)".*

66.6. Shortly afterwards, on 13 October 1995, the research proposal was discussed at the Fifth Meeting of the Hepatitis C Look Back Working Party, chaired by Dr

Metters and attended by, amongst others, Mrs Griffin of DH's Research and Development Division [WITN3430178]. Section 8 of the minutes, shows that the issue of consent was raised by Dr Metters:

> *"8.2 Mrs Griffin tabled Paper 5.2, prepared by Dr Julia Heptonstall of the Public Health Laboratory Service, proposing a central national registry of hepatitis C infection.*
>
> *8.3 Dr Mortimer regarded the setting up of a national register as a fundamental step to take. However, it was necessary to avoid contravening the Data Protection Act.*
>
> *8.4 The Chairman [Dr Metters] noted that unless there was positive consent given by a data subject at the time of collection, researchers may not test the sample for any purpose other than that for which it was collected. The same principle applied to use of data for purposes other than those for which it had been collected.*
>
> *8.5 Professor Thomas viewed the national register as an opportunity to assess the numbers affected and develop a comprehensive model, that allowed researchers to predict the rate of progression of hepatitis C and the consequent cost of providing treatment.*
>
> *8.6 Professor Zuckerman thought the scientific case for a register was overwhelming.*
>
> *8.7 Dr Gillon thought it an excellent proposal which he would discuss with colleagues in Scotland. He remained concerned, however, about the issue of consent.*
>
> *8.8 Dr Mortimer reflected that the amount of information held on the data base and available to researchers will be limited without going back to clinicians.*
>
> *8.9 The Chairman [Dr Metters] summed up by saying that the Working Party overwhelmingly supported an archive, which would be given high priority when funding was being considered. He reaffirmed that it would be important to avoid contravention of the Data Protection Act, eg by obtaining consent prospectively. Mrs Griffin said that proposals for research in those areas agreed to be a priority for DH would be taken forward by open competitive tendering"*

66.7. Following up this meeting, on 27 November 1995, Mrs Griffin indicated a willingness to fast track the proposal to funding and provided a draft letter to Dr Heptonstall outlining matters that needed to be addressed in a further revision of the paper, one of which was what arrangements would be made to satisfy the Data Protection Act [DHSC0002550_123; DHSC0002550_124;

DHSC0003533_088]. She also raised with Dr Metters the desirability of putting a submission to Ministers to inform them of the total proposed research endeavour being undertaken in relation to Hepatitis C, as part of the wider submission then being prepared by Claire Phillips [DHSC0002550_119; DHSC0003971_105; DHSC0002550_123; DHSC0002550_124; DHSC0003534_054; DHSC0004761_101; DHSC0003534_056]. £1 million had been identified for work on HCV prevalence, transmission routes and natural history of the disease, with the HCV Registry proposal being part of the latter strand of research. Dr Metters responded on 29 November 1995 [DHSC0003971_099] and Mrs Griffin wrote to Dr Heptonstall on 5 December 1995 [WITN3430179]. As well as the Data Protection Act, the need for arrangements for ethical clearance of the studies based on the registry's database was raised.

66.8. At the meeting of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplant on 8 January 1996 (also chaired by Dr Metters), Dr Toy (Senior Medical Officer in DH's RDD) noted that the Department was awaiting from Dr Heptonstall, the amended protocol for a national HCV archive which the Committee supported (Minutes §4.15) [DHSC0020692_117; DHSC0020692_118]. Later that month, on 19 January 1996, Dr Gill, Deputy Director (Information) at the CDSC, wrote to Dr Metters in his capacity as chairman of the unlinked anonymous sero surveys steering group to ask for DH encouragement and assistance with implementation of studies proposed by PHLS, of which the HCV register was one [DHSC0002550_061; DHSC0002550_062]. Dr Metters replied on 26 January 1996. He noted the good match between PHLS research proposals and the three areas of HCV research which the MBST had identified as being of the highest importance and gave details of the process for the award of research grants [WITN3430180] .

66.9. On 30 January 1996, Dr Heptonstall then wrote to Dr Toy with a formal version of the research proposal [WITN3430181; WITN3430182; WITN3430183]. Sections relevant to consent and confidentiality issues included §4.2.1; §4.4.1 and Annex B. The latter still contained the wording,

"Consent of clinician to inclusion on of case in register (? Consent of patient to inclusion in the register?)".

66.10. In February 1996, the RDD then sought and obtained views on the research proposal from outside 'referees' to obtain their views, see the letter from Dr Hall [WITN3430184] and Dr Beral [WITN3430185]. The substance of the concerns raised were conveyed to Dr Heptonstall's team seeking responses.

66.11. On 30 May 1996, DH's RDD received a proposal for a national case register for HCV infections in Scotland [WITN3430186]. This is of note because under 'Ethics' this proposal outlined that, "*The seeking of information from clinicians and patients (eg, through interview) will only be done on condition of fully informed consent.*"

66.12. On 1 December 1996, Dr Ramsay wrote to Dr Toy responding to the referees' comments and apologising for the time taken in doing so (Dr Heptonstall had left, and Dr Ramsay had now taken over the lead on the proposal) [NHBT0036431; NHBT0036430]. Dr Toy then sought further input from the referees on the amended proposal which was received and conveyed to Dr Ramsay [WITN3430187; WITN3430188; WITN3430189; WITN3430190; WITN3430191].

66.13. On 11 March 1997, Dr Robinson wrote to Dr Metters, concerned at the perceived delay in DH granting approval and funding to the HCV register proposal, which caused her serious concern and frustration [WITN3430192]. It can be seen from Dr Metters' annotations that he asked Mrs Griffin to look into the matter. The following day, 12 March 1997, Dr Toy provided Dr Metters with a chronology of events [WITN3430193]. Dr Toy had chased for responses to the referees' comments in 1996 and the current situation was that RDD was awaiting the PHLS response to one of the referee's second set of comments, which he was surprised not yet to have received. He considered that PHLS were close to being able to satisfy DH that the proposal deserved funding.

66.14. On 13 March 1997, Dr Ramsay provided her response to the further referee's comments [WITN3430194]. Dr Toy then confirmed that DH was content to commission the proposal: see his letter of 17 March 1997 [WITN3430195]. He

sought some amendments to the proposal to reflect Dr Ramsay's response to the referees' comments.

66.15. Funding approval was signed off by Dr Toy on 19 March 1997 [WITN3430196]. As regards consent, Annex B of the research project now stated as to the information to be sought from the clinician responsible for initial assessment, "Consent of clinician to include case on the register". The previous reference – to "(? Consent of patient to inclusion in the register?)" no longer appeared in this version. As previously, §4.2.1 noted that the final report form on which clinicians would report on their patients would be approved by an appropriate ethics committee.

66.16. On 12 May 1997, Dr Ramsay wrote to Dr Toy thanking him for the agreement to fund and included an amended proposal to address the matters raised by Dr Toy on 17 March 1997. She invited Dr Toy to be a member of the steering group being established. Dr Ramsay also noted that she had written to her counterparts in Wales, Northern Ireland and Scotland. The expectation was that Scotland might set up a separate system [WITN3430197]. On 19 May 1997, Dr Toy confirmed his agreement to join the steering group [DHSC0004572_033; DHSC0004572_034; WITN3430198]. On 5 August 1997, Dr Ramsay was able to advise Dr Toy that it was very likely that the national registry would cover Scotland [DHSC0004572_033]. This was welcomed by Dr Toy [WITN3430199; DHSC0004117_027].

66.17. The first steering group meeting took place on 5 January 1998. The essential importance of "either" gaining patients' consent, or anonymising patients' information, was noted in relation to the discussion of the Registration and Follow-Up Forms:

> *"AR [Dr Angela Robinson] stated the importance of including other risk factors, particularly IDU, on the form as it will be essential to ensure these were considered when conducting analysis by date of infection. GA [Dr Graeme Alexander (Chair)] raised the question of anonymity. In order to gain the participation of clinicians and approval of the MREC it was considered essential to either gain patients' consent or to anonymise the information. It was agreed that HH [Dr Helen Harris*

> *(Register Co-ordinator) would develop a mechanism that would address these concerns and adapt the MREC submission accordingly. It was also agreed that HH would add a question to the registration form addressing past HCV positive tests, as well as correct the HBV terminology."*

66.18. On 12 January 1997, Dr Helen Harris (the Co-Ordinator of the Registry) wrote to Dr Hugh Nicholas of DH's Health Protection Division [DHSC0046979_060]. She provided copies of revised Registration and follow up forms as well as proforma letters to clinicians and an information sheet for patients. Dr Harris commented:

> *"To address the issue of anonymity, these letters (and the registration form) will be issued directly from either the laboratory or the NBA (as appropriate). The completed registration forms will then be returned to the issuing authority (the NBA or the laboratory). At this point the forms will be anonymised and forwarded, un-named, to the Registry. This procedure should be self-explanatory from the enclosed letters. A flow diagram has been enclosed for further clarification. The flow diagram also shows how flags will be issued directly from either the laboratory or the NBA to ONS. Information from ONS will be passed to the Registry after anonymisation by the issuing authority. In this way no patient names will be sent to, or held on, the Register. If you have any comments regarding the above procedure, I would be very grateful to receive them by the 30 January 1998 so that I might meet the deadline (4 February 1998) for receipt of proposals to be considered at the next meeting of the North Thames MREC."*

It can be seen from these that, against the background of the approach to patient anonymisation, it was not envisaged that clinicians would be required to obtain consent for their patients' anonymised information to be placed on the Register.

66.19. The letter to clinicians stated:

> *"We have also enclosed an information sheet explaining the purposes of the Registry which you may like to pass to your patient. The patients will not be contacted directly but nevertheless, this information sheet has been provided for any clinicians who feel they would like to notify patients of their inclusion in the Register."* [WITN3430200]

66.20. The information sheet included the following:

> *"**Why do we need a National database of Hepatitis C virus infections?***
>
> *Hepatitis C is one of the more recently discovered viruses, therefore, doctors are continually learning about the disease which HCV can cause. Since there is still much to learn about how the virus is passed on and how the resulting disease affects the patient, a National database (or Register) is being set-up.*
>
> ***Who will be included in the Register and what do I have to do?***
>
> *The National Register will include information on all patients who have become infected with Hepatitis C virus on a known date. The Register will also gather information on other people who are not infected, but who may have been exposed to the virus, for example by receiving a blood transfusion from a donor who was later found to be infected with HCV. When the public health laboratory network (which monitors the spread of infections within the British population) identifies a patient who could be included in the Register, they will contact the doctor who cares for that patient and invite them to include their patient in the Register. Your doctor can then pass information (but not your name) from your medical records to the Register in order to advise us of your current status. He/she can also keep us updated with your progress. You are not required to supply any of this information yourself as the Register can obtain all these details directly from your doctor.*
>
> ***What will the information be used for, and will it be confidential?***
>
> *This information, along with information from all other registered patients, can then be used to determine how the disease progresses and how it can best be treated. The Register will enable us to learn more about how HCV is spread within the population and who might be at greatest risk of infection or of developing liver disease. The National Register will therefore be an invaluable resource for researchers and doctors alike. Every new case entered into the Register will help us to learn more about HCV.*
>
> *The Register itself is totally anonymous as no names are recorded within it. People who are granted access to information in the Register are therefore unable to link the information to individual patients."* (original emphasis) [WITN3430201]

66.21. On 23 January 1998, Dr Nicholas minuted Mr Dean in HP4B (Health Promotion Division, whose remit included research ethics) [DHSC0046979_059]. After setting out the background, Dr Nicholas wrote:

> *"4. The initial draft registration forms built in patient identifiers, including the possibility of a name, along with much patient data. There was no stipulation that consent should be obtained, this being left to the local physician. However there was a feeling among some members of the steering group that local ethics committees would not allow physicians to provide the sort of data being requested on named patients without the individual's consent; amongst the data being requested is the HIV status (important here because it is thought to influence the rate of progression of hepatitis C).*
>
> *5. Since the registration form is quite long, obtaining full informed consent could be time consuming and this requirement might dissuade physicians from entering their patients. It was also reported that experience has shown that a significant proportion of patients have refused consent for similar data to be given to those conducting clinical trials. Because these two eventualities could lead to only a proportion of patients being included and hence to a reduction in the usefulness of the project it was decided that the information should be held anonymously by the Registry, and that thus formal consent need not be sought. This will require quite a complicated protocol since (i) the blood transfusion patients will have been identified by the NBA who already have their names and will need to seek information from individual physicians before it is passed to the Registry, and (ii) in terms of seeking mortality data patients will need to be flagged with ONS and resulting data made known to the Registry.*
>
> *6. Access to data held by the Registry will, subject to the agreement of the steering group, be available to researchers. They will not have access to the patients but will be able to obtain any further data they may require from the inclusion of any necessary additional questions on to the annual follow-up forms that treating physicians will be asked to complete.*
>
> *7. I attach a recent letter I have received from the Registry Co-ordinator with copies of a flow diagram covering the procedures for registration and flagging, the letter from the NBA to the treating physician together with an information sheet for patients on the Registry, and the proposed registration and follow up forms. A letter similar to that from the NBA would be sent where infections were identified within PHLS laboratories.*

> *8. The steering group have asked for a view from the Department on the consent and confidentiality issues and I would be most grateful for your opinion of what is being proposed. Happy to discuss if you require any further information."*

66.22. On 30 January 1998. Dr Nicholas minuted Dr Metters and Dr McGovern on the draft editorial for the BMJ which the Register Secretariat hoped to submit [WITN3430202]. Dr Metters replied with some comments on the draft Editorial [WITN3430203].

66.23. On 2 February 1998, Dr Metters responded to Dr Nicholas's minute to Mr Dean of 23 January, to which he had been copied [DHSC0046979_056]. He commented:

> *"1. … When MSBT discussed the Registry, one great advantage seen in it was the prospect of being able to identify the actual date of transfusion of a unit of infected blood. This would be invaluable in documenting the natural history of Hepatitis C.*
>
> *2. If the obtaining of consent from the patients, as in your paragraph 5, is seriously to undermine the completeness of the Registry because of a number of recipients will not consent, an alternative means of maintaining the comprehensiveness of the data base should be found.*
>
> *3. It seems to be that the flow chart, attached to Helen Harris' letter of 12 January, would provide a mechanism that would ensure the registry data remains comprehensive. In this way it will be a better place to carry out the work that was originally intended."*

66.24. It is apparent from later documents that Dr Ramsay's team gained ethical approval for the project on 25 February 1998 from the North Thames Multi Centre Research Ethics Committee [NHBT0036206_001; NHBT0036206_002] (letter from Keith Eldridge to Mr Richardson seeking an extension of ethical approval).

66.25. On 31 March 1998, Dr Nicholas sent a substantive response to Dr Harris' letter [DHSC0046979_030]. He explained as follows:

> *"I indicated in my response of 21 January that I would write further once I had had the opportunity to discuss the issue with colleagues in the Department. I am now in a position to do so and I apologise for the delay.*
>
> *The Department's policy on confidentiality issues is set out in Protection and Use of Patient Information, issued with Health Service Guidelines HSG(96)18 in March 1996, and I enclose copies of both. The guidance covers a number of the issues that need to be considered in setting up the proposed registry.*
>
> *When registers are created or information is pooled, those concerned should ensure that patients know in general terms what is being done and to whom the information may be passed. The patient information sheet you supplied looks suitable for this. Although the guidance sets this approach in the context of inter-agency registers for the purpose, among other things, of joint commissioning, the general principles are relevant to registers/registries generally.*
>
> *Any research proposals requiring access to patients records require clearance by the relevant L/MREC, which must be satisfied that:*
>
> *i. arrangements to safeguard confidentiality are satisfactory;*
>
> *ii. any additional conditions relating to the use of information that the L/MREC thinks are necessary can be met;*
>
> *iii. any application to use identifiable information - without seeking formal consent from each individual - can be fully justified by the public interest.*
>
> *The Department favours the use of anonymised or aggregated information wherever possible, a preference given further impetus by the Caldicott report on the use of patient identifiable information. However anonymising information does not of itself remove the duty of confidence and so is not necessarily a means of avoiding patient consent. The main justification for that would be the public interest. But as noted above, it may be enough to tell patients in general what is being done. If any object, then the question arises as to whether a public interest should be asserted - and defended in court if necessary - or whether a scheme or project can survive with some omissions.*

I am also enclosing a copy of the booklet Chronic Disease Management Registers, the proceedings of an NHS Executive workshop, also issued in 1996 under cover of EL(96)72.

Although this has more to do with the setting up of local registers, the principles will also hold for national registers and you may find it of some use.

I hope this is helpful, and look forward to the next steering group meeting."

66.26. The Health Service Guidelines HSG(96)18 and the accompanying guidance document on "Protection and Use of Patient Information" (7 March 1996) are exhibited to this Annex at [WITN3430204].

66.27. The second meeting of the National HCV Steering Group took place on 8 April 1998. The Minute notes that, *"the register was submitted to the Multi-Centre Research Ethics Committee on the 2 February 1998, after incorporating the anonymisation procedures, amended registration forms and accompanying letters. The application was heard at their meeting on 25 February 1998 and unconditional approval was granted"* [WITN3430205]

66.28. The HCV National Register was then launched in July 1998, which was a few months before the end of Sir Kenneth's tenure as CMO [WITN3430206; SBTS0003086_073; DHSC0004026_017].

66.29. From documents available to the Inquiry, it can be seen that the position on patient consent for the HCV Register later (i.e. after Sir Kenneth's role as CMO ended) developed and changed. Although not a comprehensive review of issues arising after this point, the following are of note:

(1) At the third meeting of the Steering Group on 1 December 1998, under AOB at §12c, it was noted that: "*Dr Christopher Poynton (a Consultant Haematologist from the University Hospital of Wales) has expressed serious concerns over the register on the grounds that he feels formal consent should be sought from all patients in the study.*" The minutes went on to record that Dr Harris had sent Dr Poynton *"… full details of the register, along with confirmation that the study has the necessary*

ethical approval. He still has reservations about the project" [NHBT0035357_002].

(2) In January – February 1998, the HCV Register team sought, and obtained, ethical approval for an extension to the register to include (i) documented seroconversions and prospectively ascertained perinatally acquired infections; and (ii) requests for sera/liver biopsy specimens for central archiving. No objection appears to have been raised, at that stage, on grounds of lack of formal patient consent, although re-assurance was sought and provided on confidentiality aspects [NHBT0036206_001; NHBT0036206_002; NHBT0035352, NHBT0035353].

(3) Dr Harris and Dr Ramsay provided an Interim Progress Report dated March 1999 [DHSC0020696_010].

(4) There was significant work involved in the application for, and consideration of renewal of funding beyond the original 3 years funding period: [DHSC0004598_063] - §14 Fourth Meeting of the National HCV Register Steering Group; [NHBT0004351] - § 27-28, 18th Meeting of the Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation (MSBT); [NHBT0003578_002] - §14 Fifth Meeting of the National HCV Register Steering Group; [DHSC0004598_059] - Minute from Dr Ursula Wells to Dr Nicholas, Re: Funding for National Registry of Hepatitis C Virus Infection; [DHSC0004598_049] - Dr Ramsay's and Dr. Harris' responses to Referees' Comments: National HCV Register: Further Funding; [NHBT0003591_089] - §14 Sixth Meeting of National HCV Register Steering Group; [DHSC0006575_025] - Minute from Dr Ursula Wells to Dr Vicki King, dated 2 August 2000, confirming that a further three years of funding would be provided by the PRP (Policy Research Programme).

(5) "The HCV National Register: towards information the natural history of hepatitis c infection in the UK" (Harris; Ramsay; Heptonstall; Solden and Eldridge) was accepted for publication in the Journal of Viral Hepatitis in July 2000 [WITN3430207].

(6) At the seventh meeting of the National HCV Steering Group on 29 November 2000, "Confidentiality: GMC Guidelines" was discussed [NHBT0002447_005]. The minutes recorded that:

> *"HH [Helen Harris] drew the group's attention to paragraphs 18 to 28 of the GMC's new booklet 'Confidentiality: protecting and providing information' included in the meeting pack (in particular to section 27). HH had spoken to the CDSC Caldicott Guardian about confidentiality in relation to this project, and had been advised that because patient names were not stored in our database, it was not considered to be a 'true' Register.*
>
> *UW* [Ursula Wells, DH] *advised that these guidelines had raised many issues which will have to be resolved over the coming months (like the legality of the cancer Registries etc.). In the meantime, it was agreed that we had made every effort to ensure that the information contained in the Register was kept confidential (e.g. we have a Lay Representative on the steering group and a representative from the Department of Health, all project proposals have been passed by the MREC, and no patient names are held in the Register). Action: None at present".*

(7) Although the work of the Register was continuing, the Final Report describing its development and the completeness of the data it contained was completed in December 2000 [DHSC0038673_010]. Confidentiality and consent were addressed in §3.2.6:

> *"No patient names are recorded within the Registry database. Data, including non-nominal identifiers, are securely stored on a*

password-protected computer within a secure building, and are accessible only to key individuals. Data sets passed to external researchers, whose projects are being supported by the Registry, contain no information that could lead to identification of registered patients. As the Register collates anonymised information that is collected by clinicians during routine patient care, and requires no special intervention, there is no formal requirement to gain patient consent. The PHLS and North Thames Multi-Research Ethics Committees have approved Registry protocols and Caldicott guidelines have been adhered to."

(8) At the eighth meeting of the National HCV Steering Group on 9 January 2002, patient consent was further revisited [NHBT0002448_002]. The minutes recorded discussion in the area and a change towards obtaining formal consent from any new patients who were recruited onto the Register, but not retrospective consent for those already registered:

"Dr Barry Evans, the Caldicott Guardian for CDSC, addressed the group and described some of the recent changes in legislation/guidelines surrounding patient consent (Caldicott, Data Protection Act, Human Rights Act, BS799, Section 60 of the Health and Social Care Act etc.). BE explained that CDSC had recently made an application to the Patient Information Advisory Group (PIAG). Included within this document are 'class actions', one of which covers `infectious disease registers for public health policy development and audit'. In this document case studies are given to provide practical examples of the class actions being considered, and the HCV national register has been used as a specific example. PIAG have already considered this application and it has been passed. The class actions arising from this have now to be put to parliament by the

Secretary of State; this process may have to be undertaken every year.

It was acknowledged that guidelines and legislation surrounding patient consent were still evolving, but BE felt that CDSC were doing all they could to comply with the constantly changing regulations. UW [Ursula Wells] explained that it was not currently clear precisely what was 'legal', so we should continue to proceed as we are, but keep abreast of any future changes. BE felt that the Register was sufficiently covered by the PIAG application, however, a distinction was made between 'data' as opposed to 'clinical material', with only the former being covered by this application.

The issue of whether we should seek explicit consent from patients to refer sera and histopathology specimens to the Registry was discussed. Although the MREC had granted that formal consent was not required, the group now felt that we should probably seek formal consent from any new patients who were recruited into the Register. This change of view was felt appropriate in light of the issues arising from incidents at Alder Hey and the Bristol Royal Infirmary. The Group did not feel it appropriate to seek consent retrospectively from those patients who were already enrolled in the Register.

Action: HH to ensure that this consent is obtained for all new patients recruited into the register."

(9) This revised approach was reflected in the application made to the DH for the renewal of funding on 2 April 2002 [WITN3430208]:

"As the project does not involve any interventions of any kind, simply the central collation of routinely collected local data, both the PHLS- and the Multi-Centre Research Ethics Committees did not feel that patient consent was a requirement for participation when the project was reviewed at inception. That said, it had always been registry policy to consent patients

whose clinicians request it. In addition, patient information sheets have always been sent to the clinicians of every patient whose data are held in the register, even though this was not deemed necessary when the original protocol was considered. If our patient information sheets have been passed on by the participating clinicians, all patients would be aware that the register exists and that their data, but not their names, are held in the register without their explicit consent. Whilst we hope that the majority of patients will have received our information sheets, we do not assume that all patients have received them.

We are very aware of the need to comply with current legislation on data protection and confidentiality. This is extremely difficult because the current legislative framework is contradictory and uncertain. When the register was set-up, we were concerned that the obligation to obtain express consent would result in a level of bias that could invalidate our research. We feel that our decision not to seek explicit consent is valid and that the register does not breach the Data Protection Act 1998 or the spirit of Caldicott because: (i) individual patient care is not influenced in any way by the processing of registry data, (ii) patients are never contacted by anyone other than their normal professional carer, (iii) registry data that can be linked are only accessible to individuals who are either clinically trained or who are health care professionals owing an equivalent duty of confidentiality, (iv) the processing of the data is solely for medical research that is in the public interest, (v) the patients are not identified in any publications or reports, (vi) data security is of the highest standards, (vii) a Multi-Centre Research Ethics Committee has approved the research and agreed that obtaining explicit consent is not necessary, and (viii) the denominator population are largely aware in general terms that their data have been passed to the register for research purposes. Nevertheless, we are aware that uses of our data that are legal under the Data

Protection Act 1998 may currently remain a breach of confidentiality under Common Law.

The Public Health Laboratory Service has recently submitted an application for communicable disease surveillance and control to the Patient Information Advisory Group (PIAG). Included within this document are 'class actions', one of which covers 'infectious disease registers for public health policy development and audit'. In this document case studies are given to provide practical examples of the class actions being considered, and the HCV national register has been used as a specific example. PIAG has already considered this application and it has been passed. The class actions arising from this have now to be put to parliament by the Secretary of State, and once this is complete, we will have a more final answer. It is also possible that the HCV register may itself be placed before PIAG in a separate application at a later date.

The issue of patient consent was formally discussed at the last register steering group committee meeting, and although the ethics committees had sanctioned that consent was not necessary, it was felt that in the current climate, all new cases recruited into the register should be formally consented. It was not felt appropriate or necessary to seek retrospective consent for participation from patients who were already enrolled in the register. At the present time, we are currently amending all our standard letters, patient information sheets and associated paperwork to reflect this change in policy. This new paperwork is the paperwork that appears in the appendices and will be forwarded to the appropriate ethics committees later this month for approval. At the registry, we continue to follow the changes in guidelines/legislation as they are evolving."

(10) The records show that ethical approval was granted on this revised basis in May 2002 from the London MREC – see the exchange of

letters with Dr Harris and the MREC on 8 and 30 May 2002 [WITN3430209].

(11) The change and the ethical approval was then further discussed at the next Steering Group Meeting (the 9th meeting) on 23 July 2002 [DHSC0041457_027]:

> "*HH presented an overview of the confidentiality and consent issues as they have developed from inception of the register to date. HH explained data storage: that data are linked and anonymous, that NHS numbers are recorded and that patients are flagged in NHS central registers. HH also explained where the register 'stands' relative to current legislation, in particular the Data Protection Act (1998) and also the spirit of Caldicott: Patient care is not influenced by the processing of registry data; patients are only ever contacted by their professional carer; registry data that are linked are only accessible to individuals who are clinically trained or who have an equivalent duty of confidentiality; data is solely for medical research that is in the public interest; data security is of the highest standards; patients are not identified in publications or reports; MREC have approved the study protocols, and the denominator population are largely aware in general terms that their data have been passed to the register for research purposes.*
>
> *Section 60 of the Health and Social Care Act, 2001 was also discussed. The PHLS submitted an application to the DoHs Patient Information Advisory Group (PIAG) to support the use of patient data for communicable disease surveillance and control. The application included the request for support of longitudinal data sets and included the HCV register as a specific example. PIAG have approved this application and regulations arising from it have been passed by both houses of parliament and came into force on the 1st June 2002.*

It was agreed at the 8th steering group meeting that all new recruits to the register should be formally consented. The registry will not seek retrospective consent from patients who are already enrolled. New patient consent forms and information sheets have been designed and printed. MREC has approved both the patient consent forms and information sheets and also that retrospective consent need not be gathered for patients already enrolled. In future, consent forms will be distributed to eligible patients via their clinician, with the patient- or parent- (if under 16) information sheet.

HH drew attention to the histopathology archive: the issue of patient consent and the retained organs commission. HH particularly requested the group's views about the storage of histopathology slides for those patients who were enrolled into the register before the introduction of explicit formal consent.

The steering group agreed that the register had always followed all available guidelines, that the registry has acted responsibly, and that guidance in this area was still changing. It was therefore agreed that no additional action should be taken at this stage, but that we should continue to monitor the situation.

Action: HH to continue to monitor issues surrounding patient consent, confidentiality and retained organs."

Section 10: HIV and AIDS issues in the 1990s

Q.67 Aids Workshop in Edinburgh, September 1992

67.1. This Annex is intended to supplement what was said in Question 67 of the main statement about how priorities in relation to HIV and AIDS changed over the course of the 1990s.

67.2. The CMO Reports, which are referred to in the main statement and the Annex, are a useful source of material on this issue. The CMO Reports for 1991 to 1997 suggest the Government's priorities in relation to HIV and AIDS remained largely consistent. The overarching aim was to reduce the incidence of HIV transmission. The CMO's report for 1994 said [DHSC0007016]:

> "*The main aims of the Government's strategy on HIV infection and AIDS are to limit the further spread of HIV infection, and to ensure that resources and services are properly targeted, that the right balance is struck with other health priorities, and that initiatives to combat HIV infection and AIDS are brought within the mainstream of health care and health promotion* (page 159)."

67.3. The Government sought to reduce the incidence of infection through public education targeting high-risk groups. The 1996 CMO report noted that public health measures aimed at prevention of infection remain central to containing HIV, with further detail of the Government's HIV health promotion strategy given at p188 [DHSC0007018]. This included publication by the Department in 1995 of "*HIV and AIDS health promotion: an evolving strategy*", which placed greater emphasis on appropriate targeting of high-risk groups.

67.4. High-risk groups were identified through epidemiological data, which was collected through the voluntary confidential reporting systems operated by the PHLS AIDS Centre and the Government's programme of unlinked anonymous HIV surveys. The data throughout the period indicated that the highest risk-group was men who have sex with men. Public health education focused on sexual health by encouraging the adoption of safe patterns of sexual behaviour. This resulted in various radio and television campaigns. Injecting

Drug Users (IDUs) were also a priority, although by 1996/97, the evidence of substantial HIV transmission through injecting drug use was limited (CMO Report, 1997, p195 [DHSC0007019]).

67.5. A CMO Fact Sheet from November 1993, produced for internal use, has been identified and is referred to in Sir Kenneth's statement [WITN3430210]. The Fact Sheet is titled, *"HIV & Aids, Fact Sheet"*. The sections of particular note are highlighted below.

67.6. Section 9 noted that HIV/AIDS and Sexual Health form one of the five key areas for action under the Health of the Nation strategy. It referred to the general objective and specific targets as:

> *"**General objectives:***
>
> - *To reduce the incidence of HIV infection*
> - *To reduce the incidence of other sexually transmitted diseases*
> - *To develop further and strengthen monitoring and surveillance*
> - *To provide effective services for diagnosis and treatment of HIV and other STDs*
> - *To reduce the number of unwanted pregnancies*
> - *To ensure the provision of effective family planning services for those people who want them*
>
> ***Specific objectives:***
>
> *…*
>
> - *To reduce the percentage of injecting drug misusers who report sharing injecting equipment in the previous four weeks by at least 50% by 1997, and by at least a further 50% by the year 2000 (from 20% in 1990 to no more than 10% by 1997 and no more than 5% by the year 2000)."*

67.7. Section 10 noted that in light of recent projections and with increasing knowledge of the disease and experience of dealing with it, the Government reviewed its HIV strategy to ensure that resources and services were properly targeted, specifically *"that the right balance is struck with other health*

priorities" and *"that HIV and AIDS are brought within the mainstream of health care and health promotion"*. Key elements of the strategy were noted as: *"**prevention** (e.g. media campaigns and encouraging behaviour change amongst those at risk**), treatment and care, monitoring and surveillance and research, and international action**"*.

67.8. Section 11 addressed the strategy for *"Prevention"*. It summarised the action of the 1980s and noted that:

> *"[f]ollowing review of overall strategy in June 1993, prevention work will continue to be strengthened through the Department's programmes, the HEA, the NHS, other health care professionals, employers and support for voluntary groups, prevention work will be carried forward to:*
>
> - *Sustain and improve general public awareness including those who travel abroad;*
> - *Encourage appropriate behaviour change by increased targeting on sections of the population at particular risk including homosexual and bisexual men;*
> - *Ensure that succeeding generations of children and young people continue to receive information they need by working closely with the Department for Education…*
> - *Ensure the supply of blood, blood products and organs remains secure by screening through the blood transfusion service and public education for potential donors;*
> - *Ensure that neither patients nor health care staff are put at risk of infection by ensuring the guidelines recently published are adhered to".*

67.9. Section 12 addressed the December 1992 DH guidelines on testing, noting the need for additional and more accessible sites for HIV counselling and testing, encouraging the offer of voluntary testing for women attending antenatal clinics in higher prevalence areas and encouraging partner notification programmes for people found to be HIV positive.

Q.68 Knowledge of and involvement in Gamma Bulin recall, 1993

68.1. The MCA's submission of 5 November 1993 [DHSC0006466_031] reported that on 28 October 1993, the German Authorities told the MCA that a Germany company, UB-Plasma, had been closed down because it was suspected their Fresh Frozen Plasma ("FFP") contained HIV. The MCA had investigated. UK involvement centred on licensed products manufactured by an Austrian company, Immuno, using the implicated FFP. The MCA had issued a recall on 5 November 1993. Also, a Swiss company, Octapharma, had supplied bags of an unlicensed blood product to a single named patient in the UK. The responsible clinician had been contacted by the company. The National Institute for Biological Standards and Control ("NIBSC") were also alerted due to their role in testing samples and in batch release of blood products in the UK. The submission went on:

> "*Outcome to date*
>
> *4. The MCA is continuing to vigorously explore all potential avenues of supply of blood products to the UK market that could contain FFP from UB-Plasma. The Agency is in close touch with the German BGA and is receiving regular updates on the situation. The Agency is investigating blood products supplied to clinicians on a named patient basis and for clinical trials.*
>
> *Implications*
>
> *5. Patients in the UK have received blood products manufactured with FFP from UB-Plasma. Neither of the Immuno products has been implicated in viral transmission, however, the media are aware of the problem and the Immuno recall. Patients who have received these blood products will be concerned and will require reassurances that there is no hazard to public safety.*
>
> *Conclusion*
>
> *6. PS(H) is advised that the UK is self-sufficient in blood plasma. No blood used in transfusions in this country comes from Germany and most blood and cellular products manufactured in this country come*

from our own tested donations. However, pooled FFP is used as a starting material for a range of blood products imported into the UK. Such products are processed during manufacture to inactivate or remove potential viral contamination and thus represent no safety risk to patients. NIBSC test samples from all plasma pools used in the manufacture of blood products and test samples from finished batches prior to release. Nevertheless, where products are identified as being manufactured from plasma of UB-Plasma origin, the MCA will strongly recommend that the companies concerned recall all implicated batches to ensure total patient safety."

68.2. The MCA issued a class one (meaning "*action now*") drug alert on 5 November 1993 stating that Immuno were recalling five batches of Gammabulin, which had been distributed between January 1992 and April 1993 [WITN3430211]. They were also recalling three batches of human albumin solution, which had been distributed between September 1989 and July 1992. The alert stated that fresh plasma from UB-Plasma had been used as a starting material in these products. The alert emphasised it was a precautionary measure by Immuno and neither product was implicated in viral transmission.

68.3. A fax from the Foreign and Commonwealth Office's Bonn station dated 9 November 1993, provides some wider context about the issue [WITN3430212]. The fax reports a "*scandal*" in Germany provoked by news a public body concealed evidence of a list of individuals who contracted HIV from contaminated blood products. The German authorities had investigated and as part of the investigation the authorities discovered the HIV screening carried out by UB-Plasma was inadequate.

68.4. On 11 November 1993, the Parliamentary Under Secretary of State for Health, Tom Sackville, wrote to Dr Geoffrey Schild, Director of NIBSC, to thank NIBSC for the public reassurance they were able to give on 5 November 1993 that all blood products released for use in the UK had been

properly tested to ensure there was no risk of HIV contamination [DHSC0046990_060].

68.5. There is a Minute from Dr Rejman regarding a letter from the UK Transplant Support Services Authority ("UKTSSA") dated 24 December 1993 [DHSC0046990_016]. It has not been possible to locate the original letter. It appears from the Minute that there was some concern that organ donors in the UK may have received blood transfusions in Germany and in so doing exposed to a risk of contracting HIV. Dr Rejman's Minute explains his view that the risk of HIV infection from organ donation in these circumstances was very small. He advised that tracing the organ recipients and counselling them about the need for an HIV test would cause more anxiety than benefit.

68.6. On 9 February 1994, an internal MCA minute summarised actions taken in response to the UB Plasma recall [MHRA0020212]. These were:

> *"1. Recall of batches using UB Plasma as a source has been completed.*
>
> *2. Information has been obtained on collection centres used.*
>
> *3. We are setting up a computerised database to recall the information.*
>
> *4. We are investigating controls on sites abroad through the inspectorate group and Biotechnology Working Party.*
>
> *5. We are ensuring consistency of approach in approving centres within the EEC by taking the lead on a section in the revised notice to applicants due to be published later this year.*
>
> *6. We will be sending a letter to manufacturers reminding them of the need to provide information on the centres they use.*
>
> *7. We will be setting up a notification procedure so that changes to centres is not an undue burden on the industry an appropriate in-house procedure will be established.*
>
> *8. Pool testing for viral markers is under discussion in Europe as part of batch release procedures.*

9. We will follow-up on any unusual findings from NIBSC testing of pools."

68.7. The MSBT discussed UB Plasma at their meeting on 10 February 1994 [DHSC0020691_169]. Dr Metters is recorded in the Minutes as saying NIBSC batch testing meant whatever the problems in Germany there had been no risk in this country.

Q.69 Investigation into HIV infection through transfusion, 1997

69.1. The Inquiry has referred Sir Kenneth to four documents, one of which is an 18 page document headed *"Chronology of HRL Investigation of Liverpool Post-Transfusion HIV Infection"* [NHBT0081211]. This document (hereafter called "the Chronology document") in fact comprises three separate chronologies, one of which (the Mersey and North Wales Blood Centre chronology) has separate typed and handwritten versions. The first of these three chronologies appears to have been produced by the Hepatitis and Retrovirus Laboratory ("HRL") of PHLS. The other two appear to have been produced by those involved in local management of the incident, in Liverpool.

69.2. The Chronology document indicates the incident unfolded in March and April 1997. The first reference to the Department being made aware is 21 March 1997, when Dr Vicki King was briefed on the possibility of a case of post-transfusion HIV. This is consistent with the Minute of the same date referred to in Sir Kenneth's statement, which says the Department had just become aware of a leukaemia patient with no known risk factors for HIV having become HIV positive. By this stage, the blood service had instigated a "look-back" exercise.

69.3. The Chronology document referred to Dr King being updated at regular intervals during March and April 1997. For example, on 10 April 1997, Dr King attended a liaison meeting at PHLS, Colindale. There is also reference to Dr Rejman receiving an update. The Chronology documents should be referred to for fuller detail of how the scientific and local investigation developed.

Events from 19 April 1997 onwards

69.4. On 19 April 1997, various national newspapers reported on the incident for the first time [DHSC0006191_050].

69.5. On 21 April 1997, Mr Guinness sent a Minute to Dr Metters suggesting a review be carried out of how the incident was handled with a view to learning lessons [DHSC0006191_038]. He also indicated some concerns about how the handling could have impacted patient confidentiality. Dr Metters replied the following day to suggest the NHS Executive should initiate any such review and copying in Dr Winyard [DHSC0006191_036].

69.6. On 29 April 1997, Mr Slopecki and Mr Jenkins of BPL carried out an audit of Liverpool Blood Transfusion Centre [DHSC0006782_076]. The audit found the "look-back" exercise and identification of infected donations were handled as fast as could be expected.

69.7. On 9 May 1997, Dr King circulated a Minute, copied to Dr Metters, referencing agreement in meetings during the incident with Sir Kenneth and Dr Robinson about the need to put the full scientific facts into the public domain [WITN3430213]. Her Minute attached a draft paper by Dr Philip Mortimer of PHLS, for publication in the Lancet, called "*A UK Transmission of HIV 1 by 'Window Phase' Blood Donation*". Dr King picked up various issues, one of which was about consent to testing pre-mortem serum and revision to GMC guidance.

69.8. Dr Rejman provided comment on the PHLS paper on 12 May 1997 [DHSC0025976]. His Minute noted the draft paper referred to the implicated donor being p24 antigen positive. The paper had noted there was some evidence p24 Ag screening reduced the "window period" when infection could not be detected by screening. Dr Rejman believed the case against use of p24 Ag testing, which was not in use in the UK, could be strengthened.

69.9. On 19 May 1997, Mr Guinness provided comments by email on "*self-exclusion procedures*" and also PCR testing [DHSC0042828]. On 20 May 1997, Dr Metters sent a Minute to Dr King agreeing with Dr Rejman's references to p24 Ag testing [DHSC0031216]. He also pointed out revealing the donor's sexual orientation, as the draft paper did, could not be justified.

69.10. On 28 May 1997, Dr King wrote to Dr Mortimer setting out the comments made by Dr Metters, Dr Rejman and Mr Guinness and seeking a delay in publication [WITN3430214].

69.11. On 29 May 1997, Dr Metters circulated a Minute regarding the potential for PCR testing of blood donations to narrow the "*window period*" [DHSC0004016_047]. He attached a letter from Dr Mortimer [DHSC0004016_048], which requested the Medical Devices Agency ("MDA") provide PHLS with PCR machines for evaluation purposes. Dr Metters asked the MDA to support Dr Mortimer's request. He noted the evaluation that Dr Mortimer proposed to carry out was directly relevant to the business of the MSBT, who would be discussing PCR testing at their next meeting. The MDA replied by Minute dated 3 June 1997, saying PCR equipment was expensive and they would do their best to loan equipment but could not offer any guarantees [DHSC0004016_049].

69.12. On 19 June 1997, Dr Mortimer wrote to Dr King with a revised draft of the "*Window Phase*" paper [NHBT0008797_004]. He pushed back against any delay in publication, which apparently had been sought by local clinicians as there was a possibility of legal action by the surviving recipients. Dr King replied on 8 October 1997, saying the article provided important public health information and supporting its publication [DHSC0006905_137].

69.13. On 8 July 1997, an MSBT meeting took place at which the HIV transfusion incident was discussed [WITN3430215]. The Minutes said as follows:

> *8.1 Dr Robinson outlined the events surrounding the recent new instance of HIV transmission through labile blood components. On 2 March, a case of HIV infection at a North West hospital was reported to her, where transfusion was the suspected cause. She had advised the consultant to carry out a look-back. 113 donations and their donors were traced. All samples were archived. 39 of the donors had given blood since and had tested negative. 72 archive samples were tested at PHLS at Colindale, and infection was narrowed down by PCR to a single donor. By 9 April it was known that platelets, FFP and red cells*

from that donor had been used, and the 3 recipients had been traced. The red cell recipient had subsequently died of an unrelated illness.

8.2 The implicated donor's previous donations were checked and all 5 proved negative. The recipient of the last of these donations was traced, and agreed to be tested with negative result, indicating that the donor had sero-converted since the penultimate donation. It was later discovered that the donor's life-style should have excluded donation, but it appeared blood donation had been used as a way of securing regular HIV blood tests.

8.3 Although this had been the only case of HIV infection through blood in England since 1985, it had attracted quite disproportionate public attention. Once all the relevant facts had been clarified, the BTS had issued a press notice. There had also been some difficulty convincing local public health officials that the effects were very limited, and that the BTS had the necessary action in hand.

8.4 The Chairman congratulated the BTS and PHLS on the speed with which they had dealt with the problem, and on their handling of publicity which had avoided undue alarm. It was pointed out that the case was P24 antigen positive. 1 case in 10 million had been found in the US. The recipients of the infected donations had been told about the Department's HIV blood/tissue payment scheme.

8.5 Dr Robinson said that procedures were being reviewed so that all donors were directly asked about lifestyle factors which might mean that they should not donate, rather than simply being asked whether they had read the AIDS leaflet. The Chairman added that the Expert Advisory Group on AIDs (EAG A) were to consider whether there should be more open access to HIV screening, to discourage use of the blood donation system for confidential testing of at-risk donors.

MSBT discussed use of PCR testing and the “window period”, albeit in relation to hepatitis C only.

69.14. On 29 September 1997, Ms Corrigan sent a Minute in reply to a question whether there was any link between the HIV infection and the changes taking place at Liverpool Blood Centre [DHSC0006775_003]. She pointed out that upon retesting the infected blood did not contain HIV antibodies, which would have shown up during routine testing. Further the donor concealed lifestyle information which should have led to self-exclusion. There was no blood service error. Ms Corrigan's Minute was sent to Professor Cash to inform his ongoing review of plans for Liverpool Blood Transfusion Centre [DHSC0006775_002].

Reference in the CMO Report for 1997:

69.15. The 1997 CMO report makes brief reference to this incident on p197 [DHSC0007019]. It notes that this was the first documented incidence of an HIV infectious donation entering the blood supply in England since anti-HIV testing began in 1985.

Section 11: High Purity Products

Q.70 Use of High Purity products for HIV positive patients

70.1. This Annex to Section 11: High Purity products sets out what appears, on the face of the documentary record, to be the more significant developments in the debate around high purity products from the period shortly before Sir Kenneth became CMO for England and continues up to late 1992. It has been drafted to assist Sir Kenneth with the preparation of his statement and to assist the Inquiry.

Third edition of "Recommendations on the choice of therapeutic products"

70.2. On 1 August 1990, the UK Regional Haemophilia Centre Directors' Committee ("the Regional Directors' Committee") published the third edition of a document called "*Recommendations on choice of therapeutic products for the treatment of non-inhibitor patients with Haemophilia A, Haemophilia B and von Willebrand's disease*" ("the Third Recommendations") [PRSE0003809]. This included the observation that factor concentrates in the UK by then had a very small risk of transmission of HIV or hepatitis viruses but that an issue of increasing importance was the possibility that contaminants in the product may adversely affect immune function. The Regional Directors referred to the evidential picture of the efficacies of different products being incomplete, and the fact the newer HP products may carry hazards not yet recognised, including the possibility that HP concentrates have an increased propensity to provoke inhibitors, but concluded:

> "*5.1.4 We acknowledge the paucity of evidence concerning the additional benefits of HP concentrates. However, it appears self-evident to us that the presence of contaminants and impurities in therapeutic products is undesirable, and therefore should be minimised. Our consensus view is that if it were not for their current high cost, and provided that further experience confirms there is no increased risk of inhibitor development, HP products would be preferred for the routine treatment of haemophilia for reasons of*

possible superior safety, particularly if manufactured from volunteer donor plasma."

70.3. The Regional Directors went on to say that since cost considerations did apply, consideration may be given to use of HP products in certain patient groups only. They were unable to make firm recommendations, but some members of the committee suggested HIV positive patients with compromised immune function should be considered.

70.4. The Department of Health was not involved in the drafting of the Third Recommendations. Dr Rejman often attended meetings of the Regional Directors, including a meeting on 12 February 1990 when the Regional Directors discussed a draft version of the Third Recommendations. His notes of the meeting record that Dr Kernoff, who was the author of the draft, was of the view there was "*no hard evidence that high purity meant the product was any better*" [DHSC0006824_056]. Equally, Dr Savidge's view was that third-generation products gave fewer immune problems. Dr Rejman's handwritten comments also refer to a concern that less pure factor concentrates might cause haemophiliacs who had received concentrates contaminated with HIV to seroconvert. Dr Rejman's note also refers to him telling the Regional Directors that Armour Pharmaceutical Company Limited's "Monoclate-P" product had been granted a licence recently by the CSM but on the understandings the company make no claim as to increased safety or usefulness in immuno-compromised patients.

70.5. Following publication of the Third Recommendations, Dr Rejman attended a meeting of the UK Haemophilia Centre Directors' Organisation ("UKHCDO") on 21 September 1990. The UKHCDO's Minutes recorded that there were widely held views and as yet no international agreement, but pressure was growing to use HP Factor VIII [HCDO0000015_021]. No recommendations were then available regarding HP Factor IX. Dr Rejman attended a further meeting of the Regional Directors' Committee on 4 February 1991. The Minutes noted there was a wide-ranging discussion regarding the suitability of HP products, with some Directors unconvinced and expressing concern about

cost implications; their use in previously untreated patients; the use of non-UK donor plasma; and, possible risk of inhibitor development [HCDO0000440]. Dr Kernoff remarked that "*everyone realised that the scientific evaluation of the high purity products has not been established.*"

Correspondence to Department of Health following the Third Recommendations

70.6. Two days after publication of the Third Recommendations, on 23 September 1990, an article appeared in the Independent newspaper claiming HIV positive haemophiliacs were at risk of developing AIDS prematurely due to impurities in Factor VIII. An official within the Department produced an internal Minute the following day responding to the article by saying there was no significant proof to show AIDS would develop more quickly as a result of use of IP Factor VIII and the theoretical benefits of HP Factor VIII, of which at the time only imported American Monoclate-P was available, did not justify the extra cost [WITN3430216]. The Minute also emphasised the individual choice of clinicians.

70.7. There followed correspondence to the Department from various parts on the topic of the Third Recommendations. On 8 January 1991, the then Secretary of State, Mr Waldegrave, was sent a letter from John Marshall MP that enclosed a letter from Armour that said Haemophilia Directors had recommended use of Armour product but there was pressure from Regional Health Authorities ("RHAs") to use cheaper, NHS IP product. Armour also complained about a perceived lack of level playing field with the Blood Products Laboratory [WITN3430217; WITN3430218; and WITN3430219].

70.8. Baroness Hooper replied to Mr Marshall on 25 February 1991 saying there was no restriction on sale of imported blood products and emphasising that it was for clinicians to make decisions on appropriate treatment for individual patients and that good prescribing must take account of cost as well as efficacy and safety [HSOC0002631]. She further noted disproportionate expenditure on the drugs bill could be to the detriment of other patient services and local decisions must be made about allocation of resources. Baroness Hooper's letter did not accept the suggestion by Armour that

haemophilia patients were being given inappropriate treatment on grounds of cost. With regard to the Third Recommendations, Baroness Hooper noted that the Regional Directors recommended a number of different products for treatment of haemophilia and that, with respect to HP Factor VIII, they had "*put forward some suggestions about situations where high purity concentrates might be considered beneficial*".

70.9. In a further letter dated 7 May 1991, Baroness Hooper wrote to Richard Caborn MP, who had forwarded another letter from Armour. She noted that the introduction of HP Factor VIII was a relatively recent development and BPL's HP product has recently come on to the market [DHSC0006902_026].

70.10. On 4 February 1991, Mrs Bottomley replied to a letter from Lord Kilmarnock, Chair of The All Party Group on AIDS [HSOC0002637]. She emphasised the freedom of clinicians to prescribe, within local priorities, and said:

> "*I must say that there is no proof to show that AIDS will develop more quickly in HIV positive haemophiliacs as a result of receiving intermediate Factor VIII rather than the more expensive high purity product. Haemophilia Centre Directors are aware that "high purity" Factor VIII is known to have the possibility of carrying a higher risk of producing an inhibitor or antibody to Factor VIII. There is by no means a consensus of opinion from the Haemophilia Centre Directors that imported "high purity" Factor VIII is preferable to intermediate Factor VIII products.*"

70.11. On 26 June 1991, Mrs Bottomley replied to a further letter from Mr Marshall which had again enclosed a letter from Armour [WITN3430220]. She responded to Armour's "*level playing field*" argument regarding the allegedly artificially low cost of BPL's IP product (8Y). Further, she noted that Armour's Monoclate-P would no longer be the only HP product on the market, as other products had either come or were about to come on to the market, and it was hoped that prices of HP Factor VIII would fall as a consequence.

70.12. On 12 November 1991, Mr Waldegrave held a meeting with the Haemophilia Society and Mr Marshall, in large part to discuss the impact of NHS reforms

on haemophilia care. Dr Rejman and two other officials from the Department, Mr Canavan, of the Department's Health Care Division, and Mr David Burrage, also attended. Insofar as HP products were concerned, the briefing for the meeting makes passing reference to the Department's line being that clinicians needed to be sure benefit of HP products justified additional cost and the Department would not support recommendations, proposed by the Haemophilia Society, which would have the effect of putting pressure on clinicians to prescribe an HP product [WITN3430221].

70.13. On 20 January 1992, Mrs Bottomley replied to a letter from Mr David Watters of the Haemophilia Society, which had set out the Haemophilia Society's belief all haemophiliacs should have access to HP products [DHSC0003990_034]. Mrs Bottomley repeated the point that clinicians have freedom of choice but need to have regard to whether cost justifies benefit. She noted in making treatment decisions clinicians would take into account the Third Recommendations, albeit the document contained suggestions about use in certain patient groups, rather than firm recommendations. She said she was not aware of any evidence haemophilia patients were receiving inappropriate treatment on grounds of cost. On 21 January 1992, a letter in similar terms was sent from Mr Waldegrave to Lord Morris, who had forwarded correspondence from the Haemophilia Society [DHSC0046255_026].

Fourth edition of "Recommendations on the choice of therapeutic products"

70.14. On 1 February 1992, the BMJ published a letter written by the Chair of UKHCDO, Dr Mayne, responding to an article by Professor John Cash that was published in the BMJ the previous September [WITN3430222]. Dr Mayne's letter says that Professor Cash's article had apparently been perceived by purchasers to call into question the clinical benefit of HP Factor VIII when set against increased cost. Dr Mayne's response acknowledged there remained a question whether HP FVIII prevents down regulation of the immune system but said "*the place of high purity Factor VIII is emerging*".

70.15. On 10 February 1992, the Regional Directors' Committee met and further debated the evidence about IP and HP products [HCDO0000443]. Dr Rejman was due to attend but was late and missed the meeting. Dr Christine Lee is recorded in the Minutes as having said that both products, IP and HP, were not harmful and there would be financial implications if all patients had to receive the HP product. The Regional Directors agreed for the purpose of drafting any recommendations that financial considerations should be left aside. The Regional Directors discussed Dr Savidge's draft of the revised recommendations document. Dr Savidge said he would circulate the final document to Haemophilia Directors within a week.

70.16. Sometime following the meeting, on an unspecified date in 1992, the journal "Blood Coagulation and Fibrinolysis", Vol 3, 1992 published the UKHCDO's revised recommendations ("the Fourth Recommendations"), which stated [BART0000877]:

> "*5.1.2 Specific Recommendations*
> *(i) HIV antibody positive patients. In HIV seropositive haemophilia patients requiring blood product therapy, high purity (HP) factor VIII/IX products should replace IP materials to restrict immunosuppression.*"

Correspondence to Department of Health following the Fourth Recommendations

70.17. On 24 February 1992, an internal Minute was sent from Mr Alan Davey, of the Department's AIDS Unit, to Mr Canavan regarding a query raised by the Royal Free Hospital who had been led to believe additional funds would be made available for HP Factor VIII [DHSC0020843_190]. Mr Davey commented:

> *"It is not possible for any additional funds to come from AIDS monies as there was no provision made in PES [Public Expenditure Surveys] and we did not get anything like the amount we required from the settlement. Therefore our budget is already stretched to encompass existing pressures. Besides, the provision of blood products relates to the haemophilia rather than to the HIV status of the individual, and is not an appropriate call on AIDS budgets."*

70.18. The view taken internally within the Department early on was that the provision of blood products to haemophiliacs was not considered to be a matter for which it was appropriate to use earmarked AIDS funds. Mr Canavan replied in a Minute of 5 March 1992 [WITN3430223]. He confirmed there was no intention to provide special funding for HP Factor VIII and that to do so would "*open the flood gates*" to claims for special funding of other high cost pharmaceuticals.

70.19. Mr Canavan's Minute referred to the possibility that "*it may be some months before any new guidance is issued* [by the Regional Directors]", which suggests either that publication of the Fourth Recommendations in the journals did not come until slightly later in 1992 or, if it had already been published, that the Department were not in receipt of a copy at the date of Mr Canavan's Minute. There is a letter from Dr Aronstam, a Regional Director, to his clinical colleagues circulating a final copy of the Fourth Recommendations, which is dated 5 March 1992 [DHSC0020843_186].

70.20. Mr Davey replied to Mr Canavan by Minute dated 22 April 1992, which attached a letter from the Regional AIDS Co-ordinator at Wessex RHA. The Wessex RHA letter made specific reference to recent recommendations from the Regional Directors' Committee and asked how the Department viewed the status of the report and whether extra funding would be forthcoming, but did not specifically mention earmarked AIDS funds [DHSC0003983_120]. Mr Davey noted he had still not seen a copy of the Fourth Recommendations. He repeated his earlier view that it would not be appropriate to fund HP products using ring-fenced AIDS money but sought views of colleagues in the Department. He attached a draft letter which says the Department will "*take action*" against Regions who use AIDS money in this way.

70.21. Mr Canavan replied further by a minute dated 1 May 1992, in which he confirmed the Department had now had sight of the Fourth Recommendations and agreed with the AIDS Unit's stance [DHSC0002574_027]. He referred to a misapprehension about Mr Waldegrave's recent meeting with the Haemophilia Society; there was neither mention at the meeting of funding Factor VIII nor was any commitment given to provide additional funding.

70.22. The Department received other correspondence in this period from health authorities concerned about the spending implications arising from the Regional Directors' Committee's recommendation about HIV positive haemophiliacs. For example, on 15 May 1992, the Managing Director of the West Midlands RHA, Stuart Fletcher, wrote to the Chief Executive of the NHS Management Executive, Duncan Nichol, saying "*there is a substantial body of opinion in the country amongst clinicians that the high purity product has limited if any advantage for haemophiliacs*" and referred to Professor Cash's article in the BMJ. He said he was concerned about, first, the lack of discussion of the matter with regional health authorities and, secondly, the cost implications [DHSC0002461_058].

Request for national guidance and whether can use earmarked AIDS funds

70.23. On 29 May 1992, Dr Winyard, Director of Public Health at Wessex RHA, wrote to Dr Walford asking for a national policy directive on the funding of HP Factor VIII. Dr Metters replied to Dr Winyard on 22 June 1992, saying regions should finance purchase of HP products through main funds. Regions were best placed to decide how to allocate available resources. This correspondence between Dr Winyard and Dr Walford / Dr Metters from May / June 1992 is dealt with in more detail in the main body of Sir Kenneth's statement.

70.24. On 7 July 1992**,** Mr Nichol, as NHS Chief Executive, replied to the letter from West Midlands RHA in similar terms to those used by Dr Metters [DHSC0020843_013].

70.25. The draft reply from Mr Nichol to West Midlands RHA had been circulated amongst officials in the Department. Dr Hilary Pickles, of the Research and Development Division, commented in a Minute of 24 June 1992 that the benefit of HP Factor VIII was "*so marginal – and not affecting overall mortality – that it cannot possibly justify the massive extra bill*" [WITN3430224].

70.26. Dr Winyard sent a second letter on 6 July 1992 by way of a reply to Dr Metters. His letter sought a "*definitive statement*" on whether it would be permissible to use specific HIV funding (i.e. the earmarked AIDS fund) to

cover the use of HP Factor VIII for HIV positive haemophilia patients [DHSC0002461_024].

70.27. Dr Winyard's letter was not copied to Sir Kenneth. The handwritten comments indicate the response was coordinated by Dr Metters with advice from officials. Dr Metters sought advice from the AIDS Unit and the matter was discussed in internal Minutes [WITN3430225; DHSC0002461_014; and DHSC0020843_149].

70.28. Dr Peter Exon's Minute refers to RHAs having used AIDS monies to fund Factor VIII, against Department advice. This links with a letter Dr Exon received from Dr Lee on 1 July 1991 saying the Royal Free Hospital had been using AIDS budget money since 1985 to cover some costs related to IP Factor VIII and asking for support from AIDS monies [DHSC0032206_007]. Of relevance to note also is Ms Johnson-Laird's Minute of 6 August 1992, which refers to the "*inconvenient fact*" that the Department did not bid for costs of HP products during the PES negotiations.

70.29. Dr Gwyneth Lewis, Head of the AIDS Unit, replied on behalf of Dr Metters to Dr Winyard by letter of 18 August 1992 [DHSC0002462_051]. She confirmed HP Factor VIII should be funded from main NHS allocations and said:

> "*Although I acknowledge that HIV may have led the drive for the development of high purity Factor VIII it is inconceivable that non-HIV infected haemophiliacs will not demand the purest Factor available. Additionally, as Dr Metters points out, the price differential between normal and high purity Factor VIII is likely to be short term, and it would be unrealistic to separate the additional costs of the high purity product given to HIV positive haemophiliacs from those who are sero-negative. For all these reasons we do not feel that specific earmarked funds are required to allow for the introduction of purified Factor VIII for sero-positive haemophiliacs.*"

70.30. The material contents of Dr Lewis' letter to Dr Winyard were repeated in a circular sent to the profession the following day [BART0002435_002]. The

decision was also communicated to individual clinicians who had raised funding concerns, for example [DHSC0020843_135].

Response to Dr Lewis' letter of 18 August 1992

70.31. On 4 September 1992, Dr Rejman attended a meeting of the Regional Directors' Committee. The Minutes show Dr Lee circulated the letter from Dr Lewis. The Regional Directors expressed concern and some were "*dismayed*". The Regional Directors also acknowledged the Fourth Recommendations had provoked "*substantial comment and criticism*" [HCDO0000444].

70.32. Dr Lewis was sent a letter on 1 October 1992 from Dr Hill, Queen Elizabeth Hospital, saying the reason for using HP Factor VIII was it may preserve the CD4 count and so improve the prognosis for haemophiliacs with HIV and therefore it could be considered an HIV treatment [DHSC0020843_130]. Other similar letters were received from clinicians, for example, Dr Peter Jones of the Northern Regional Haemophilia Service, who confirmed his RHA were providing extra finance for HP Factor VIII from earmarked AIDS funds [DHSC0004773_017].

70.33. The Department also received Private Office correspondence regarding Dr Lewis' letter. On 6 October 1992, Mr Marshall wrote to the Prime Minister, John Major [DHSC0004002_117]. His letter enclosed a Times newspaper article critical of a "*Whitehall ruling*" meaning haemophiliacs infected with HIV were being "*denied*" life lengthening treatment [BART0002435_006]. The same article was sent to the Parliamentary Under Secretary of State, who by then was Tom Sackville, by Sir John Hannam MP [DHSC0002463_216]. On 26 October 1992, the All Party Disablement Group in Parliament wrote to the Prime Minister pressing for the Department to reverse its decision and allow AIDS funds to be used to provide HP Factor VIII to HIV positive haemophiliacs [DHSC0002464_016].

70.34. During this period, Armour also wrote to Dr Lewis challenging the assertion in her letter that the price differential between IP and HP Factor VIII would be short term only [DHSC0002463_031]. The Haemophilia Society also wrote to

Dr Lewis [DHSC0020843_104] and to Mrs Bottomley [HSOC0002584] asking for the instructions from the AIDS Unit to be withdrawn.

70.35. A handwritten note of 19 October was circulated within the AIDS Unit in reference to the "*spike*" of letters received following Dr Lewis' letter of 18 August [WITN3430226]. The note reiterated the rationale behind the Department's stance and said "*We can't possibly go back on what we've said, since allowing AIDS money to be used for HIV+ haemophiliacs now would open the door for special money to be demanded when use of the high purity Factor VIII was extended to other haemophiliacs…colleagues elsewhere would be most upset*".

Dr Winyard's third letter – Department policy on funding Factor VIII

70.36. On 5 October 1992, Dr Winyard wrote directly to Sir Kenneth seeking clarification of the Department's policy on use of HP Factor VIII [DHSC0002462_023]. The letter Dr Winyard referred to from Mr Sackville is at [DHSC0020843_177].

70.37. Officials, including Dr Rejman, liaised over a draft reply to be sent by Sir Kenneth, which was sent on 10 November 1992. This correspondence between Dr Winyard and Sir Kenneth is dealt with in more detail in the main body of Sir Kenneth's statement.

Further Departmental debate and correspondence regarding Dr Lewis' letter and use of AIDS funds

70.38. On 16 November 1992, Dr Lee wrote to Dr Abrams, Chairman of the Expert Advisory Group on AIDS ('EAGA') and a DCMO regarding Dr Lewis' letter [DHSC0002464_106]. Dr Lee referred to her letter published in the BMJ on 7 March 1992 [DHSC0003982_015], which concerned a study carried out at the Royal Free Hospital and advocated that the cost of HP Factor VIII should be part of HIV treatment. There is a handwritten comment by Dr Metters on the face of Dr Lee's letter saying the letter was not a matter for EAGA and asked Dr Rejman and Dr Lewis to provide advice and a draft reply.

70.39. Also, on 16 November 1992, Dr Pickles sent Dr Rejman a minute commenting on an article titled "Blood Money" published in the Health Service Journal

WITN3430227 and HSOC0002582]. The article concerned the Department's stance on AIDS earmarked funds not being used to purchase HP Factor VIII. Dr Pickles commented there was no reliable evidence to show HP Factor VIII had greater efficacy or could increase survival time in HIV infected haemophiliacs. The prospect of health economics research to demonstrate the resources used by haemophilia patients was considered.

70.40. On 18 November 1992, Mrs Bottomley (who by now was the Secretary of State, rather than Minister of State for Health) replied to the Haemophilia Society's letter, referred to above, which had challenged the decision set out in Dr Lewis' letter [UHMB0000005_097]. Mrs Bottomley made clear the Department was not advocating denial of treatment to haemophiliacs with HIV. Her letter noted concern still existed amongst some clinicians about the relative advantages of HP products and differences between the different forms of HP Factor VIII. She further emphasised points made previously about prescribing decisions being a matter for clinicians; regions were best placed to decide how to introduce medical advances from the growth money for the health service; and central funding could be achieved only by "*top-slicing*" RHAs' funding allocation.

70.41. Mrs Bottomley's letter went on to explain why the use of earmarked AIDS funds was inappropriate: HIV infection and AIDS were of uneven incidence and had placed a particular burden on the Thames regions. Earmarking of AIDS money was introduced as part of the strategy to contain the epidemic and "*Funding this new product…which is essentially for the treatment of haemophilia*" was thus not considered an appropriate use of AIDS funds.

70.42. For the purpose of answering a Parliamentary Question, a minute of 27 November 1992 also sought to explain why it was considered inappropriate to use AIDS funds for high purity Factor VIII. This minute cited the same point about containment of the epidemic, but also explained that there was concern that HIV negative patients would also demand HP products and that it was unfair to differentiate sources of funding for haemophiliacs based on their HIV status [WITN3430228].

70.43. The Secretary of State's letter was circulated to all recipients of Dr Lewis' letter of August 1992 [UHMB0000005_095].

Correspondence from clinicians regarding research into HP products

70.44. Dr Lee sent two letters to Sir Kenneth in late 1992 supporting the use of HP products for HIV positive haemophiliac patients. These letters are addressed further in the main body of Sir Kenneth's statement.

70.45. The documents attached to Dr Lee's first letter are likely to have been a paper by de Biasi et al, published in "Blood" journal on 15 October 1991 [BART0002478], which suggested very high purity concentrates may slow immunologic deterioration in HIV positive haemophiliacs, and her own letter to the BMJ of 7 March 1992, referred to above.

70.46. The document attached to Dr Lee's second letter is likely to have been an undated abstract of a paper by Seremetis et al called "High-purity vs. intermediate purity Factor VIII in HIV+ haemophiliacs" [DHSC0002464_098], which provided evidence monoclonally purified concentrates were associated with better preservation of CD4 lymphocytes in asymptomatic HIV positive patients with haemophilia.

70.47. Sir Kenneth's reply to Dr Lee, dated 4 December 1992, is considered further in the main body of the statement. Sir Kenneth's letter referred to a presentation Dr Lee gave at World Aids Day. As an aside, the available documents show that a briefing was prepared for the Prime Minister on the subject of World Aids Day. The draft version referred to '*data which have just been published in the USA*' [WITN3430229], amended to '*Accumulating data*' in the final version [WITN3430230], which had lent further support to claims HP Factor VIII was preferable for HIV positive haemophiliacs.

December 1992 meeting of UKHCDO

70.48. On 10 December 1992, Dr Rejman attended a UKHCDO meeting at which the Minutes record he restated the Department's view that it was unhappy with the Fourth Recommendations: it was felt there was insufficient scientific evidence to support the need for HP products for HIV positive patients and regretted it had not been subject to peer review [HCDO0000447]. The minute

refers to Dr Lee having a discussion with Sir Kenneth about Factor VIII at the Royal Free Hospital, a discussion which is addressed in the main body of the statement. The available documents show that the following day Dr Rejman sent a minute to Dr Lewis regarding the meeting, saying it was "*quite obvious that there* [is] *still disagreement among the Regional Directors as to whether high purity Factor VIII is indeed better for HIV positive haemophiliacs.*" [DHSC0002464_029]. He appended a paper by Dr Meenu Wadhwa et al called "Mechanisms of inhibition of T cell IL-2 secretion by factor VIII concentrates", published 27 June 1992, and highlighted the final paragraph, which said that the conclusion of de Biasi et al that HP were superior to IP concentrates for treatment of HIV patients "*should be treated with caution.*"

Policy change

70.49. The Department's change in policy on HP products is detailed in the ministerial submission dated 4 December 1992. The Secretary of State's decision was communicated to the profession by Sir Kenneth by way of a letter to the profession and also a press release. Further detail regarding the decision to change policy is given in the main body of the statement.

Subsequent developments

70.50. On 23 December 1992, an internal minute was circulated by Mr William Urry, which confirmed the Department would not wish to go beyond the position that it was the differential between IP and HP that could be legitimately funded from the AIDS budget, rather than the full cost of HP Factor VIII [DHSC0002464_086]. The minute also noted that haemophiliacs with HIV use significantly more Factor VIII than normal in the last six months of their life.

70.51. On 10 May 1993, Dr Sergeant sent a minute to Dr Lewis concerning a letter received from Dr Muir Gray, which had apparently called for a randomised controlled trial [DHSC0041364_085]. Dr Sergeant's minute notes all the trials have been small, have relied on CD4 count changes only and the variation between different HP products makes interpretation difficult. Dr Sergeant noted it was therefore unsurprising there was a difference of opinion amongst clinicians and the line to Dr Gray should be that the CMO's letter of 14

December 1992 was not giving guidance to clinicians and that it was up to the individual clinician whether to prescribe an HP product.

70.52. On 28 June 1993, Dr Winyard, who was by then Medical Director of the NHS Management Executive, commented on a draft response to Dr Muir Gray [DHSC0002466_059]. Dr Winyard questioned whether the Department would support an RHA which refused to fund HP Factor VIII on grounds of lack of evidence of efficacy. Dr Sergeant's handwritten comments of 1 July 1993 said the Department's position would be it could not support an RHA which refused to fund HP Factor VIII without contradicting the position set out in the CMO's letter to the profession.

70.53. On 23 July 1993, Dr Metters replied to Dr Winyard's minute and reiterated that it was for clinicians to make decisions "*within locally agreed priorities available resources*" [DHSC0002466_047]. While there were firm opinions on the merits of HP Factor VIII and the science remained contestable, Dr Metters said unless new evidence emerged of a lack of benefit of HP products there was no basis to change the position taken in the CMO's letter to the profession. A reply was thereafter sent by Dr Winyard to Dr Muir Gray setting out this position on 3 August 1993 [DHSC0002466_046].

70.54. The available documents show that in early 1994, the Department wrote to an RHA setting out that to assist with funding HP Factor VIII changes had been made to the formula for allocation of funding and that a contribution towards the excess costs of high purity Factor VIII has been built into the treatment and care element of the HIV budget for 1994 to 1995 [DHSC0003511_027].

Section 12: Recombinant

Q.71 Introduction of recombinant products in the UK

71.1. This Annex to Section 12: Recombinant products sets out what appears, on the face of the documentary record, to be the more significant developments in England during Sir Kenneth's time in office. The Annex refers on occasion to developments in the other three nations, where such developments are apparent from the available documents. It has been drafted to assist Sir Kenneth with the preparation of his statement and to assist the Inquiry.

71.2. In April 1993, the Haemophilia Society newsletter reported rFVIII had been licensed in the USA and Sweden [WITN3430231]. The same article quoted Dr Charles Hay saying:

> "*plasma fractionation technology and methods of viral inactivation have advanced considerably in recent years…Recombinant factor VIII is similar in presentation, safety and efficiency to monoclonally purified factor VIII…and would not appear to offer any clear cut advantages over these products at the present time.*"

71.3. On 28 September 1993, a UK product licence was granted to Baxter Healthcare Limited in respect of a rFVIII product called "Recombinate" [SHPL0000224_096]. On 21 June 1994, Bayer AG launched their rFVIII product called "Kogenate" in the UK. These "*first generation*" products were manufactured using animal and human proteins in the cell culture medium and with human albumin to stabilise the product.

71.4. On 26 October 1993, the European Commission's Biotechnology/Pharmacy Working Party discussed blood products [WITN3430232]. Dr Sloggem of the MCA took part in the discussions and a summary was sent to the Department the following day. The document set out concerns about transmission by blood products of non-enveloped viruses, for example parvovirus B19 or hepatitis A, and recommended viral inactivation measures for both enveloped and non-enveloped viruses. The document noted rFVIII products were free of these particular blood borne viruses.

71.5. In November 1993, Dr Hay wrote an article in the Haemophilia Society newsletter in which he noted the rFVIII molecule may differ subtly from the pdFVIII molecule [WITN3430233]. If so, inhibitors may arise more frequently with rFVIII. He said clinical trials must answer this question before rFVIII is adopted widely.

Considerations for NHS purchasers

71.6. On 7 April 1993, Mr Canavan provided comments on a booklet on haemophilia in which he noted the view of his division was that introduction of recombinant products would be one of three major issues in haemophilia to confront purchasers over the next three years, with considerable cost implications [WITN3430234].

71.7. On 25 June 1993, the Department issued Health Service Guidelines on "Provision of haemophilia treatment and care" (HSG(93)30) [HCDO0000269_062]. Dr Rejman was named as the Department's point of contact. The guidance "*reminds NHS purchasers of the considerations which they will need to take into account in order to secure continuity of access to comprehensive treatment and care for these patients*" [i.e. those suffering from haemophilia and related conditions]. The Haemophilia Society and UKHCDO were involved in the discussions that led to the issue of HSG(93)30. No specific reference was made in the HSG to different types of factor concentrates.

UKHCDO meeting and correspondence between clinicians and MPs and the Department – 1995

71.8. On 11 November 1994, Dr Colvin, then Chair of UKHCDO, wrote to Dr Rejman requesting a formal meeting to discuss funding for factor concentrates and haemophilia care, including the impact of rFVIII on the market [BART0000648_001]. Dr Rejman circulated the letter by Minute dated 16 November 1994 [DHSC0041361_107]. Dr Rejman noted there seemed to be marked differences between purchasers about the type of concentrate for which they were willing to pay. It had been hoped HSG(93)30 would mean such concerns were resolved "*in the field*".

71.9. On 18 November 1994, Dr Lee of the Royal Free Hospital wrote to Sir Kenneth. Her letter is addressed further in the main body of Sir Kenneth's statement. Dr Lee's letter was circulated to officials by Dr Rejman in a minute dated 1 December 1994 [WITN3430235]. The Minute carried a handwritten comment, possibly from Dr Metters, making the point it is "*unethical to use a more expensive treatment if there is no reasonable likelihood of greater benefit*" and the decision should be for local purchasers. Dr Rejman attached a background note [DHSC0003540_149].

71.10. Dr Metters replied to Dr Lee on behalf of Sir Kenneth on 15 December 1994 [BART0000634_002]. He said he had been advised there was "*no evidence that recombinant Factor VIII is any safer than plasma derived Factor VIII at the present time*". He noted it contained plasma derived albumin as a carrier. He referred to the fact rFVIII was not without side effects, seemingly a reference to the then possibility that rFVIII was linked with a higher incidence of inhibitors. Dr Metters referred to the guidance issued to purchasers (HSG(93)30) and emphasised purchasers "*must be assured that the money they spend is determined by the efficacy of treatment as well as value for money*".

71.11. On 24 January 1995, a meeting took place between UKHCDO, Dr Rejman and Department officials [WITN3430236]. Dr Colvin's minutes of the meeting recorded that the UKHCDO group emphasised the "*perceived*" safety of rFVIII and predicted that its usage would continue to rise. The Department's view was, according to Dr Colvin, that funding for factor concentrates would be determined by negotiations between purchasers and providers and no commitment was made to provide any additional top sliced funding.

71.12. On 23 March 1995, Dr Rejman circulated a line to take and background [DHSC0002422_031] on an embargoed Lancet letter from Dr Lee and others at the Royal Free Hospital entitled "*Life-threatening human parvovirus B19 infection in immunocompetent haemophilia*" [RLIT0001241]. Dr Rejman's document confirmed there was then no inactivation step to totally remove parvovirus B19. He noted it was a common infection in children and healthy adults who were infected generally suffered mild illness only, so was not of

significant clinical concern. Dr Rejman's view was that the description of the incident as life threatening was somewhat exaggerated. The plasma concentrate was not necessarily the cause of infection. He concluded that the much higher cost of rFVIII did not justify the "*very little*" extra benefit.

71.13. On 7 April 1995, Dr Lee replied to Dr Metters' letter of 15 December 1994 [BART0000634_001]. She had been awaiting publication in the Lancet about the parvovirus B19 case. Dr Lee said she disputed Dr Metters' assertion that there was no evidence that rFVIII was safer than plasma derived even with albumin being used currently as a stabiliser. She referred to hepatitis A and more recently parvovirus transmission from plasma derived products. She argued there were compelling reasons to use recombinants for patients who had not received treatment before; such patients would have predominantly been children. She suggested the "*side-effect*" of inhibitor production occurred with both recombinant and pdFVIII. On cost, the cost of litigation should enter the equation, she said.

71.14. On 24 April 1995, Dr Rejman circulated Dr Lee's letter to colleagues in his division [DHSC0041361_103]. He queried whether Dr Metters should be advised to give a brief superficial reply to avoid protracted correspondence. He attached notes on the letter [DHSC0032208_030]. Dr Rejman's notes said while there was anxiety about undiscovered viruses there must also be questions about undiscovered long term side effects of rFVIII. There was no agreement whether rFVIII produced more inhibitors than plasma derived products but was believed to produce at least as many. He said there was still debate about hepatitis A transmission. Parvovirus infections mostly produced no major clinical symptoms so were a poor justification of a significant increase in expenditure.

71.15. On 28 April 1995, Dr Frances Rotblat of the MCA sent a Minute to Dr Rejman to assist with the response to Dr Lee [DHSC0041361_085]:

> "*2. There is no safety reason why Recombinant Factor VIII should not be used. In particular I think it is important to stop emphasising the presence of albumin which has a long history of safe use. This kind of*

comment to experts in the Haemophilia field is likely to cause a great deal of irritancy.

3. It has to be accepted that the plasma derived products currently available are likely to be transmitting parvovirus. No one is clear how concerned we should be about this from a parvovirus/medical point of view. In general, and particularly in children, this is a mild and often sub-clinical disease. However, it is obvious that for very good reasons there are sensitivities relating to the transmission of any virus by blood products administered to haemophiliacs.

4. There is currently no compelling evidence that the incidence of inhibitors after treatment with recombinant product is any different from that seen with plasma derived material. The problem seems to be roughly the same for both types of product."

71.16. On 12 May 1995, Dr Rejman sent Dr Metters a Minute with a draft reply to Dr Lee [DHSC0032208_014]. He attached a background note that brought together the points he made previously [DHSC0032208_016]. He also attached two letters in the Lancet in response to Dr Lee's Lancet letter, one of which was from the Haemophilia Society supporting the use of rFVIII [WITN3430237]. Before Dr Metters had replied substantively to Dr Lee, Dr Lee sent a further letter to Dr Metters on 17 May 1995 [DHSC0002458_132]. She said she had sought without avail to persuade hospital finance to fund rFVIII. Purchasers would take advice from the Department and Dr Metters' comments about safety of rFVIII in his December 1994 letter would make it difficult to implement a change in practice.

71.17. Dr Rejman provided further advice on the draft response to Dr Lee by Minute dated 22 May 1995 [DHSC0003540_130]. He noted the reference in the Haemophilia Society's letter to risk from CJD was "*a red herring*" because it was not believed blood transmitted CJD. He acknowledged there may be "*some sense*" in giving rFVIII to adults or children who had not previously received treatment, but the relevance of children under 10 was not scientific. He conceded the point about safety of rFVIII in Dr Metters' letter of 15 December 1994 could have been clearer, but ultimately remained of the view

avoidance of parvovirus B19 was the only safety factor to distinguish rFVIII from a plasma derived equivalent.

71.18. Dr Metters replied substantively to Dr Lee's two letters on 25 May 1995 [BART0000633]. He said:

> "*As you are aware, it is generally accepted that the treatment of patients with blood and medicinal products derived from human blood and plasma is not without risk. Safeguards have been put in place to minimise the risk of transmission of viruses. The safety of blood products depends on a number of factors, which, taken together reduce, as far as is possible, the risk of viral transmission. These include the screening of donors, the testing of donations, plasma pool testing and the ability of the manufacturing processes to remove or inactivate viruses, and viral marker tests that can be undertaken on certain finished products. They relate to the manufacture of all blood products, Factor VIII, immunoglobulins and albumin. Although steps are taken and will continue to be taken to minimise risk, these safeguards cannot guarantee, absolutely, the removal of that risk. Consequently, the treatment of patients with recombinant Factor VIII, containing human serum albumin as a stabiliser, is also not without risk.*"
>
> […]
>
> "*Taking into account the state-of-art regarding the manufacture and control of medicinal products derived from blood and plasma, some patients with haemophilia may benefit from treatment with recombinant Factor VIII. In your letter you refer to certain categories of patients where you would think recombinant Factor VIII may be appropriate. If this is the case, then you should be able to support this position on the basis of scientific and clinical need. I think you will agree, it is preferable to consider the individual circumstances of each patient with haemophilia rather than making generalisations.*"

71.19. Letters were sent from Dr Lee to John Marshall MP in this period [DHSC0002467_386; WITN3430238 and WITN3430239]. Mr Marshall wrote

three times to Virginia Bottomley, the Secretary of State, enclosing the letters he had received from Dr Lee [WITN3430240 and WITN3430241]. Mr Tom Sackville, Parliamentary Under Secretary of State for Health, replied on each occasion [WITN3430242; WITN3430243 and WITN3430244]. Mr Sackville's letters enclosed copies of correspondence to Dr Lee from Dr Metters and therefore did not appear to add anything substantive.

71.20. On 4 July 1995, Mr Cynog Dafis MP wrote to Mrs Bottomley saying recombinant products should be offered to haemophiliacs to eliminate any possibility of undetected viruses. Mr Sackville replied on her behalf using the 'line' taken in Dr Metters' letter of 25 May 1995. This line was used to respond to other correspondence to the Department on this issue around this time.

71.21. On 16 September 1995, the BMJ published a letter from clinicians at the Scottish National Blood Transfusion Service ("SNBTS") [DHSC0003986_048]. The letter asserted that Dr Lee's belief, set out in her BMJ article of 24 June 1995 [BAYP0000033_076], that rFVIII could not transmit bloodborne viruses was incorrect. The SNBTS letter argued all biological substances can harbour infectious agents, and consequently all biopharmaceutical products carry some risk of infection.

71.22. On 2 November 1995, Dr Colvin and Dr Lee wrote to the Secretary of State, Mr Stephen Dorrell, enclosing results of a survey conducted within UKHCDO [DHSC0006173_008]. The documents indicate that this survey and the letter caused controversy within UKHCDO [HCDO0000456]. The letter protested that two centres only had secured funds for rFVIII and that current policy caused regional variations in the type of care delivered.

71.23. Dr Rejman replied on behalf of Mr Dorrell on 11 December 1995 [TORB0000092]. He repeated the approach contained in Dr Metters' letter of 25 May 1995. He also pointed out that purchasers, rather than centres, secured funds. The Department had issued guidance (i.e. HSG(93)30) to help purchasers place contracts for the care of haemophilia patients.

Meeting with Armour Pharmaceutical

71.24. As mentioned in the main body of the statement, the Inquiry has referred Sir Kenneth to documents concerning a meeting between the UK's Permanent

Representation in Brussels, Mr Angus Lapsley, and the pharmaceutical company Rhone-Poulenc Rorer ("RPR"), who owned Armour Pharmaceutical.

71.25. RPR's agent's letter of 16 May 1995 [DHSC0032052_033] concerns a meeting to discuss European practices on "*blood collection, fractionation, and related technology development*". Mr Lapsley sought background information from the Department. He was sent a Minute by the Department's EU branch on 26 May 1995 [DHSC0032052_029]. Dr Rejman provided input. The Minute referred to Armour pushing for their rFVIII to be accepted as safer, which the Department had not done. Mr Lapsley was advised to not discuss any matters of detail concerning blood or blood products but instead stick closely to the general position of the UK.

71.26. Mr Lapsley's reply to the Department of 30 May 1995 confirmed the Department's Minute arrived too late for his meeting but in the event none of the areas of potential controversy came up and there was no discussion of UK domestic policy [WITN3430245].

Request for national policy

71.27. The letter dated 15 June 1995 from Sir Colin Dollery about the possibility of national policy for funding haemophilia treatment and Sir Kenneth's reply is dealt with in the main body of Sir Kenneth's statement.

VAT on recombinant products

71.28. Dr Rejman circulated a Minute on 2 November 1995 [DHSC0003540_096] concerning VAT. The Minute noted in early 1994 some manufacturers of rFVIII wrote to HM Customs & Excise ("HMCE") asking for rFVIII to be exempt from VAT on grounds it contained human albumin. HMCE agreed to the exemption without reference to the Department, or expert opinion. In early 1995, Sir Colin Walker, Chief Executive of the NBA, apparently complained to HMCE that it was unfair to exempt rFVIII from VAT, since the active ingredient was not a blood product. HMCE discussed the matter with Dr Rejman.

71.29. On 15 September 1995, HMCE wrote to Dr Rejman to say they had revised their view that recombinant products should be relieved from VAT as human blood [WITN3430246]. All recombinant products would be liable to VAT from

1 November 1995. HMCE wrote to Dr Rejman again on 20 October 1995 to say pharmaceutical companies had sought reconsideration. HMCE asked Dr Rejman for guidance on whether rFVIII fell within the legislative exemption [WITN3430247]. Dr Rejman replied to HMCE on 4 December 1995 to confirm the Department's view was that rFVIII was not derived from human blood, so not exempt.

71.30. The Department received correspondence from various parts about the issue of VAT on rFVIII. On 8 November 1995, the Haemophilia Society wrote to Mr Dorrell objecting to HMCE's decision to impose VAT (then at 17.5%) [HSOC0008698]. The Haemophilia Society emphasised their belief that newly diagnosed children in particular should receive rFVIII. The imposition of VAT might lead to children being taken off the product. The Haemophilia Society wrote in similar terms to Kenneth Clarke MP, Chancellor of the Exchequer, on 24 November 1995 [HSOC0008693]. On 21 December 1995, Dr Savidge, as Chair of the "Recombinant Factor VIII Users' Group" wrote separately to Mr Dorrell [HSOC0008709] and Mr Clarke [DHSC0002458_068] objecting to the decision to impose VAT.

71.31. On 27 November 1995, a written answer was drafted to respond to a Parliamentary Question on whether the Department would cover the extra cost of VAT on rFVIII [DHSC0004060_025]. The attached background document [WITN3430248] set out the Department's line that VAT was a matter for HMCE. The Department provided help in clarifying certain medical and scientific questions relevant to the status of the product. The HMCE ruling was based on the fact that while recombinant products contained human albumin, that was not the active ingredient. Albumin was used in various other drugs which attracted VAT. Finally, the position was said to be in line with other EC Member States and a change to UK law would have required amendment of the relevant EC Directive. This line was relied upon to respond to the Haemophilia Society [WITN3430249] and to Dr Savidge [WITN3430250]. Ministers in the Department took the view there was no reason to make representations to the Chancellor about liability for VAT on recombinant products or to fund the use of rFVIII [WITN3430251].

71.32. On 12 March 1996, John Goulston, Director of Finance at the Royal Free Hospital, wrote to Colin Reeves, Director of Finance at the NHS Executive [DHSC0003540_060]. He raised the cost differential between plasma derived and recombinant products, partly due to the latter being subject to VAT. He asked for recombinant products to be put forwards as a costs pressure during the 1997/98 Public Expenditure Survey ("PES") round. His letter attached a paper from Dr Lee dated 1 February 1996 arguing that all children should be offered rFVIII [DHSC0003540_061].

71.33. Dr Rejman commented on the letter and Dr Lee's paper in a Minute to Mr Paul Pudlo dated 20 March 1996 [DHSC0003540_055]. He critiqued the contents and noted "*what is being requested is a gradual change from plasma derived Factor VIII to a more expensive recombinant Factor VIII on rather tenuous grounds*." Mr Pudlo replied on the same day [WITN3430252]. For reasons set out in Dr Rejman's Minute and Dr Metters' letter of 25 May 1995, the advice of Mr Pudlo's division was that recombinant products should not be raised as a PES pressure.

71.34. On 1 April 1996, Dr Savidge wrote a further letter to Mr Clarke [DHSC0003540_049]. Dr Savidge's letter argued rFVIII was significantly safer than plasma derived, particularly by reference to parvovirus B-19 and risk of unknown pathogens. In respect of VAT, Dr Savidge complained about different treatment for plasma derived and recombinant products. Plasma products were receiving an unfair market advantage. On 26 April 1996, Dr Rejman wrote to HMCE, who had been passed the letter to Mr Clarke, to assist with a reply to Dr Savidge [DHSC0003540_042]. The letter noted the Department did not recognise Dr Savidge's "Recombinant Factor VIII Users' Group".

71.35. Baxter's appeal to the VAT Tribunal against the imposition of VAT on rFVIII was dismissed in January 1997. VAT therefore continued to be levied on recombinant products from 1 November 1995 onwards.

Haemophilia Society's HCV report

71.36. On 19 February 1996, the Haemophilia Society wrote to Mr Dorrell enclosing a copy of their "Haemophilia and Hepatitis C Research Report" ("the HCV

report"). The Department had supported the research with a grant. The HCV report made six broad recommendations, one of which was funding to replace plasma derived products with recombinants. The Haemophilia Society emphasised the risk of transmission of unknown viruses.

71.37. On 20 March 1996, a departmental briefing was sent to Mr John Horam MP, Parliamentary Under Secretary of State for Health, ahead of his meeting with the Haemophilia Society on 26 March 1996 [WITN3430253]. The briefing included a section on funding for recombinant products (and VAT). In respect of safety of blood products, the briefing maintained the line set out in Dr Metters' letter of 25 May 1995. VAT was a matter for HMCE. The decision whether to use rFVIII was for the clinician in light of available resources and needs of individual patients. On 18 June 1996, the Haemophilia Society followed up the meeting with a letter to Mr Horam calling for the widespread introduction of recombinant products [HSOC0014319].

BPL / NBA

71.38. On 15 January 1996, Sir Graham Hart, Permanent Secretary, sent a Minute to Kevin Guinness regarding a meeting with Sir Colin Walker of the NBA [DHSC0004416_017]. Sir Colin Walker raised concern about BPL's financial problems and indicated that "*BPL is losing market share in the UK as recombinant Factor VIII gathers momentum*". The Minute referred to a forthcoming meeting between Sir Colin Walker and Mr Horam. In a similar vein, Dr Rejman's Minute to Mr Scofield of 24 April 1995 raised the impact of rFVIII on BPL operations and the price of plasma [WITN3430254].

71.39. On 10 May 1996, Mr Guinness put up a submission to Mr Horam regarding options for the future of BPL [WITN3430255]. BPL's share of the plasma derived Factor VIII market was being eroded by entry of rFVIII. rFVIII made up 1% of the UK Factor VIII market in 1993 but was projected to rise to 20-30% in 1996. The submission noted:

> "*Its* [rFVIII] *sales pitch has been that it is safer (which is true in the sense that there are known – and probably unknown – infectious agents which are not destroyed in the fractionation process, although*

the known but not fully destroyed viruses are thought to be of little importance for most patients)."

It further noted the future penetration of rFVIII would be determined by the price differential and any major episode of infection resulting from use of pdFVIII. The overall conclusion was a situation had come about where there was a surplus of plasma and BPL's prospects seemed likely to decline.

71.40. On 18 July 1996, a paper on BPL was sent by Mr Murray, a Department official, to Mr Guinness, which noted "*BPL face substantial losses in their historic main market as recombinant Factor VIII products increase their market penetration*" [DHSC0004454_059; DHSC0004454_060].

71.41. On 25 July 1996, Mr Guinness attended an NBA board meeting [DHSC0046928_129]. BPL's marketing director reported that BPL feared the forthcoming UKHCDO guidelines favouring rFVIII would have a significant impact on BPL sales.

Position in Scotland

71.42. On 3 July 1996, Mr Pudlo sent a Minute to Mr Horam, copied to Mr Dorrell, Sir Graham and Dr Metters, alerting them to an imminent announcement by the Secretary of State for Scotland of central funding for rFVIII [SCGV0000116_153]. The Minute reminded Mr Horam of the Haemophilia Society's proposal for widespread introduction of recombinants and recent Parliamentary pressure to exempt recombinant products from VAT. The Minute explained that the SNBTS supplied plasma derived products without charge. The additional cost of using rFVIII in Scotland was therefore very much greater than in England. Scottish Ministers announced a £1m central injection to address the disincentive in Scotland against using rFVIII. The Scottish policy decision was not made on safety grounds.

Hepatitis A in children treated with pdFVIII

71.43. The main body of Sir Kenneth's statement refers to an MCA investigation from August 1996 into three cases of hepatitis A in children who had received plasma derived FVIII. The incident led to letters to the Department from concerned patients and parents of haemophiliac children. An example

response to such letters is from Malo Harvey of the NHS Executive dated 6 September 1996 [WITN3430256]. The letter indicated that the infected children had not been vaccinated against hepatitis A. Vaccination against hepatitis A had been recommended for patients treated with blood products because it was known that viral inactivation processes were less efficient at inactivating non-enveloped viruses, such as hepatitis A.

NBA recall of "Replenate" pdFVIII

71.44. In August 1996, the MCA were notified that a batch of Replenate pdFVIII was produced from a plasma pool that tested positive for HCV. NBA issued a voluntary recall, which the Department supported. This led to further calls for specific funding for recombinant products. This issue is dealt with further in the main body of Sir Kenneth's statement.

UKHCDO guidelines on recombinant products

71.45. In **January 1997**, the journal "*Haemophilia*" published the final version of the UKHCDO's "*Guidelines on therapeutic products to treat haemophilia and other hereditary coagulation disorders*" ("the UKHCDO Guidelines") [BART0000875]. These replaced the Haemophilia Directors' 1992 publication, referred to elsewhere in this statement as "the Fourth Recommendations". The UKHCDO Guidelines made the following specific recommendations:

> "*6.2.2.1. Haemophilia A – factor VIII deficiency*
>
> […]
>
> *Recombinant factor VIII is the treatment of choice for all patients. If the introduction of recombinant factor VIII has to be prioritized then those who may benefit most should receive it first. Priority should therefore be given to those who have been least exposed to blood products in the past. These will most commonly be children.*"

A list then followed in priority order, namely: (i) previously untreated patients (usually small children); (ii) HCV negative patients; (iii) HCV positive patients; and (iv) HIV positive patients.

71.46. Save for a recombinant factor VIIa used for inhibitor management, called "NovoSeven", Factor VIII was the only licenced recombinant product at the

time of publication. Hope was expressed that in the future rFVIII would be available without human albumin or animal or human proteins.

71.47. The background to the publication of the UKHCDO Guidelines and the Department's involvement is set out below.

71.48. On 19 June 1996, Dr Colvin wrote Sir Kenneth enclosing a copy of the draft guidelines and asking for comment [DHSC0003986_026]. Further detail is given in the main body of the statement.

71.49. On 11 July 1996, Dr Rejman circulated a Minute regarding the draft guidelines, which referred to a meeting arranged for 8 August 1996 with Dr Colvin and Dr Ludlam to discuss the Department's view and invited input from officials [DHSC0032212_017]. Handwritten comments on the Minute query why UKHCDO had sent their draft guidelines to Sir Kenneth.

71.50. On 16 July 1996, Mr Pink replied to Dr Rejman saying the guidance (in then draft format) was not robustly evidence-based, showed no evidence of support from the relevant professional body nor did they indicate the involvement of purchasers of healthcare or patients in their production [DHSC0032212_007]. Mr Pink's subsequent Minute of 2 October 1996 noted the UKHCDO draft was not clinical guidelines and contrasted with the mechanism by which clinical guidelines gained national approval [DHSC0032212_006].

71.51. On 16 September 1996, Dr Rejman attended part of a UKHCDO executive committee meeting. The draft guidelines were discussed. His Minute of 17 September 1996 to Mr Guinness suggested that the Department had not responded in writing to the request for comment on the draft [WITN4486054]. He used the meeting as an opportunity to repeat the Department's line that the decision was for purchasers and extra expenditure on rFVIII when pdFVIII was an acceptable alternative would deny funds to other patients.

71.52. On 3 October 1996, Dr Rejman attended the UKHCDO AGM. Publication of the guidelines was delayed due to professional indemnity concerns, but draft versions were in circulation amongst clinicians, provider trusts and purchasers. His Minute, copied to Sir Kenneth's private office and referred to in the main body of the statement, raised concern that the wording of the

latest draft might imply the Department had approved the guidelines. Dr Rejman had asked for modification to the wording in this respect, but this was rejected.

71.53. Dr Rejman circulated a further Minute the following day, which confirmed UKHCDO members had accepted the guidelines unanimously [DHSC0002576_034]. There was debate about the link between rFVIII and inhibitors, particularly in young children. Some treaters expressed concern about what the recommendation to use rFVIII would mean for their haemophilia budget. The Minute also referred to a UK shortage of rFVIII in 1995, although the precise reason for this was not clear. Dr Hill and Dr Savidge had expressed the view that if the UK converted fully to rFVIII there would not be enough to go round.

71.54. Dr Winyard, as NHS Medical Director and head of the directorate responsible for clinical guidelines, decided it was necessary to make clear to the NHS that the Department of Health did not endorse the UKHCDO Guidelines [WITN3430257; WITN3430258; and WITN3430259]. On 10 October 1996, Dr Winyard wrote to Dr Ludlam, then Chair of UKHCDO, to request amendment to the draft [HCDO0000277_135]. He said further:

> "*there is now considerable confusion in the NHS as to the status of these guidelines. We are therefore sending a message out via the Public Health link, making it clear that we have not approved the guidelines and that our position continues to be that Health Authorities will need to consider carefully the evidence in support of the recommendation in the guidelines that recombinant factor VIII is the treatment of choice for all patients, bearing in mind the good safety record of products derived from human plasma. They will also need to consider any case for additional expenditure on the treatment of haemophiliacs alongside other calls on their resources.*"

Dr Winyard's message was disseminated to all directors of public health on 11 October 1996 [WITN3430260].

71.55. On 9 October 1996, Pat Spellman, of HCD-PH, proposed commissioning professionally developed guidelines on use of Factor VIII products [DHSC0044009_012]. It was considered it would help the Department to be able say "*we await evidence-based guidelines*". Dr Winyard, by Minute of 14 October 1996, counselled against such a proposal. Confidence was needed that any such guidelines would be acceptable to the Department, particularly as regarded cost effectiveness [DHSC0044009_005]. Mr Guinness, by Minute of 7 November 1996, added some additional difficulties with drawing up clinical guidelines [DHSC0044009_004]. He suggested a short note setting out the Department's view on the current evidence might better assist purchasers.

71.56. On 10 December 1996, Dr Winyard wrote to Dr Ludlam regarding his Public Health Link message [HCDO0000277_137]. He expressed thanks for removal of reference to the Department from the pre-publication version. Subsequent enquiries suggested health authorities and trusts were interested in the NHS Executive's view of the rFVIII recommendation. Dr Winyard confirmed the line remained that purchasers should seek assurance the money they spend is determined by efficacy of treatment as well as value for money and related to individual patient circumstances.

71.57. Dr Ludlam replied on 30 December 1996 [WITN3430261] asking if the NHS Executive had reservations about the accuracy of the guidance and to identify any errors. Dr Rejman replied on behalf of Dr Winyard on 13 February 1997 repeating the Department's view that the case had not been made for the recommendations in respect of rFVIII [BART0000922_006].

71.58. Following publication of the UKHCDO Guidelines in January 1997, Dr Ludlam and Dr Hay had a letter published in the BMJ on 8 March 1997 [HSOC0000334]. They argued there was a "postcode lottery" around access to rFVIII. Responsibility had been abrogated to local purchasers. They criticised the Department for providing no evidence that rFVIII should not be the treatment of choice and called on the Department to engage in dialogue and show leadership.

Haemophilia Society campaign

71.59. I referred above to the HCV report produced by the Haemophilia Society and their letter to Mr Horam of 18 June 1996 seeking recombinant products for all. Following their letter, the Haemophilia Society continued to press the point.

71.60. On 1 October 1996, Mr Horam replied to the Haemophilia Society [HSOC0023572]. He made no mention of rFVIII. Christine Corrigan, a Department official, advised on Mr Horam's response. Her Minute said funding of rFVIII was likely to dominate the Haemophilia Society's future campaign agenda, but the recommendation was to say nothing as the message was another negative one [WITN3430262]. The view of her division was the benefits of rFVIII, save for certain limited circumstances, were being exaggerated. The Department would not wish to signal that this should be a priority for additional expenditure.

71.61. On 3 October 1996, the Haemophilia Society wrote to Mr Horam referring to their previous call for the Department to centrally finance recombinants for all haemophiliacs [HSOC0014299]. On 11 October 1996, the Haemophilia Society wrote to Mr Dorrell [HSOC0003907]. The letter referred to the consensus reached at the UKHCDO AGM that rFVIII should be the treatment of choice for patients with haemophilia A and to levying VAT.

71.62. On 25 October 1996, Mr Horam replied to the letter of 3 October [HSOC0003918], maintaining the line set out previously. On 12 November 1996, Mr Horam replied on behalf of Mr Dorrell to the 11 October letter [BART0002289]. He repeated the previous line on VAT. As to the UKHCDO Guidelines, he said on the basis of drafts seen the case for recommending general use of rFVIII had not been made out. The Department's line on funding was:

> "*The Department* […] *does not consider that the case for recommending the general use of recombinant Factor VIII has been made. As you know the Department does not allocate money to support specific treatments for particular patient groups. Accordingly, as I said in my previous letter, haemophiliacs are in no different position with regard to recombinant Factor VIII than that of any other*

patient where alternative treatments are available. We do not believe that we should direct health authorities as to which products to use. Individual health authorities will need to consider very carefully the evidence presented in support of the recommendations in the UKHCDO document, and the case for additional expenditure on the treatment of haemophiliacs alongside other calls on their resources, bearing in mind the good safety record of products derived from human plasma."

71.63. In late 2016, the NHS Executive replied to a number of letters sent by haemophilia patients and their families to ministers regarding recombinant products, for example [WITN3430263].

71.64. On 3 February 1997, Mr Horam replied to a letter from Rhodri Morgan MP, which had enclosed a letter from the Manor House Group, who were a sub-group of the Haemophilia Society [WITN3430264]. The letter noted the Department made no estimates of the cost of treating all haemophiliacs, or all who are children, with rFVIII.

71.65. On 3 March 1997, the Haemophilia Society wrote separate letters to Mr Dorrell and Mr Horam [WITN3430265; WITN3430266]. The letter to Mr Dorrell referred to the "postcode lottery" and sought central funding of rFVIII for the first two priority groups identified by UKHCDO. The letter to Mr Horam asked for evidence from the Department to support its claim the case for rFVIII was not made out. The letter also expressed concern that Dr Winyard's Public Health Link message suggested the Department actively opposed the UKHCDO Guidelines. Further that Dr Winyard's reference to the "*good safety record*" of plasma products was misleading and was being used by health authorities as justification for not funding rFVIII.

71.66. Dr Rejman advised on a reply in a Minute dated 10 March 1997 [DHSC0004290_075]. He noted the Haemophilia Society seemed to be trying to force the Department to make a scientific case against the UKHCDO Guidelines and use of recombinant. It was for clinicians to make the case for use of a more expensive product. He suggested a reply in general terms. Mr

Horam replied to the letters to him and to Mr Dorrell by letter dated 27 March 1997 [DHSC0004290_071].

Developments following 1997 General Election

71.67. Following the change of government after the May 1997 election, the Haemophilia Society wrote to Frank Dobson MP, Secretary of State, and Baroness Jay, Minister of State for Health in the House of Lords [WITN3430267; WITN3430268]. The letters raised the issue of a "postcode lottery" over children's access to rFVIII. They argued the internal market was an inappropriate model for funding specialist services, like haemophilia, and a barrier to equitable introduction of new expensive treatments. The Haemophilia Society proposed a "*national commissioning framework*" and sought a meeting with ministers to discuss.

71.68. On 26 June 1997, Dr Ludlam wrote to Mr Dobson requesting a meeting to discuss whether an agreed national policy for rFVIII could be developed to ensure equity of healthcare delivery [HCDO0000275_166]. The reply to Dr Ludlam on behalf of Mr Dobson dated 30 July 1997 said Mr Dobson had agreed to listen to the Haemophilia Society's ideas for a national commission framework for rFVIII at a forthcoming meeting on hepatitis C compensation [HCDO0000275_167]. The UKHDCO's offer of a meeting would be considered once ministers had considered the Haemophilia Society's ideas more fully.

71.69. On 21 August 1997, Dr Ludlam wrote to Dr Mike McGovern, who had taken over Dr Rejman's role as Department representative at UKHCDO meetings [DHSC0041241_071], asking for a meeting. UKHCDO wished to discuss recombinant products and funding and contracting for haemophilia care. Dr Ludlam also wrote direct to Mr Dobson on 29 August 1997, repeating UKHCDO's concern about inequitable provision of haemophilia care, particularly in relation to availability of rFVIII [HCDO0000275_201]. Dr Ludlum suggested this could be addressed by modification of contracting and funding arrangements. Baroness Jay replied on 29 September 1997, confirming the Comprehensive Spending Review, announced in July 1997, would review all aspects of the Department's spending [WITN3430269].

71.70. On 8 September 1997, Ms Corrigan sent a briefing to Mr Dobson ahead of his meeting with the Haemophilia Society [WITN3430270]. The briefing noted the new Government had stated one of their aims was to reduce or remove inequity in access to health services. Appendix E summarised the Department's line on rFVIII, which was largely as per Mr Horam's letter of 12 November 1996. She added the following points, which had been raised previously by the Department: (i) use of albumin as stabiliser; (ii) risk of inhibitor development; (iii) theoretical risk of viral transmission arising from use of mammalian cell cultures; (iv) risk of formation of antibodies to animal proteins, which are present in trace amounts; and, (v) absence of evidence of long term outcome of treatment. Plasma derived products were a "*safe, effective and cheaper alternative*".

71.71. Mr Dobson's meeting with the Haemophilia Society took place on 10 September 1997. The Department's note recorded the Haemophilia Society raised the "*patchy*" provision of rFVIII across the nation and said haemophilia care should sit outside the current NHS funding system [WITN3430271]. Mr Dobson invited them to make their views known to the Comprehensive Spending Review team.

71.72. Following the meeting, Mr Dobson asked for a note on the broader considerations around hepatitis C compensation and rFVIII and the cost of providing rFVIII to children. A handwritten note on a draft letter dated 18 September 1997 on the issue of hepatitis C compensation stated: "*Ministers have asked Chris Corrigan to look at offering things other than compensation: one of the things she is looking at is funding for Recombinant Factor VIII*" [WITN3430272]. On 26 September 1997, Ms Corrigan wrote to the Treasury regarding BPL. She noted Mr Dobson was considering a request for central funding of rFVIII and if agreed it would "*clearly impact significantly on BPL's position*" [DHSC0004454_004].

Concern about transmission of vCJD by blood and blood products

71.73. On 6 October 1997, Sir Kenneth made a public statement regarding the unknown risk of whether vCJD could be transmitted through blood and blood

products [WITN3430053]. This issue is referred to further in the main body of the statement.

71.74. On 25 November 1997, the UKHCDO issued a public statement on vCJD [SBTS0003131_180]. The statement referred to batches of pdFVIII withdrawn in the UK by the manufacturer (BPL) because they were produced from plasma containing donations from individuals who subsequently developed vCJD. They called for urgent implementation of the recommendations contained in the UKHCDO Guidelines and recommended strongly the use of rFVIII for all people with haemophilia A. For those patients for whom recombinants were not available, they advised the risk of vCJD transmission would be reduced by using concentrates prepared from donor plasma collected in countries with no recorded cases of vCJD or BSE.

71.75. On 28 November 1997, Mr Dobson wrote to the Haemophilia Society apologising for the delay in responding to matters raised at the meeting on 10 September 1997 [HSOC0016902]. The issue of rFVIII had been further complicated by the need to address concerns about safety of the blood supply in the context of vCJD. Mr Dobson referenced the need to make best use of available resources before commenting:

> "[W]*e are surprised, as I believe you are also, at the recent press statement of the UK Haemophilia Directors Organisation about the use of recombinant Factor VIII and plasma derived coagulation products sourced from US plasma. This conflicts with the advice from the Spongiform Encephalopathy Advisory Committee (SEAC) and the advisory committee on the Microbiological Safety of Blood and Tissues for Transfusion (MSBT) and indeed with that from CPMP which advises the European drug regulatory authority. We share your anxiety about the impact of this advice on the management of people with haemophilia.*"

71.76. Sir Kenneth's statement makes reference to a document concerning a meeting on 22 January 1998 [WITN3430054]. The document refers to Dr Frank Hill and Dr Mike Williams urging a change to use of rFVIII or US plasma products. Dr Hill was a member of UKHCDO. The context of this meeting was

a group of public health doctors in the West Midlands who were asked to review the health authority's decision not to fund rFVIII in light of concerns over vCJD. Dr Caron Grainger was involved as a member of the public health directorate in NHS Executive West Midlands.

Impact on BPL of UKHCDO press release

71.77. On 26 November 1997, Sir Colin Walker wrote to Baroness Jay, copied to Dr Winyard, warning of the financial consequences for BPL of the UKHCDO recommendation to use non-UK plasma [WITN3430273]. Significant extra funding would be needed to make up for the loss in sales of plasma products.

71.78. BPL's concerns were reflected in a paper on blood services produced by the Department's Health Service Directorate for the NHS Executive Board in January 1998 [WITN3430274]. The paper set out various issues contributing to the strategic and financial uncertainty facing the blood service. In the face of declining NHS market following development of rFVIII, BPL had been making good some of its losses by selling plasma abroad. Concern about vCJD transmission had seen overseas purchasers cancel BPL contracts. Further, the home market was under pressure due to the UKHCDO's public statement. Health authorities were reporting increased pressure from clinicians and patients and a number had undertaken to review their decision not to fund rFVIII. The collapse of BPL was considered a realistic possible outcome. The paper concluded by emphasising the importance of keeping local commissioner's aware of central thinking and strategy on new or perceived risks, in particular in relation to vCJD and Factor VIII.

Move towards national policy on use of rFVIII

71.79. On 28 January 1998, Dr Winyard emailed Dr McGovern referring to the possibility of a move towards some form of national policy on use of rFVIII [DHSC0006258_079]. He said he was concerned about the potential complication of inhibitor development. Dr McGovern replied the same day referring to a regional report which suggested the literature was not conclusive but "*certainly does not suggest any increased incidence*" of inhibitor following use of rFVIII [WITN3430275].

71.80. On 5 February 1998, Dr Metters and Dr Winyard put up a major submission to Mr Dobson and Baroness Jay, which opened with reference to the theoretical risk that vCJD could be transmitted through blood products [CABO0000014_017]. There was growing concern about the safety of UK blood. SEAC had not yet produced its assessment of the risk of vCJD transmission through blood, which was expected by the end of the month. It was expected the Committee on Safety of Medicines ("CSM") would recommend a move away from blood products made from UK plasma wherever possible.

71.81. The submission proposed four options, which fell into two categories. The first category, based "*purely on science and logic*", was to await the outcome of the risk assessment and if inconclusive, await further evidence. This would do nothing to restore public confidence. The alternative category, based on public health and public confidence, was to take action now to minimise risk, even though this would be seen as running counter to the evidence-based approach to decision making the Department sought to encourage in the NHS.

71.82. The submission attached a position paper detailing the four options [DHNI0000042_081]. Option 3 involved allowing BPL to import non-UK plasma and providing limited funding of recombinant products for children and previously untreated patients. The submission described this option as "*probably better in terms of safety, public confidence, international support, and cost*". The submission noted such an approach risked seriously undermining established policy that decisions on priorities for use of scarce resources should be based on evidence of clinical and cost effectiveness. The Government would need to stress it was acting exceptionally to meet the understandable concern of people with haemophilia and to restore public confidence.

71.83. On 10 February 1998, Dr Metters and Dr Winyard sent a Minute to Mr Dobson, Baroness Jay and Tessa Jowell MP, the Minister of State for Public Health [DHSC0038661_039]. The Minute followed a meeting the previous day. Reference was made to Mr Dobson's wish to move as soon as possible

to recombinant products for children and previously untreated patients. Mr Dobson also wished to free up BPL to import non-UK plasma and to develop blood products from non-UK sources.

71.84. On 13 February 1998, Mr Dobson's private office put up a submission to the Prime Minister [WITN3430276] with attached paper on vCJD and blood [WITN3430277]. The Minute referred to the theoretical, and as yet unquantifiable, risk vCJD might be transmissible through blood products. It said there was currently no hard science and the SEAC risk assessment was likely to be inconclusive. The Minute proposed allowing BPL to import plasma and at the same time moving to recombinants for previously untreated patients and children. This would go "*part way towards meeting the concerns raised with me and through the media in recent months by the UK haemophilia community*". The announcement should be made before the CPMP's statement on 27 February 1998.

71.85. On 17 February 1998, Mr Dobson wrote to Alastair Darling MP, Chief Secretary to the Treasury, about the policy cost [CABO0000014_003]. The costs for 1999/00 beyond would be included in the discussions on the outcome of the Comprehensive Spending Review in the Department. The move to recombinant products for children and previously untreated patients would cost £4.1m (£2.6m to NHS trusts for the treatment and £1.5m in lost sales for BPL) in 1998-99. This would be funded centrally and through the Department's existing budget. The cost of freeing up BPL to import non-UK plasma was anticipated to be £18.4m and a request was made for access to the Treasury's Reserve for 1998/99. The decision on how to fund leucodepletion would be deferred pending further SEAC advice.

71.86. On 24 February 1998, Mr Darling replied to say he agreed to the announcement of the move to non-UK plasma source, but the Department needed to look at ways of funding the cost without a Reserve claim [SCGV0000061_083].

71.87. On 26 February 1998, the Department issued a press release about the use of imported plasma and rFVIII [WITN3430278]. The steps to import plasma, and the extension of a recall of blood products linked to vCJD cases, were

explicitly linked to further precautionary advice received the same day from the CSM about the theoretical risk that vCJD could be transmitted by plasma derived products [WITN3430279]. In respect of FVIII, the announcement was said to be the outcome of a "review" of the NHS' provision of Factor VIII. The press release quoted Mr Dobson as saying:

> "*The Haemophilia Society, amongst others, have highlighted their concern about blood borne infections and, in particular, the effect which those concerns have on families with haemophiliac children. Though the risk of nvCJD transmission is hypothetical, nevertheless the fear of it is very real to this group which has previously been affected by both HIV and Hepatitis C transmitted from Factor VIII.*
>
> *So I have decided that all health authorities must make arrangements to ensure that the synthetic version of Factor VIII, known as recombinant, is made available to those children under the age of 16 who are not already receiving it, and to new patients.*"

71.88. The same day Mr Dobson wrote to the Haemophilia Society following their meeting on 10 September 1997 [RHAL0000441_002]. He reiterated the Department did not accept the clinical case had been made for the general use of recombinants. He acknowledged the experience of past problems with blood borne infections and concern about unknown viruses. He further acknowledged those fears had been fuelled by the latest developments in relation to vCJD, particularly for families with children. This was the reason for the announcement.

Events following February 1998 recombinant policy announcement

71.89. On 27 February 1998, Dr Winyard, Dr McGovern and Ms Corrigan met with UKHCDO [HCDO0000465 at item 4]. The possibility of including hepatitis C negative patients within the central funding was discussed, although no commitment was made by the Department. It was reiterated that the Department would not approve the UKHCDO Guidelines.

71.90. On 3 March 1998, the Scottish Office sent Ms Corrigan a submission and draft speaking note for the Secretary of State for Scotland [WITN3430280]. The covering submission from the Scottish Office explained that a health board consortium-led national approach to funding rFVIII had been set up in Scotland in 1997. Concern over vCJD had prompted the consortium to recommend all health boards move to use of rFVIII for all patients. While the UK Government was not making any extra central funds available, the effect would be that Scotland would be 100% recombinant within the next year.

71.91. Ms Corrigan replied the same day picking up details in the draft speech [DHSC0006258_062]. She emphasised Mr Dobson's announcement regarding recombinant products was in response to concerns of the haemophilia community, not in response to CSM advice. She said the Department did not accept there was any evidence to show recombinant products were "safer". Further, the announcement about importation of plasma and the announcement about recombinant products were to a large extent unrelated but had been made together because No 10 wished to avoid too many announcements which raised the subject of vCJD.

71.92. On 17 March 1998, Dr Winyard, as Director of Health Services, NHS Executive, issued the Health Service Circular ("HSC") 1998/033 [HCDO0000133_021]. This directed NHS trusts to take steps to ensure in the year beginning 1 April 1998 children under 16 and previously untreated patients had access to rFVIII, where recommended by their clinician. Where health authorities or trusts were unable to obtain adequate supplies of rFVIII for these groups, they should agree with clinicians an order of priority. Additional funding was to be made available in 1998/99 to those health authorities incurring extra costs to implement Mr Dobson's decision.

71.93. A related Minute from Ms Corrigan noted the decision to impose an age limit of 15 was not based on science [WITN3430281]. The representations had referred to children and a decision had to be taken about where to draw the line. It also reflected the fact many children in the group would be less likely to be infected with other blood borne viruses. The upper age limit also mirrored that initially agreed in Scotland.

71.94. On 30 March 1998, Ms Corrigan attended a meeting of UKHCDO [HCDO0000465]. HSC 1998/033 was discussed, and the Directors were invited to write to Ms Corrigan with any difficulties they identified. The point was made to Ms Corrigan that because manufacturers had not been given prior notice of the new arrangements, they would not be able to supply all under 16 year olds immediately.

71.95. On 7 April 1998, Dr Metters replied to a letter from the Faculty of Public Health Medicine [WITN3430282; WITN3430283]. The Faculty had argued it was unethical and impractical to deny older patients the same level of safety on the grounds rFVIII costs more than pdFVIII. Dr Metters' reply pointed out the agreement to use imported plasma had removed the hypothetical risk of transmission of vCJD. Further, the Department did not accept the clinical case had been made out for general provision of rFVIII.

71.96. On 29 May 1998, Dr Ludlam wrote to Mr Dobson to say recombinant Factor IX ("rFIX") would become available in the UK in July and asked for confirmation of the funding arrangements [DHSC0020876_093]. On 21 August 1998, Paul Boateng MP, the Parliamentary Under Secretary of State for Health, replied on behalf of Mr Dobson [WITN3430284]. He said licensing issues meant the product was unlikely to become available as soon as expected. The issue of funding would be considered in the context of the earlier decision on rFVIII but only once it is clear when rFIX will be introduced.

71.97. On 21 August 1998, Dr Winyard issued HSC 1998/147 [DHSC0006258_050]. This explained to health authorities how to claim additional funding following Mr Dobson's announcement. The additional funding was available only in respect of patients, in the relevant categories, who had not already received recombinant product. The funding arrangement was for 1998/99 only and subsequent provision would have to be met through health authorities' general allocation. Sufficient supplies of rFVIII to meet the total new demand were expected to be available from September.

September 1998 onwards

71.98. Sir Kenneth left his post as CMO for England in September 1998. Without attempting any kind of comprehensive review of issues arising in the six months or so after he left office, the following are of note:

a) On 12 October 1998, Dr Ludlam, wrote to other members of the UKHCDO Executive Committee [DHSC0006917_050]. Dr Ludlam was seeking views as to which patients currently on recombinant FVIII should revert to plasma derived concentrate should the need arise. Haemophilia Directors had expressed anxiety about some purchasers not continuing to fund rFVIII, particularly for those under 16, and the prospect of further price increases. He attached an earlier letter he had written to Dr Winyard in this regard.

b) On 3 November 1998, a submission was put to Baroness Hayman, Parliamentary Under Secretary of State for Health in the Lords, on NHS blood prices for 1999 to 2000 [DHSC0043857_112]. The submission raised the potential impact on the following year's blood prices of the combined effect of leucodepletion, importation of non-UK plasma, destruction of UK plasma, NAT testing and measures to increase blood donations. The announcement of Health Authority allocations was to be made the following week. The submission noted that this increase in blood prices would be coming into effect on top of the cost of the provision of rFVIII for previously untreated patients and children under 16, which health authorities were due to take on from 1999.

c) On 30 November 1998, Dr McGovern sent a submission to Baroness Hayman on haemophilia B and rFIX [DHSC0004591_080]. Dr McGovern advised rFIX should be used for new patients with haemophilia B and those under 16 years of age, as was the case for haemophilia A patients. He said because the sums involved were smaller and no central provision had been made for rFIX, health authorities should be asked to meet the cost from existing budgets. Dr McGovern suggested that the Department should communicate in

these terms with the health service, the Haemophilia Society and UKHCDO and also publicise it in the CMO's proposed letter to clinicians about treatment with non UK blood products. Baroness Hayman agreed to this course on 7 December 1998 [DHSC0042287_006].

d) On 4 January 1999, Dr McGovern provided Baroness Hayman with a note about haemophilia, rFVIII and hepatitis C [DHSC0041158_182]. The note responded to the argument rFVIII should be available for all haemophilia A patients, as follows:

> "*There are three issues - clinical effectiveness, availability and cost. Clinical effectiveness: quite simply, no study to date has demonstrated that recombinant factor VIII is good value and this is the Department's current position. This is likely to change when/if prices fall. Availability: the product is made by Baxter laboratories and demand currently outstrips supply. There is not enough of the currently licensed recombinant factor VIII to support treatment of those under 16 and new patients. Other second and third generation products are under development and it is likely that the companies are depending on unsatisfied demand for the Baxter product to drive sales of these ever newer and more expensive products. Cost: the likely extra cost of providing recombinant factor VIII to all people in England with haemophilia A would be in the order of £50 million pa, bringing the average total cost of treatment alone for these 2,000 patients to £77-80 million pa.*"

e) On local negotiation over treatment, Dr McGovern pointed out that the fact the Department did not support a policy of rFVIII for all did not mean clinicians could not prescribe it or health authorities should not pay for it. He said those providing care had to do so in the context of local need and affordability unfortunately was part of this consideration.

He noted this was the kind of area which NICE would address when set up later in 1999.

f) On 22 January 1999, HSC 1999/006 on rFIX was issued [DHSC0004591_076]. The summary explained that the move to using recombinant factor IX for previously untreated patients and children under 16 would result in small in-year cost pressures for health authorities and NHS trusts. From April 1999, the cost of rFIX should be met from general allocations.

Q.72 Haemophiliac patients' access to recombinant blood products

72.1. See Personal Statement

Section 13: vCJD

Q.73 The Emergence of vCJD

73.1. See Personal Statement.

Q.74 Evidence to the Strategic Review of the PHLS

74.1. See Personal Statement.

Q.75, Q.76 Offers of Help from PHLS

75.1. See Personal Statement.

76.1. See Personal Statement.

Q.77 CMO letter of 1 July 1996

77.1. Question 77 relates to the CMO's letter of 1 July 1996.

77.2. In July – August 1996, further measures to introduce donor questions to ensure that a family history of CJD were identified and introduced. This Annex outlines documents supplied by the IBI for the purpose of this question.

77.3. On 1 July 1996, CJD was discussed at a meeting of the UK Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI). The minutes record discussion of proposals on donor selection [JPAC0000109_025]. It stated that:

> *"The proposals will ensure that selection procedures conform to Council of Europe guidelines. SNBTS were unhappy about the possible questioning of donors to reveal the identity of relatives with CJD. PF agreed that this should not take place at the donor session, and it was envisaged that it would be at the responsibility of the consultant in donor care to follow up any family history in an appropriate and sensitive manner."*

77.4. The implementation date was confirmed as 1 August 1996.

77.5. On 8 July 1996, Dr George Galea (SNBTS North of Scotland) wrote to Dr Virge James (National Blood Service) [JPAC0000166_075]. Dr Galea stated:

> *"Many thanks also for discussions on CJD family history. I am enclosing the version going to SNBTS Donor Consultants. If you have any comments; particularly relating to obtaining details of relatives, please let me know. Unless I hear from you, I will issue towards the end of this week. I am also issuing a set to our Tissue Nurses so that they can incorporate them into their questionnaires. I have already spoken to Ruth Warwick, Chair of the SAC on Tissue Banking, about our initiatives on the blood donor side and I will give her a copy of what I have as soon as I am sure you have no significant comments."*

77.6. On 10 July 1996, the National Blood Service convened a meeting of Consultants in Donor Health [JPAC0000166_059]. It was explained that because of *"political pressures as much as any clinical reasons it will become necessary to include in the questioning of all donors specific reference to CJD".* Consequently, it was proposed from 1 August 1996 to introduce a question for all donors to answer.

77.7. On 16 July 1996, Dr Virge James wrote to Dr Warwick (North London Transfusion Centre) [JPAC0000166_074]. Enclosed was the Concessionary Letter No.6 which provided an explanation on the questions that donors had to be asked. It was confirmed that this would be implemented from 1 August 1996.

77.8. On 24 July 1996, Dr James wrote to Consultants with Donor Health Responsibilities and others following the meeting on 10 July 1996 [JPAC0000166_058]. Attached to this letter was a leaflet to be given to donors who have a family history of CJD [JPAC0000166_060]. This leaflet was produced at the Cambridge Centre. It confirmed that from 1 August 1996, Blood Transfusion Services in the UK were required to ask all blood donors whether they have a family history of CJD. It provided background information on CJD and confirmed that "*where a close family member with CJD is a direct blood line relative e.g., parent, brother, child, people will be advised not to*

give blood". Also attached to the letter of 24 July 1996 was a follow-up letter to be sent to donors who had a family history of CJD [JPAC0000166_061].

Q.78 CJD Lookback Exercise

78.1. The Inquiry has asked a series of questions about the CJD Lookback Exercise that was initiated in 1996. This was a proposal discussed by the UK Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) and the MSBT. It was carried out by the CJD Unit in Edinburgh together with the Blood Transfusion Service, following consideration of any ethical issues by the Lothian Ethics Committee.

78.2. Looking at the papers supplied and adding other relevant documents, notably the minutes of the MSBT (chaired by Dr Metters), the following emerges.

78.3. In May 1995, the advice of the MSBT was that a Lookback exercise should not be carried out: see the minutes of the meeting of 25 May 1995 [MHRA0023194]. The MSBT discussed a proposal from SACCTI that one should be carried out but rejected it on the basis that there was insufficient scientific justification for such an exercise (see paragraph 6.6). This view was confirmed in early 1996: see the minutes of the meeting held on 8 January 1996 [DHSC0020692_118] which set out the CPMP's expert group's position on CJD and the safety of blood products and recorded at paragraph 7.8: *"While Canada was doing a full lookback exercise, the MSBT confirmed its earlier advice that the UK should not do so."*

78.4. It is apparent that this stance changed, in the course of 1996. The matter was reconsidered by the MSBT on 2 May 1996; relevantly, this was following the receipt of information about the new variant of CJD (vCJD) and its announcement in March 1996 (see Question 77), as well as a letter from Dr Will sent on 29 April 1996 (see [DHSC0032286_084], below, responding to it). In this May meeting [SBTS0000518], the MSBT discussed (amongst other things) the topic of a "lookback", noting that Dr Will had reported that there were 50 patients identified with CJD who had given blood. In addition, the meeting noted that of the 10 new cases of CJD variant, one was known to be a blood donor. The meeting agreed that Dr Will's proposal should be

developed into a research proposal. *"Ethical clearance would be essential given the implications";* it was made clear that GPs and patients would not be contacted. *"It was agreed that the CJD surveillance unit and the Blood Transfusion Services would prepare a protocol to be submitted to the Health Departments"* (paragraph 6.10).

78.5. The decisions of the meeting were confirmed in a letter from Dr Metters to Dr Will, sent on 13 May 1996 [DHSC0032286_084] and making further comments on the possible study design. Dr Angela Robinson (Medical Director, NBA) was to write to take the practical aspects of this forward.

78.6. On 1 July 1996, there was a meeting of SACTTI, chaired by Dr Flanagan. The minutes of that meeting [JPAC0000109_025] record that recommendations for a lookback exercise were made, involving the exchange of information between the Transfusion Service. The exercise was aimed at establishing whether recipients of donations from individuals who had later developed CJD themselves ever appeared on the CJD register. It was noted (paragraph 6.4) that Dr Angela Robinson would present the recommendations of SACTTI to the MSBT. The same sub-paragraph noted:

> *"…However, it had been considered unethical to inform the recipients of such donations,* [recipients of donations from those who had later developed CJD] *because there was as yet no evidence of risk (Prof Ian Kennedy)…"*

78.7. The MSBT met on 2 July 1996 and was updated on the progress of the design of the lookback exercise [SBTS0000519]. The first draft of the protocol (see further paragraph 78.10 below) was tabled. The meeting heard that Professor Ian Kennedy had been consulted: *"His advice was that recipients of blood from a CJD patient should not be informed, but that the position should be reviewed in the event of the development of a diagnostic test or effective intervention. The Chair commented that such advice did not obviate the need to refer the protocol to an Ethics Committee"* (paragraph 5.5).

78.8. On 10 July 1996, a National Blood Service meeting of Consultants in Donor Health took place [JPAC0000166_059]. The primary topic of discussion was the exclusion of potential blood donors based on questioning about whether

they or any family members had suffered from CJD, but the feasibility of a lookback exercise (relating to patients who had received previous units from donors who answered "yes") was also discussed. The minutes recorded that Dr Pat Hewitt had visited Professor Ian Kennedy to seek expert advice on the ethics of the exercise and that along with Dr Jack Gillon and Dr Bob Will of the CJD Surveillance Unit, she would be making proposals. There was a discussion of guidance emerging from other jurisdictions (notably America: see [JPAC0000166_062], which is the AABB policy) but *"It was generally felt that these Guidelines are inappropriate to the UK".*

78.9. Following this meeting, the minutes were circulated together with a copy of a leaflet to be given to donors who have a family history of CJD and other relevant information about CJD [JPAC0000166_058]; see Question 77 and the documents referred to.[30]

78.10. On 4 November 1996, there was a further meeting of SACTTI [NHBT0010921]. The minutes of the meeting noted (paragraph 8) that the proposals for a lookback exercise were with the relevant Ethics Committees and would then go to the MSBT. The document [WITN3430285] is a copy of the final draft of the proposed *"retrospective study to examine a possible link between Creutzfeld Jacob Disease and Blood Transfusion."* The covering page (probably prepared for the MSBT meeting on 18 November 1996) noted that *"An application for ethical approval has now been submitted in the required format by Dr RG Will to the Lothian Research Ethics Committee."* The proposal's authors were Dr Will, Dr Gillon (SNBTS) and Dr Hewitt (NBS).

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[30] The Inquiry have also referred Sir Kenneth to a letter from Dr V James to Dr Ruth Warwick, dated 16 July 1996 [JPAC0000166_074]. The letter was written to Dr Warwick in her capacity as the Chairman of the Special Advisory Committee on Tissue Banking; Dr James expressed his view that she should be kept updated on appropriate communications for Consultants in Donor Health, following discussion surrounding CJD and blood donors. Dr James enquired as to what precautions were being taken with regards to exclusionary criteria for organ donors (in addition to blood donors). The Inquiry has referred Sir Kenneth to two further letters of July 1996 (one from and one to Dr V James) [JPAC0000166_075] & [JPAC0000166_058]. They were not sent to or by Sir Kenneth, nor do they appear to have been copied to his Private Office and again are not central to any consideration of lookback.

A detailed account of the study's design was set out, including the reasons why the lookback would take place without the notification of the recipient, namely:

"1. There is no screening test available which can detect the possibility of an individual being susceptible to development to [sic] CJD in the future.

2. There is no diagnostic test available to detect whether an individual has been infected with the agent which causes CJD.

3. The diagnosis of CJD can only be made with certainty by examination of pathology specimens post-mortem.

4. There is no intervention which can be offered to individuals detected to be at risk of developing disease, or to those who have already developed symptomatic disease."

78.11. The proposal added that *"should there be any change in the capacity to diagnose the disease, or if any intervention becomes available in the future, then the transfusion services should have in place a mechanism for identifying the identified recipients."*

78.12. A report to SACTTI dated 30 January 1997 [JPAC0000109_021] subsequently noted that the Lothian Research Ethics Committee had given formal approval for the lookback exercise following a meeting of the National CJD Surveillance Unit on 24 January 1997. The report noted that attendees at the meeting included Dr Gillon, Dr Hewitt and Dr R. G. Will. The SACTTI report summarised the two elements of the look-back:

a. Forward-Looking. *"a formal look back from CJD patients who have acted as blood donors. The CJD unit holds, in its database, the identity of CJD patients known or believed... to have been donors before development of CJD. It was agreed that Dr Will will provide an individual form for each patient".* These forms were to be distributed to the individual transfusion centres in the UK, to identify the donors. Once a transfusion centre identified a donor, a look-back form would be sent to the consultant haematologist at the hospital concerned for each donation traced in the transfusion centre

records. Information on the recipients of the donations received would be channelled back to the CJD unit for checking of the database.

b. Reverse lookback: this involved identifying the donors, whose donations were transfused to patients who subsequently developed CJD and were reported to these surveillance unit. "*The starting point will therefore be a CJD case with a history of blood transfusion."* Information about these cases would then be passed to the relevant blood transfusion centre. The consultant haematologist at the hospital concerned should be able to provide information about the donations transfused: *"These will be traced back to the donor and donor identifiers transmitted to the CJD Surveillance Unit..."*

78.13. The report set out the reasons why it was considered appropriate to conduct a lookback exercise without informing the recipient of the transfusion or their GP. The ethical reasons were evidently taken from the Research Proposal which has been summarised above; the language is the same as that above.

78.14. The document also contained a detailed discussion of the patient confidentiality issues which arose, as well as of the treatment of fractionated blood products.

Q.79 Media Briefing of 6 October 1997

79.1. See Personal Statement.

Q.80 Recall of vCJD-implicated blood products in October 1997

80.1. It will be recalled that the CMO's statement of 6 October 1997, it was stated:

> *"The safety of blood and blood products has been considered on several occasions by SEAC and also by WHO, Council of Europe, CPMP and MSBT. All have concluded that any risk of contracting CJD through blood or blood derivatives is negligible. In keeping with our European partners and CPMP advice we have not withdrawn blood products where one of the contributing donors has developed CJD.*

> *However the Government will take any further measures which become scientifically necessary to safeguard the integrity of our supply of blood and blood products."* [DHSC0041442_171, see Question 79].

80.2. Ministers had been updated on events by Ms Corrigan on 7 October, following the media briefing of 6 October.

80.3. On 10 October 1997, Ms Corrigan sent a further submission to the Secretary of State for Health, Frank Dobson MP, and the Minister of State for Health in the House of Lords ('MS (L)'), Baroness Margaret Jay. It was copied to the CMO's Private Office [DHSC0041442_132]. The submission noted that officials recommended the withdrawal of nvCJD implicated blood products, after consultation with the Committee for Proprietary Medicinal Products ('CPMP'). The submission outlined the framework within which decisions in respect of blood and blood products operated:

> *'3. Blood products that are licensed as medicines are subject to EU competence. The current recommendation of the Committee of Proprietary Medicinal Products (CPMP) is that there is no scientific justification for the withdrawal of implicated blood products. That recommendation, which was reviewed and reconfirmed in March 1997, was however based on the scientific evidence relating to classic CJD.'*

80.4. The author considered, in detail, the actions that might be taken with respect to implicated blood products: i.e., blood and blood products taken from a donor who was subsequently found to be suffering from CJD. The action in respect of blood (red blood cells and platelets) was straightforward; they would automatically be withdrawn. The submission dealt in detail with the less straightforward issue of blood products manufactured from a plasma pool which included a donation from someone later found to be suffering from nvCJD. She recommended recall of such products:

> *"5. Despite the lack of scientific evidence of any risk of nv CJD transmission through blood components, there is equally no evidence to the contrary. As we do not know if there is a risk or not, it would perhaps seem wiser to err on the side of caution and, provided*

alternative sources of the same product are available, withdraw the product.

[…]

9. In the absence of any scientific risk assessment, and on grounds both of public health and public perception, officials would recommend withdrawal of all implicated products, provided alternative products are available."

80.5. But the author also recommended that the issue be put to the EU's Committee on Proprietary Medicinal Products (CPMP) for its views, as unilateral action was not likely to be well received.

80.6. A draft paper for the CPMP's Biotech Working Party was attached: *'Blood Products and New Variant CJD,'* prepared by the Medicines Control Agency ('MCA') [DHSC0041442_109; DHSC0041442_110]. It rehearsed the previous decisions of the CPMP, reaffirmed in March 1997, that recall of blood products was not justified on account of any risk of CJD as there was no evidence it could be transmitted by blood or blood derivatives. It noted that potential risk from blood transfusion had also been considered and discounted on 23 September 1997, by the Committee of Experts in Blood Transfusion and Immunohaematology of the Council of Europe: there was no evidence of such transmission. It rehearsed the precautionary measures nonetheless taken with respect to blood donors by regulatory authorities, including the UK, before referring to the emerging evidence relating to nvCJD. It concluded: *"In the absence of reassurance the UK believes that as a purely precautionary measure it would be prudent to recall batches of blood products from the market when a donor to a plasma pool is subsequently diagnosed with nvCJD."*

80.7. From subsequent submissions, it appears that this strategy was approved by Ministers on 13 October 1997 (see paragraph 80.8 below and the submission cited there).

80.8. It also appears that the strategy of consulting the CPMP, with the approval of Ministers, had been devised by Dr Metters: see his minute of 8 October 1997 to Dr Jeffrys and Ms Corrigan (copied to the CMO's office), setting her

submission in train [DHSC0041442_160]. He noted that the NBA and CJD Surveillance Unit were already tracing what had happened to donations from the three (possibly four) blood donors who had developed nvCJD. This raised the question of what to do with blood products with a long shelf life that might be unused. MS(L) was already aware of the problem.

80.9. On 16 October, Dr Tsang of the MCA updated Dr Jeffreys (Director of the MCA's Licensing Division) as well as others at DH as to the report made by the Biotech Working Party of CPMP to the CPMP [see DHSC0041442_075]. The BWP's report itself is at [DHSC0041442_083]. This noted that a Position Paper had been tabled by the UK on 14 October, to seek a preliminary position from the CPMP and its WP on the risk of transmission of nvCJD via plasma-derived medicinal products. It noted that the latest evidence available suggested that nvCJD was a different disease entity from classical CJD, but it was likely to be caused by the same agent as BSE. There was a lack of evidence to allow an adequate assessment of the risks of transmission of nvCJD via plasma-derived products:

> *"*[…] *given the low number of cases, the short time scale over which nvCJD has appeared, and the limited diagnostic tools available, there is a lack of epidemiological or pathological evidence to allow an adequate assessment of the risks of transmission of nvCJD via plasma-derived products.*
>
> *7. In view of this, the BWP agrees with the UK proposal and takes the view that, in the absence of reassurance, as a purely precautionary measure, it would seem prudent to withdraw batches of medicinal blood products from the market when a donor to a plasma pool is subsequently diagnosed with nvCJD."*

80.10. The majority of the BWP made this a recommendation. There was also to be a further scientific review of the evidence by a meeting of experts on 27 October.

80.11. Dr Jeffreys reported back, outlining these developments, to Dr Metters and other civil servants (but not the CMO's office) on 15 October [NHBT0005416].

He noted that the position would be considered by the CPMP the next week and suggested that Ministers should be informed at that stage. In the event, Ministers were updated by Ms Corrigan on 16 October [DHSC0041443_246] by a submission copied to the CMO's office. The submission also noted that Panorama was planning a programme on nvCJD, with the emphasis on blood infectivity.

80.12. On 23 October 1997, Ministers and the Director of the MCA, Dr Jones, were updated by Dr Jeffreys of the MCA's Licensing Division on developments [DHSC0041442_050]. There were a number of copyees, including the CMO's Private Office. Dr Jeffreys noted that the Working Party had met last week and supported the UK's recommendation that there should be a recall of batches of blood products if a blood donation to a plasma pool was subsequently found to have been made from a person who developed nvCJD. The Plenary CPMP subsequently accepted the WP recommendation. Decisions on the possible recall of products containing plasma derived excipients had been deferred, but would be considered subsequently by a meeting of experts that was likely to include UK experts: Professors Pattison, Collinge and Will.

80.13. Ministers were invited to note the action that had been taken and that the UK's recommendation had been endorsed by the CPMP.

80.14. There is a further note for MCA colleagues summarising the CPMP discussions from Dr Jefferys at [WITN3430286].

80.15. An internal note from Mr Nigel Goulding to Dr Gordon Munro dated 24 October 1997 gives further background on the impetus for the BPL recall. It was generated both as a result of information about the status of a blood donor who gave blood in 1994, and information on the CPMP decision from Dr Jeffrys [DHSC0041261_149].

80.16. [DHSC0004290_043] is a submission dated 29 October 1997 from Ms Corrigan to the Private Offices of the Secretary of State and Minister of State (Lords). It was copied to the CMO's Private Office. It outlined the steps to be taken following the minute of 23 October. Ministers were informed of a *"product recall which will take place tomorrow as a result of the current tracing*

exercise to locate such products." A copy of the proposed BPL product notice was attached. It was said to make it clear that this was a "*precautionary measure only"* and that "*on the advice of an Ethics Committee, patients should not be informed of the reasons for the recall".* The NBA were preparing a Press Statement, as was the Department. Ms Corrigan noted that the response of the media was difficult to predict, but there might be quite a lot of interest as it was the first nvCJD-linked recall. "*Our aim, however, will be to play it down as much as possible. This is, after all, likely to be the first of a series of such recalls."*

80.17. [DHSC0004805_023] is a copy of the DH 'line to take' on the recall dated 30 October 1997. It noted that "*CPMP have made it clear that they see this as a purely precautionary measure, prompted by the fact that there is, as yet, no epidemiological data available on nvCJD."*

80.18. [GGCL0000109_011] is a fax dated 29 October 1997 from BPL to one of its 'customers' (i.e. a hospital or similar) giving information on the Product Recall. It repeated the information about the affected products and stated that this was a precautionary measure related to post donation information. *"Subsequent to donation the donor was found not to have met the current health requirements for C-JD. The advice from the Lothian Ethical committee is that the recipients (patients) should not be informed that the product that they have received has been recalled for this reason".*

80.19. [NHBT0005408_004] is the NBA's press release of the same date. It was announced that the NBA had *"*[…] *initiated a recall of plasma products (Albumin and Factor VIII) from 26 distribution sites in England'.* [JPAC0000167_065], dated 30 October 1997, is a copy of the NBA's Q&As with regards to the recall of plasma products.

80.20. [NHBT0005408_006] is a letter from 30 October 1997 from Dr Mike McGovern of the NHS Executive to Dr Robinson of the NBA, outlining the communication procedures between the NBS, BPL and CJD Surveillance Unit if suspected or confirmed cases of nvCJD were identified as blood donors. This was a response to [NHBT0009049], a letter from Dr Robinson to Dr

Metters dated 29 October 1997, asking for information on how the nvCJD lookback work would be carried out.

80.21. Information on a further recall in November is to be found at [WITN3430074], from MCA. The CMO's office was included in the long list of copyees.

80.22. In a submission from DH officials to SoS and MS (L) dated 31 October 1997 [DHSC0041442_006], copied to the CMO's Private Office, the recommendation of the Spongiform Encephalopathy Advisory Committee's ('SEAC'), that the National Blood Service ('NBS') should plan for leucodepletion (the removal of leucocytes i.e. white blood cells from donated blood) to be implemented, was presented to Ministers. SEAC's recommendation arose from a SEAC meeting on 24 October 1997, in which it considered the CPMP's recommendation to recall nvCJD implicated products and what further action may be necessary.

80.23. A further submission from DH officials to SoS and MS (L) dated 3 November 1997 was also copied to the CMO's Private Office [DHSC0006535_149]. DH officials suggested that Ministers adopt SEAC's recommendation and attached a draft press release announcing the implementation of SEAC's advice as well as the recall of nvCJD implicated blood and blood products as a precautionary measure [DHSC0006535_149; WITN3430287].

Q.81 SEAC Recommendations of 24 October 1997

81.1. On 24 October 1997, a Spongiform Encephalopathy Advisory Committee ('SEAC') meeting took place [DHSC0041442_053; DHSC0041442_054]. SEAC discussed the CPMP recommendation to recall nvCJD implicated products as well as any other measures that could be taken to mitigate potential transmission of nvCJD by blood and blood products. In a submission to Ministers dated 27 October 1997, the main items concluded at the SEAC meeting were listed, including that the Committee:-

> *'Recommended that a strategy to reduce risk from blood products for transplantation be put in place. This would involve;*
> - *setting up systems for leucodepletion (removal of white cells) of blood for transplantation;*

- *risk analysis to assess whether UK blood should cease to be used for transplantation purposes;*

[…]

On the grounds that it would be imprudent to wait, that there was no species barrier involved in human blood transfusion (one of the key risk reduction factors) and that the levels of pre-clinical infected cases was unknown, the Committee recommended that white cells should be removed (a process known as leucodepletion) from blood and blood products before use. The National Blood Service has already drawn up a paper assessing such a strategy. The Committee noted that there would be a lead in time of at least a year for the blood transfusion service to gear up because this was a complicated procedure.

5. The Committee also recommended that a risk assessment should be carried out using a range of assumed levels of pre-clinical cases. This could then be used to assess whether leucodepletion would have a significant effect on the one hand or that UK blood should cease to be used altogether at the other extreme' [DHSC0041442_049].

81.2. In a submission from DH officials dated 31 October 1997 [DHSC0041442_002] the conclusions of the SEAC meeting on 24 October 1997 were further relayed to SoS as follows:

'The meeting concluded that it could not be assumed that the pathogenesis of nvCJD was the same as the classic form of the disease. In particular emerging scientific information seemed to suggest more involvement of lymphoreticular tissue possible involving circulating lymphocytes. They therefore recommended that as a precautionary policy the Government should consider extending the use of leucodepleted blood and blood products as far as practical.'

81.3. In a further submission from DH officials to SoS and MS (L) dated 31 October 1997 [DHSC0041442_006] an update was provided *'[…] on developments since the CPMP recommendation on the precautionary withdrawal and quarantine of unused blood products derived from donors who have subsequently developed nvCJD'* as follows:

> *'SEAC*
>
> *2. The CPMP recommendation was put to SEAC, who were asked to consider whether, in light of the latest developments in scientific evidence on transmission of nvCJD, the action currently being taken in respect of blood and blood products to try and prevent transmission was sufficient*
>
> […]
>
> *3. SEAC discussed the issue on 24 October. They decided that the most recent studies suggested that white cells might be the carrying agent, in which case leucodepletion would be a potential precautionary measure. However, given the assessment of the very low risk of transmission and the magnitude of the task involved in introducing leucodepletion (both in practical and cost terms), it was essential that a proper risk assessment was carried out before any firm recommendation was given. Such an assessment would probably take two to three months.*
>
> *4. SEAC were, however, also aware of the fact that the National Blood Service would require an extensive lead-in period of up to a year to gear themselves up for 100% leucodepletion. They were concerned that, should the risk assessment lead them to recommend such action, then several months preparation time would have been lost. They therefore also recommended that, while the risk assessment was carried out, planning for leucodepletion should go ahead in anticipation.'*

81.4. On 3 November 1997, another submission was sent from DH officials to SoS and MS (L) outlining SEAC's advice to Ministers as well as the views of the

Advisory Committee on the Microbiological Safety of Blood and Tissues ('MSBT') as follows [DHSC0006535_149]:

> *'7. On Monday 27 October MSBT considered the practical implications of SEAC's advice. Leucodepletion of all donated blood would be a major and resource-intensive step. MSBT agreed that a risk assessment should be carried out.*
>
> […]
>
> *8. As it would take the Blood Service several months to plan the introduction of leucodepletion, MSBT endorsed SEAC's recommendation to prevent any delays at a later stage, planning for the introduction of leucodepletion should not be further delayed. It would be particularly important to ensure that the current, basically secure, system for screening all donated blood should not be put at risk and therefore the feasibility and practicality of leucodepletion need to be carefully planned.'*

81.5. The 3 November 1997 submission attached a draft press release announcing: (i) Ministers' acceptance of SEAC's advice to conduct a risk assessment of the potential human to human transmission of nvCJD through blood and blood products whilst also instructing the NBA to commence work on the possible extension of leucodepletion of blood; and (ii) the recall of nvCJD implicated blood and blood products as a precautionary measure [WITN3430287].

81.6. The final press release was issued on 6 November 1997 [WITN3430288].

Q.82 Changes to the Lookback Exercise, October 1997

82.1. Question 82 referred to the fact that in October 1997, the protocol for the Edinburgh CJDU Lookback exercise changed, to require the Unit to inform the Blood Services without delay of any suspected or confirmed case of nvCJD who had been a blood donor, particularly when the donation was recent. This was a change needed in the light of the CPMP recommendation that a recall should be undertaken if a blood donation to a plasma pool was subsequently found to have been made from a person who developed nvCJD (Question 80

refers) and the SEAC meeting of 24 October 1997 and the subsequent MSBT meeting. Recalls affected both blood and blood products; see [NHBT0009049]. There were letters from Dr Metters to the Blood Service as a result (see [NHBT0005408_006]) and to Dr Will at the CJDU [NHBT0009036], this also confirmed that the 'lookback' in respect of CJD cases would continue as planned.

Q.83 Further Recall of Blood Products, January 1998

83.1. See Personal Statement.

Q.84 Precautionary Measures, February and April 1998

84.1. To provide further detail regarding the issue of review of risks from non-UK plasma, associated with the decision to ban the use of UK-plasma in February 1998, the following documents have been identified as being of relevance:-

(1) There is evidence of clinical concerns about this decision. See for example the letter from Professor Tedder of 7 May 1998 to the National Blood Service (Dr Flanagan); it was copied to Professor Pattison and passed to DH officials [DHSC0004467_111]. Professor Tedder was concerned about the *"apparent lack of balance*" regarding the potential hazard of nvCJD transmission through blood products in the UK. He worried that *"by removing ourselves from using UK plasma for UK patients we are turning our back on all the documented benefits to safety of being self-sufficient in plasma*." He asked that this issue be discussed at that month's SACTTI meeting.

(2) There is a general account of the precautions that would have to be adopted by BPL at [MHRA0034749_013], a CSM press release of 13 May 1998. See also the briefing from Ms Christine Corrigan and attached Q & A of the same date [WITN3430289].

(3) It is apparent that BPL staff gave the matter detailed consideration. An oral account of the precautions being taken was given to the MSBT on 4 June 1998 by Dr Snape [see WITN3430290; WITN3430291] contains a detailed technical justification for the MCA from Dr Snape / BPL for some changes to

be made. The MCA/MHRA would presumably hold further records if needed, and/or be in a position to explain details of product licences issued or varied.

(4) [DHSC0042287_069] is a minute from Ms Skinner dated 26 June 1998 to the SoS, concerning the first shipments of US blood plasma to BPL; these could not be used as they did not have MCA approval, but would be used for test purposes. The minute suggests that precautions or their implementation were kept under Ministerial review, at least at that date.

Q.85 Det Norske Veritas draft report, April 1998

85.1. See Personal Statement

Q.86 SEAC Recommendations and Leucodepletion

86.1. See Personal Statement

Q.87 Press Statement of 17 July 1998 - Leucodepletion

87.1. There are a number of documents dated 16 and 17 July 1998 which refer to the need to react quickly to emerging events or news stories. It appears that a press release that had been provisionally scheduled for 21 July: see [WITN3430292], an email dated 14 July. This refers to the efforts to find a date for a "low-key" announcement and mentions having 21 July in mind.

87.2. However, documents from 16 and 17 July suggest that these plans were overtaken by events and the announcement had to be made early on 17 July as a result.

87.3. See Ms Corrigan's briefing notes to Mr Knight (DH Press and Publicity Division, or PPD) dated 16 July [at DHSC0038513_043 and WITN3430293]. They give context about an anticipated speech from a Dr Dealler at a conference being held in York, and about anticipated press stories.[31] There is

[31] [WITN3430295] is the briefing which follows on, in the file, from Ms Corrigan's note of 16 July at [WITN3430293], but the last page of the briefing note is a reference to events and the press release issued on 17 July, so this second document may date from 17 July.

also [WITN3430294] which is a short account of, or reaction to, the presentation by Dr Dealler.

87.4. On 17 July, Ms Corrigan prepared a detailed Q&A to accompany the leucodepletion announcement that she referred to as being "hastily prepared." [DHSC0041249_078]. It was again sent to Mr Knight, as well as numerous copyees.

87.5. There is a one page fax at [WITN3430296] from Dr Metters' Office (at 9:48) which refers to "this" (presumably the press release) having been approved by the SoS.

87.6. An exchange of minutes on the day, relating to the erroneous omission of the Public Summary of SEAC's advice to government from the release [see WITN3430297], refers to *"the speed with which we had to react to events today"* [DHSC0038638_030]. The author, Mr Knight, replied to the complaint: *"I thought we managed particularly well under immense pressure and the story is now slipping down the news agenda… From a tip-off point of view, it was regrettable that there was no DoH representation at the York conference where this story appears to [have] sprung from, thanks to Dr Dealler."*

87.7. There is a personal letter of thanks from Mr Dobson (the Secretary of State) to Dr Metters dated 17 July 1998 at [DHSC0020862_011], copied to the CMO. Again, this refers to swift reactions in responding to events. The Secretary of State wrote *"You will know better than I that it is crucial to all we do that people are not alarmed unnecessarily about the safety of the blood supply or indeed the safety of giving blood."*

Section 14: Other blood borne viruses

Q.88 Testing and/or screening for rare viral infections

88.1. Sir Kenneth's statement refers to a minute of 19 November 1993, sent by Dr McGovern, in which Sir Kenneth requested a paper on which organisms were tested for and which were not. The developments following this request were as follows:

88.2. On 7 December 1993, Dr Rejman sent Dr Metters a first draft of a paper on screening for rare viral infections, in response to Sir Kenneth's request [DHSC0003529_036; WITN3430298].

88.3. Dr Metters replied to Dr Rejman with comments on the draft on 9 December 1993 [DHSC0042296_098].

88.4. The Permanent Secretary, Sir Graham Hart, provided further comments on 15 December 1993 [WITN3430299].

88.5. On 7 January 1994, Mr Canavan sent Dr Metters a revised draft of the paper [WITN3430300].

88.6. On 12 January 1994, Dr Metters replied to Mr Canavan with further comments [DHSC0042296_089].

88.7. On 18 January 1994, Dr Rejman and Mr Canavan sent a submission to ministers on the issue of screening for rare viral infections [WITN3430301; WITN3430302] (the version sent by the Inquiry at [DHSC0042296_065] appears to be an earlier draft). It was concluded that blood transfusion was inherently unsafe, and no matter how many tests were conducted, transmission of infection would occur. The tests themselves may not be infallible and there was a risk of human and machine error. The submission sought the Ministers' views on: "*whether the principle of ex-gratia compensation should be further considered. The alternative will be the introduction of progressively greater numbers of screening tests for all blood donated in the UK, even when the number of recipients at risk of harm for rare and unusual infections transmissible by blood transfusion will be very small.*"

88.8. On 26 January 1994, Sir Kenneth sent a minute to Ms Melanie Harper (Private Secretary to Thomas Sackville, the Parliamentary Under Secretary of State for Health) regarding screening blood for rare viral infections [DHSC0042296_063]. This minute is discussed further in Sir Kenneth's personal statement.

Q.88(a) Parvovirus B19

88a.1 On 12 August 1992, Professor John Cash (National and Medical Scientific Director of the SNBTS), wrote to Dr Metters (DCMO) regarding increasing interest in parvovirus contamination of fractioned plasma products, particularly because of the limited efficiency of currently used virus inactivation procedures [SBTS0000065_103]. The letter enclosed a manuscript submitted to the Journal of Clinical Microbiology titled 'Detection of Parvovirus B19 in Blood Donations: A model system for screening by Polymerase Chain Reaction' (McOmish et al) [ARCH0003416]. The manuscript concerned a highly sensitive and rapid method for routinely screening large numbers of blood donations for parvovirus. It concluded that the methods developed in this study for PCR screening could be applied routinely to prevent transmission of parvovirus in blood and blood products. It also recommended that PCR screening could be used for detection and exclusion of a range of other transmission-associated viruses.

88a.2 On 10 September 1992, Dr Rejman sent a minute to Dr Metters regarding the manuscript [WITN3430303]. Dr Rejman indicated that following discussions with Mr Canavan they felt that the manuscript should be circulated to members of the ACVSB. Dr Rejman acknowledged that: *"several complex issues are raised and at the present moment we are not aware of any specific pressure from the UK for the introduction of testing."* He noted that testing for parvovirus was not part of the EC or Council of Europe requirements, nor was it mentioned as an option. Furthermore, he stated that: "*the concept of testing pools as opposed to testing individual*

donations is against the principles of current EC and Council of Europe guidelines. Any such change would need consultation with European colleagues." Dr Rejman also highlighted that the authors of the manuscript had not explored in detail the issue of costs, or the time involved in doing the tests.

88a.3 The manuscript was circulated to members of the ACVSB and was discussed at the meeting on 29 September 1992 [WITN3430304]. The minutes recorded that there was no agreement amongst the members as to the degree of risk parvovirus posed in fractionised products. It was stated that effective testing could only be done on single donations and not on pools. Viral inactivation of parvovirus was raised as an alternative to testing. The ACVSB secretariat undertook to investigate screening possibilities in consultation with Professor Tedder (Head of Division of Virology, University College and Middlesex School of Medicine) and to prepare a paper for the next meeting.

88a.4 At the next meeting of the ACVSB, on 9 February 1993, Professor Tedder tabled a paper on parvovirus and blood transfusion [WITN3430305]. The committee agreed to postpone discussion of the paper until a later meeting. Also, additional material on screening blood donations for parvovirus was to be provided by the Secretariat.

88a.5 In mid-1993, the ACVSB was replaced by the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT). On 4 October 1993, the MSBT held its first meeting. It was decided that the MSBT would return to the subject of parvovirus at a forthcoming meeting.

88a.6 On 18 November 1994, Dr Lee of the Royal Free Hospital wrote to Sir Kenneth [BART0000634_003]. Her letter is discussed further in Sir Kenneth's personal statement.

88a.7 At the meeting of the MSBT, on 8 January 1996, the minutes recorded that the members discussed that the MSBT needed to: *"take a look at where it was going on screening generally*." The committee agreed to Dr Rejman's proposal that parvovirus should be on the agenda for the next meeting [WITN3430306].

88a.8 At the next MSBT meeting, held on 2 May 1996, parvovirus was an item on the agenda [SBTS0000518]. The record indicated that members were not aware of any country then screening blood donors routinely for parvovirus. It was agreed that a combination of selective screening and gamma irradiation – which inactivates parvovirus – would be the best way of protecting vulnerable people. It was agreed that as an action point, Dr Robinson (Medical Officer, National Blood Authority) would investigate the logistics of selectively testing for, and inactivating, parvovirus.

88a.9 On 18 November 1996, Dr Robinson presented her paper on parvovirus at a meeting of the MSBT, as agreed at the last meeting of 2 July 1996 [SBTS0000518]. Dr Robinson spoke briefly about her paper, indicating that parvovirus was a difficult seasonal virus and that improved technology was needed for pool testing. It was agreed that "*no steps needed to be added to the paper*" presented by Dr Robinson. No further documents relating to Dr Robinson's paper have been identified during the period that Sir Kenneth served as CMO.

Q88(b): Cytomegalovirus

88b.1 At the meeting of the UK Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI), held on 1 July 1996, the issue of cytomegalovirus (CMV) antibody testing was on the agenda [JPAC0000109_025]. The committee discussed whether CMV assays detecting immunoglobulin G (IgG) only, which offered some operational advantages, would miss significant numbers of potentially infectious donors. It was agreed that the views of experts in this area should be sought before a policy decision was made.

88b.2 On 9 August 1996, Dr John Barbara (Head of Microbiology, National Blood Service and a member of SACTTI) wrote to nominated experts regarding CMV antibody testing [JPAC0000109_026]. He indicated that SACTTI had been "*asked to make a recommendation on whether blood donor screening assays for detection of anti-CMV should be able to detect IgM as well as*

IgG classes of CMV antibody". Dr Barbara requested expert views on whether tests should be able to detect both classes of antibody or just IgG.

88b.3 On 13 August 1996, Dr Tim Wreghitt (Public Health Laboratory Service, East) responded to Dr Barbara's request for expert views on whether screening assays for detecting CMV antibodies should detect CMV IgM as well as CMV IgG antibodies [JPAC0000109_027]. Dr Wreghitt identified two issues which he believed would affect this decision:

> *"1. What is the lag time between the development of CMV IgM and IgG antibodies. In our limited experience, this time is short and the matter of a few days at the most.*
>
> *2. How accurate are CMV IgM assays? I think there is a problem here. Using the manufacturers' cut off values, false positive values at the lower end of the reactivity are fairly common. Higher level results are almost always confirmable (as I'm sure you know)."*

88b.4 Dr Wreghitt stated that on balance he was not in favour of including IgM in the screening. He felt it would "*offer very little advantage and produce non-specificity problems*".

88b.5 On 16 August 1996, Professor P Morgan-Capner (Public Health Laboratory Service, North West) responded to Dr Barbara's request for expert views [JPAC0000109_028]. He stated that he had no personal experience or expertise on CMV antibody testing. However, he provided the following view:

> *"To attempt to capture the maximum number of people actively or latently infected with CMV would require a test detecting both CMV IgG and IgM as in the first few days at onset of acute infection serological response may be IgM only....*
>
> *Hence is this increased detectability worth the extra resources if one presumes an M/G test will be more expensive than a G test alone."*

88b.6 On 4 September 1996, Dr JC Booth (St George's Hospital Medical School, Reader in Virology) responded to Dr Barbara's request for expert views [JPAC0000109_029]. Dr Booth stated:

> *"I know of no good information on the length of time after primary infection during which a patient is likely to test CMV IgM-positive while remaining CMV IgG-negative.*
>
> *It is obviously very desirable to minimise the risk of transmission of CMV infection in CMV IgG-negative blood that is destined for giving to immunosuppressed patients, including premature babies. I can recall, many years ago, a premature baby who died as a result of transfusion-acquired CMV infection. Testing for CMV IgM would only be effective in eliminating part of this problem and a major uncertainty would be the reliability and sensitivity of the tests which were used for detecting the CMV IgM."*

88b.7 At the meeting of the SACTTI, held on 4 November 1996, the issue of CMV antibody testing was on the agenda [JPAC0000109_025]. The minutes recorded:

> *"The theoretical benefit of an IgM component to the assay was recognised, but in the absence of suitable systems for sensitivity determination it was recognised that confirmation of this theoretical role could not be easily demonstrated... It was however recognised that combined IgM/IgG assays were available and that the track record of safety of CMV antibody negative components was largely based on the use of such assays."*

88b.8 An agreed action point was that Dr John Barbara would review use of CMV tests within the National Blood Service.

Q88(c): Anti-HBc

88c.1 The ACVSB met on 25 February 1991 and discussed testing blood donors for anti-HBc [NHBT0000042_058]. Dr Rejman raised doubts about the value of anti-HBc testing and "*asked the Committee to consider whether all healthy blood donors with a history of jaundice more than 12 months prior to the proposed donation should be tested for anti-HBc.*" In addition, the Committee was asked to consider whether there was a case for screening all donations for anti-HBc to avoid transmission of hepatitis B.

88c.2 At the next meeting of the ACVSB, on 21 May 1991, Professor Zuckerman (Director of the WHO Centre and Dean of the Royal Free Hospital School of Medicine) stated the quality of anti HBc tests would have to be improved markedly before it would be worthwhile introducing routine screening for any group [NHBT0000042_080]. Professor Tedder (Head of Division of Virology, University College and Middlesex School of Medicine) agreed with Professor Zuckerman. Professor Tedder was of the view that donors with a history of jaundice were the wrong group to consider for screening. The committee agreed that there was no case for routine anti-HBc testing of blood donors with a history of jaundice.

88c.3 On 9 February 1993, the ACVSB met and agreed that there was a need for a national policy on screening arrangements for anti-HBc [NHBT0000079_087]. This followed the proposal by the Northern Regional Transfusion Centre to introduce anti-HBc testing from 1 April 1993. The issue of anti-HBc screening was discussed by the ACVSB in the context of detecting hepatitis B transmission.

88c.4 On 10 May 1993, Mr Canavan wrote to Dr Metters regarding routine screening of blood for anti-HBc [DHSC0006815_030]. Mr Canavan confirmed that the Northern RTC, which had "*threatened*" to pursue the anti-HBc screening, would no longer do so and would adhere to the national screening policy.

88c.5 On 10 June 1993, Dr Metters wrote to Dr Harold Gunson concerning the results of an anti-HBc trial [JPAC0000036_106]. This was anti-HBc pilot screening trials conducted in four RTCs, namely Liverpool, Glasgow,

Cambridge and North London. Dr Metters hoped that the UK Advisory Committee on Transfusion Transmitted Diseases (ACTTD) would defer any recommendation on the introduction of routine screening until more information was available. Dr Metters indicated that there was no information about the costs of nationwide donor screening or the indirect costs associated with routine anti-HBc screening in the paper which accompanied the results of the anti-HBc trial. Dr Metters stated that Dr Rejman would write to Dr Gunson on how the MSBT could be provided with the missing information.

88c.6 On 28 June 1993, Dr Gunson wrote to Dr Metters in reply [WITN3430307]. Dr Gunson stated that the ACTTD would not make a recommendation for the introduction of routine screening for anti-HBc. Dr Gunson stated that there were various issues which remained unresolved. Specifically, he referred to the issue of cost and stated as follows:

> *"I can tell you that these test kits cost between 60-70p each plus VAT but there is then the problem of confirmatory testing and whether we should introduce a level of anti-HBs in the blood to indicate that the donation is safe. This is a departure from the normal screening and will require considerable changes in computer programmes at RTCs."*

88c.7 On 7 July 1993, Dr A M George (Welsh DCMO) wrote to Dr Metters concerning the introduction of anti-HBc for blood donor screening [WITN3430307]. He indicated that he had received a query from the Medical Director of the NBTS (Wales) with regard to funding for anti-HBc tests. Dr George referred to the meeting of the ACVSB on 9 February 1993 in which it was reported that a pilot study in the Mersey region would have ended on 31 March 1993 and that the results would have been evaluated before a decision was made on a UK policy. Dr George recommended that if a policy has been decided then the screening test should be synchronised throughout the UK.

88c.8 On 27 July 1993, Dr Metters wrote to Dr George in reply [WITN3430308]. Dr Metters confirmed that there had been no decision to introduce testing

and that the results of the NBTS pilot trial would be referred to the MSBT. Dr Metters concluded by stating, "*In keeping with the normal practice, advice from the Committee will be given to all Health Ministers so that the policy on whether or not to test for anti-HBc can be decided for the UK as whole*."

88c.9 On 26 July 1993, Professor Tedder wrote to Dr Metters concerning amongst other things anti-HBc screening [DHSC0002543_074]. Professor Tedder stated:

> *"As you will know there is no doubt that anti-HBc screening would significantly reduce the burden of post transfusion hepatitis B in the UK. It may only amount to some 100 or so infections a year that are clinically apparent, but these and all secondary infections which result from them very likely would be stopped by the introduction and anti-HCV screening... You will be aware already of litigation in the offing against transfusion centres who have transmitted hepatitis B to recipients from anti-HBc-only carriers. We need to have a number of questions answered, since a request has come from the Department of Health to move slowly on this screening I would be grateful to know what steps the Department is going to undertake to underwrite the protection of transfusion centres who would have been willing to introduce anti-HBc screening, who will now find themselves subject to litigation from injured patients."*

88c.10 On 26 August 1993, Dr Metters responded to Professor Tedder's letter of 26 July 1993, which concerned the introduction of anti-HBc screening [WITN3430309]. Dr Metters stated as follows:

> "*As you will recall from your time on the ACVSB the fact that a test is available is not in itself sufficient reason for introducing it for all donated blood. An advisory committee needs to ensure that all relevant factors have been taken into account in formulating its advice to Ministers... There would be little point in putting the report to the MSBT while such important questions remained unanswered. I understand that you*

would have some concerns about the performance of some commercial anti- HBs assays were anti- HBc testing to be introduced."

88c.11 On 7 September 1993, Professor Tedder replied to Dr Metters [WITN3430310]. He stated:

"*Like so many other things somebody is going to have to make a decision as to whether to spend the money on the cost of putting in place a screening programme, which I think could be done scientifically and clinically without too much of a problem, or paying the cost of the litigation which will naturally arise in view of the high profile which hepatitis B has at the moment*."

Professor Tedder concluded by stating that he would have "*little sympathy*" with Dr Metters if he did "*not introduce anti-HBc screening in the near future*".

88c.12 On 4 October 1993, the MSBT met and discussed the routine screening of blood for anti-HBc [WITN3430311]. The issue before the MSBT was whether it was worthwhile to supplement HBsAg testing, which did not detect all hepatitis B transmission, with testing for anti-HBc. The unanimous view of the committee was that Ministers were to be advised that the introduction of routine screening for anti-HBc in blood donations and organs or tissues for transplantation was inappropriate.

88c.13 On 14 October 1993, Dr McGovern (Private Secretary to Sir Kenneth) wrote a minute to Dr P Bourdillon (DH, HC(M) about informing ministers about testing for anti-HBc [DHSC0004020_030]. On 15 October 1993, Dr Bourdillon sent a minute to Dr Rejman requesting that Dr Rejman should "*start the ball rolling for a submission to ministers*" following Dr McGovern's minute [WITN3430312].

88c.14 On 22 October 1993, Dr Metters sent a minute to Dr Rejman and Mr Canavan concerning the MSBT's recommendation against anti-HBc screening [WITN3430313]. Dr Metters stated that they needed to follow up

on the MSBT's question of principle regarding cost-effectiveness of introducing screening tests for very rare infections. The question was posed by Dr Metters as follows:

> "*The key question is, should an effective screening test for a very rare transmissible infection be introduced, because it is available and effective when the cost of general introduction throughout the service would cost £x million per annum. For such rare infections transmissible through blood transfusion, would it not be more cost-effective to provide ex-gratia compensation for any blood recipient whose infection was demonstrably the result of transfusion?"*

Dr Metters clarified that this argument had no influence on the MSBT's recommendation on anti-HBc screening, however the question would inevitably recur. Therefore, it was timely for the issue to be put to Ministers.

88c.15 On 9 November 1993, Mr Canavan sent a minute to the Private Secretary to the Parliamentary Under Secretary of State for Health (at that time, Tom Sackville) Ms Harper, concerning potential controversy following the MSBT's advice against the introduction of routine screening for anti-HBc [DHSC0004709_142]. Mr Canavan indicated that there had been some surprise among the RTCs committee about the unanimous position of the MSBT concerning anti-HBc screening. However, only one RTC Director had restated support for routine screening. Also, the manufacturers of test kits had been surprised in view of the signals they had received from RTCs.

88c.16 On 4 November 1993, a submission was drafted seeking the Parliamentary Under Secretary's approval of the advice of the MSBT that *"at the present time it is inappropriate to introduce routine testing of blood donations and tissues/organs for hepatitis B core antibody (anti-HBc)"* [DHSC0004709_147]. In explaining the factors which the MSBT had considered to be important, the following was outlined as major considerations:

> *"major deficiencies in the tests (a high number of false positives, and lack of reliable confirmatory tests);*

uncertainty over the benefits of the tests, set against the considerable costs, estimated at £3m annually, which could be put to better use. The introduction of testing might prevent a very small number of transfusion transmitted infections (probably nearer 10 than 100) but even in that small number half would have no clinical symptoms and the majority of the remainder would have no permanent effects. The Committee considered that the cost/benefit argument was strongly against routine testing."

88c.17 The Parliamentary Under Secretary was asked to approve the advice of the MSBT that the present position should be maintained and routine testing of blood (and tissue/organs) for anti-HBc should not be introduced.

88c.18 On 11 January 1994, Mr R Burrage (Department of Health) sent a minute to Dr Metters indicating that Mr Sackville had requested a meeting with officials and the National Blood Authority on anti-HBc testing [DHSC0004709_112]. Furthermore, Mr Burrage stated that there had been no feedback from the Minister on the submission of 4 November 1993 "*other than to question the presentational impact of any decision not to test*".

88c.19 On 4 February 1994, the Parliamentary Under Secretary's Private Secretary sent a note to Dr Metters, Dr Rejman and Mr Canavan which recorded the points agreed by the Parliamentary Under Secretary of State for Health at a meeting the previous week to discuss the submissions of 18 January 1993 and 4 November 1993 [DHSC0042296_061]. It recorded as follows:

"PS (H) approved the advice of the MSBT that the present position should be maintained on Anti-HBc and that routine testing of blood (and tissue/organs) should not yet be introduced. However, the situation should be kept under regular review by the Advisory Committee.

PS (H) did not approve the principle of ex-gratia payments as set out in the 18 January submission. He understood that this line could be

defended on the grounds that the tests in question were not yet scientifically robust enough to be introduced. However, as with the issue of Anti-HBc, the position would be reviewed by Ministers if the tests were developed to such a point that routine testing by NBTS was viable."

88c.20 Therefore, it was concluded that no further work was needed on the issue of anti-HBc screening within the Department of Health.

Q88 (d): Hepatitis G

88d.1 Minutes of the MSBT meeting on 8 January 1996 recorded discussion of new hepatitis viruses, which included hepatitis G [WITN3430314]. Dr Mortimer (Public Health Laboratory Service) indicated that there would be a paper appearing in the American publication 'Science' discussing hepatitis G. He said that hepatitis G and hepatitis GB-C appeared to be the same agent.

88d.2 On 25 January 1996, Dr Nicholas wrote to Dr Harvey (Private Secretary to Sir Kenneth), regarding a report which was likely to appear in 'Science' which detailed the recent discovery of hepatitis G [DHSC0004469_048]. Dr Nicholas noted there was no routine test available for HGV. This document is discussed further in Sir Kenneth's personal statement.

88d.3 On 2 May 1996, the MSBT held a meeting at which Hepatitis G was discussed [DHSC0041177_077]. The minutes recorded that Dr Metters *"summarised the discussion as indicating the Committee's need for a structured set of questions about the epidemiology, transmission and natural history of Hepatitis G, and a strategy to answer those questions. In order to take this forward it was agreed that Dr Rejman should get a subgroup together to look at what research needs to be done in the light of the discussion."*

88d.4 On 13 May 1996, an Advisory Group on Hepatitis meeting took place. The minutes recorded, under the heading 'new Hepatitis Viruses', that: "*knowledge of Hepatitis G is at an early stage to assess what morbidity may be associated with infection.... There is currently no antibody test"*

[DHSC0046989_100]. The group also considered inactivation of hepatitis G virus.

88d.5 On 14 October 1996, Dr Rejman sent a minute to Dr Metters concerning the hepatitis G paper for the MSBT meeting on 18th November 1996 [DHSC0004751_147]. Dr Rejman referred to the work of the Hepatitis G Research Group, a sub-group which he was asked to convene, to consider research into hepatitis G. The overall view at the meeting of this sub-group in July 1996 to consider research into hepatitis G was that: *"because of patent restrictions, all the research that is being carried out into hepatitis G is very much under the control of the commercial companies. The most that individuals can do is to co-operate with that research, but there appears to be no way in which the Department could significantly influence such research".*

88d.6 Furthermore, Dr Rejman explained that as a consequence of the position on research, the meeting of the sub-group in July 1996 moved into general discussion on matters outside the strict remit of the group, such as hepatitis G screening. Dr Rejman stated that he hoped the MSBT meeting on 18 November 1996 would reach the following conclusion:

> *"at the present time it is not feasible to routinely test blood donations for hepatitis G and that much work is needed to determine its clinical significance, although it is likely that in most individuals it is mild. For patent reasons, much of the research is under the control of the patent holders and clinicians are co-operating with the commercial companies in research efforts."*

88d.7 On 21 October 1996, Dr Rejman sent a further minute to Dr Metters concerning the hepatitis G paper for the MSBT meeting on 18 November 1996 [DHSC0004751_131]. He requested that Mr W Connell (Department of Health) should outline the exact position of the Department in respect of patented innovations to which the Department had contributed nothing. This was in relation to the research being carried out into hepatitis G by

commercial companies. Dr Rejman referred to the subgroup he was asked to convene to look at research into hepatitis G. He reiterated his position from the minute of 14 October 1996.

88d.8 On 24 October 1996, Dr John Toy (Department of Health) wrote to Dr Metters concerning Dr Rejman's minute of 21 October 1996 [DHSC0004751_127]. He acknowledged that all the control in relation to research into hepatitis G was under the control of the commercial companies. However, he believed the Department should not "*fail through want of trying*". He recommended attempting to come to acceptable arrangements with the relevant companies. He stated that areas which still required research in this area included: "*what are the full clinical consequences resulting from hepatitis G virus infection, either alone or in combination with similar viruses*." He acknowledged the lack of a RDD research budget for new research projects.

88d.9 On 24 October 1996, Dr Metters responded to Dr Rejman's minute of 21 October 1996 [DHSC0004751_128]. He stated that, "*I recognise MSBT has limited options when the only people that have tests for Hepatitis G are commercial companies. However, this is only one factor the Committee has to consider in advising Ministers on what action, if any, the Health Departments and the UK Transfusions Services should take*."

88d.10 On 18 November 1996, the MSBT held a meeting at which hepatitis G was on the agenda [WITN3430315]. Specifically, the issue of further research into hepatitis G was discussed. The minutes do not record any discussion on routine testing or screening for hepatitis G.

Section 15: Financial assistance trusts and schemes

Q.89 Financial assistance to those infected with HIV through transfusion or donated organs

89.1. On 29 November 1991, Mr Strachan Heppell minuted the Private Secretary to the Secretary of State (who was then Mr William Waldegrave) [WITN3430316]. The minute was copied to Sir Kenneth's Private Secretary, Dr Nicholas, the Permanent Secretary and Dr Abrams and Dr Metters (DCMOs). The minute followed a discussion between Mr Heppell and the Private Secretary to the Secretary of State and attached a draft letter to the Chief Secretary of the Treasury (to be sent from the Secretary of State) setting out two proposed options for the provision of financial support to those non-haemophiliac patients infected with HIV in the course of treatment with blood transfusions or donated organs. The minute also reflected on the fact that two additional groups (those infected with Hepatitis and those treated with Human Growth Hormone) were believed to be preparing legal action against the Department and that from a policy perspective, extending eligibility would leave a less secure ringfence on claims for no-fault compensation.

89.2. On 2 December 1991, the Permanent Secretary, Sir Christopher France, replied to Mr Heppell's minute of 29 November 1991 [DHSC0002931_005]. The reply was copied to Sir Kenneth's Private Office. The Permanent Secretary noted that he shared Mr Heppell's misgivings from a policy perspective. He went on:

> *"… 2 It is never very comfortable to resist claims for compensation from those who have encountered major problems through no fault of their own or anyone else. But unless Government is prepared to draw a line and stick to it, it will end up with a de facto (very expensive) no-fault compensation system.*
>
> *3 The ringfence around the haemophiliacs is bound to be attacked, but we are unlikely ever to find a better one if we abandon it. The haemophiliacs were doubly disadvantaged by their existing, hereditary disease which already affected their position on employment, insurance and the like. They can be separated from other victims of*

> *medical accidents, but the next defensible boundary is not easy to see. I advise long reflection before we move further into no-fault compensation for medical accidents. Is this really the most pressing marginal case for the deployment of money from the health programme?"*

89.3. On 5 December 1991, the Private Secretary to the Secretary of State, minuted the Private Secretaries of the Minister of State for Health (Ms Virginia Bottomley); the Parliamentary Under Secretary of State for Health (Mr Stephen Dorrell); and the Parliamentary Under Secretary of State in the Lords (Baroness Hooper) [WITN3430317]. The minute was copied to Sir Kenneth's Private Office. Mr Waldegrave sought the views of the three ministers on the minute from the Permanent Secretary.

89.4. On 14 February 1992, Mr Scofield wrote to the Private Secretaries of Mr Waldegrave and Ms Bottomley [WITN3430318]. He attached a draft Written Reply to a Parliamentary Question from Sir Michael McNair Wilson MP, which confirmed that financial support would be extended to non-haemophiliacs. Also attached was a note to editors and a Q&A. This was copied to a list that included Sir Kenneth's Private Office.

89.5. On 20 February 1992, Mr Scofield wrote again to the Private Secretary to Mr Waldegrave [NHBT0015117_001]. There was again, a long list of copy recipients that included Sir Kenneth's Private Office. This Ministerial Submission sought Mr Waldegrave's agreement to the outline of the scheme for assessment and payment of claims against the (newly publicised) scheme for blood transfusion and tissue recipients infected with HIV. Under the heading of 'Expert Panel' he wrote:

> *"15. Mr Benet Hytner QC, who is an experienced personal injuries lawyer, has agreed to chair the expert panel. Medical colleagues are considering who might be approached to serve as medical assessors and we shall let Secretary of State know the names as soon as possible. The panel will need a formal remit and guidelines and we now propose to begin discussing these with Mr Hytner."*

Q.90 Financial assistance for those infected with HCV

90.1. The following documents have been identified (in chronological order) as they are either documents that were provided (in the main, as a copy recipient) to Sir Kenneth's Office, or where it is thought that they may give context to Sir Kenneth's response to the Inquiry's question about the extent of his involvement.

Unless stated otherwise, the documents referred to below were copied to Sir Kenneth's Private Office.

1994

90.2. In 1994 (not specifically dated), Mr John Sharpe (of HP(A)3) minuted Ms O'Brien (Private Secretary to the Minister of State for Public Health (the incumbent in the role had changed in July 1994 from Mr Brian Mawhiney to Mr Gerald Malone)) [DHSC0042268_137]. The minute was copied to a large list of recipients. The minute discussed the need to respond to a civil action brought on behalf of patients who had been treated with human growth hormone (HGH) and who had then died of Creutzfeldt Jakob Disease (CJD). The minute analysed the financial provision for those who had been infected with HIV and under the heading of "*Arguments against exploring an Out of Court settlement",* at §20, it said:

> *"20. If a payment were made, even if only to those patients who have contracted CJD, this could open the flood gates for haemophiliac patients and blood transfusions patients who have become infected with hepatitis, primarily hepatitis C rather than hepatitis B. Virtually every haemophilia patient who has ever been given blood products has become hepatitis C positive."*

The minute concluded that (§24):

> *"If a settlement were offered at this early stage, then it is very likely that haemophilia patients and blood transfusion recipients infected with hepatitis C could ask for similar treatment. The cost could be £150-200m."*

90.3. On 11 January 1994, Dr Metters as DCMO and Chair of the MSBT (Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation) and Dr Angela Robinson (Medical Director of the National Blood Authority), held a media briefing at Richmond House, Whitehall announcing the 'Look Back' to identify patients who had been infected by Hepatitis C [NHBT0005855]. Dr Nicholas (no longer Sir Kenneth's Private Secretary) was also in attendance. It does not appear that the briefing pack was sent to the CMO's Office. Whilst the 'Look Back' is addressed in more detail elsewhere in the statement (Section 7), this document has been included here as it indicates Dr Metters' role and the position taken by Government at that time. Within the notes for supplementary questions there is a section ('G' at p.10) on the question of compensation for those affected, which stated:

"G1 WILL COMPENSATION BE PAID TO THOSE AFFECTED?

• No

• The Government does not accept that there was any question of negligence upon the part of the NHS.

G2 WILL THE GOVERNMENT INTRODUCE A NO FAULT COMPENSATION

SCHEME?

• No

• The Government are opposed to a no-fault compensation scheme.

[Note for information. The Government opposes no-fault compensation for five reasons;

i) the proof of causation is still needed, and it could be just as difficult to establish that medical treatment had caused injury - and that it was not a foreseeable and reasonable result of treatment - as it would be to prove that someone had been negligent;

ii) there would be unfairness to others, in that those disabled as a result of a medical accident would be compensated but those disabled as a result of disease would not:

iii) it is quite possible that the costs falling on the NHS could increase substantially and this would inevitably reduce the amount available for direct patient care;

iv) negligence in the health care field is not considered to be fundamentally any different from negligence in any other walk of life, where claims for compensation are resolved through the courts;

v) the present system arguably has a deterrent effect on malpractice and no fault compensation could conceivably make doctors less careful.]

G3 WILL EX GRATIA PAYMENTS BE MADE AS WAS DONE FOR THOSE INFECTED WITH HIV?

• No

• The case does not have the exceptional circumstances as did the HIV infection where those affected were all expected to die very shortly and were subjected to significant social problems including ostracism.

[Note for information. Costs of the HIV Haemophilia payment scheme have reached £81 million. (This includes £15 million paid to the Macfarlane Trusts for the special needs of HIV haemophilia patients and their families.)

Costs of the scheme of payments for those infected with HIV through blood or tissue transfer has reached £3.5 million including £0.5 million paid to the Eileen Trust for the special needs of this group.]"

90.4. On 13 November 1994, Dr Rejman and Mr Canavan minuted Dr Metters and the Private Secretary to the Parliamentary Under Secretary of State, Mr Thomas Sackville, [WITN3430319]. The minute discussed the principle of

whether ex-gratia payments should be introduced as an alternative to screening for rare viral infections and sought the Minister's view.

90.5. On 16 November 1994, Mr Burrage minuted the Private Offices of Ms Virginia Bottomley (Secretary of State for Health), Mr Gerald Malone (Minister of State for Public Health), Mr John Bowis (Parliamentary Under Secretary of State for Health), Mr Thomas Sackville (Parliamentary Under Secretary of State for Health) and Baroness Cumberlege (Minister of State for Public Health in the Lords) [WITN3430320]. The minute was copied to several recipients including Dr Metters as DCMO. The minute had a background note, statement from the Haemophilia Society and 'Lines to Take' attached to it, which confirmed the position of the day, that no compensation would be offered.

(Of the three documents referred to Sir Kenneth by the Inquiry to assist him in answering Question 90: [DHSC0003527_008] is a copy of page one of the above minute, [DHSC0002548_159] is a copy of the line to take and [DHSC0002501_103] appears to be a version of the background note at page three of the minute.)

90.6. In December 1994 there were a number of communications concerning the development of a Panorama television production examining Hepatitis C. For example [WITN3430137] and [WITN3430321]. This is discussed in greater detail in Section 7.

90.7. On 9 December 1994, Mr Scofield minuted Dr Metters, Mr Heppell and Mr Shaw [WITN3430322]. In the minute, Mr Scofield commented on the increased interest in hepatitis C (with the Panorama programme being prepared) and warned of a mounting campaign for compensation. He noted that the Permanent Secretary (by then Mr Graham Hart) had held a meeting on 25 November to consider the Department's advice to Ministers as regards compensation and under the heading of *"Handling"* he set out the following (at §§9 & 10):

> *"9 It is important to clarify who is responsible for individual aspects of Hepatitis C. I have addressed this minute to Dr Metters because of his responsibility for the MSBT; to Mr Heppell since OPU still formerly work*

to him on HIV litigation matters and to John Shaw as my line manager. As I see it:

i) The responsibility for hepatitis issues is shared amongst a number of policy divisions, including the following:

CA OPU Roger Scofield and HC(M)1 Dr Rejman for blood borne diseases and associated compensation claims and safety of the blood supply (although this may move post Banks?).

HP(A)1 Miss Mithani and HP(M) Dr Nicholas for hepatitis as an infectious disease.

ii) Other divisions having an interest in aspects of hepatitis C, include:

ASPU Mr Waterhouse for liver services

HP(A)3 Mr Sharpe for any implications Ministers decisions on hepatitis C might have on settlement of the CJD claims (and vice versa). There may be others.

iii) The Banks Report recommends that general policy on claims for harm caused by NHS treatment should be located in the NHS Executive along with issues such as complaints and consumerism. This would suggest CA QUAC. As far as I know no decision has been taken on this yet.

10 Although CA OPU and HC(M)1 have taken the lead so far, it could be argued that those responsible for hepatitis as a condition should carry the torch. I should be glad of any comments from addressees which might clarify their own specific interest and contribution into the overall response."

90.8. On 14 December 1994, Dr Metters replied to Mr Scofield [WITN3430323]. He cautioned that "*non negligent harm*" raised questions of public policy and that therefore should fall to the Public Health Group rather than the NHS Executive. Included within the same document is a minute from Mr Scofield dated two days earlier, sent to Dr Rejman, Dr Melia, Dr Nicholas and others and copied to Dr Metters (and others, but not to Sir Kenneth's office). That minute set out the first draft of a paper setting out the background to claims of

compensation from those infected with HCV. It is expressed as being the basis of a submission to Ministers and it sought the input from addressees on the draft in general and specifically identifies areas upon which comment is sought by each individual addressee.

90.9. On 22 December 1994, Mr Scofield then minuted Mr Sackville, copied to the Secretary of State, the other Health Ministers and others (pages 2 to 16 of [WITN3430324]). The minute set out recommendations for a "look-back" programme and gave extensive background.

90.10. On 23 December 1994, Mr Heppell replied to Mr Scofield [WITN3430324]. The minute was not copied to Sir Kenneth. Mr Heppell stated:

> *"…No faults liability (a better term than no fault compensation) - or "no negligence harm" as Dr Metters called it. Overall policy has rested with HSSG whilst responsibility for individual issues, eg HIV, CJD has gone to the divisions concerned. Permanent Secretary agreed at the Public Health Group Steering Committee on 22 December that, given its pan Department scope, this responsibility should remain in the WD with the new Health Promotion Division.*
>
> *Hepatitis C I - and Dr Metters - am well content that your branch should continue to take the lead for the Department in handling compensation claims etc.*
>
> *HIV Has the time come for me to drop out of HIV litigation matters? I should be happy to hand over to Mr Shaw."*

1995

90.11. On 10 January 1995, Mr Scofield minuted the Private Secretary to Mr Sackville [WITN3430325]. The minute confirmed that all three territorial Health Departments had signed up to the look back exercise. It included a 'Lines to take' document which stated (§1) [DHSC0003555_130]:

> *"We have great sympathy with those who may have been injected with Hepatitis C through NHS treatment. We do not accept there has been negligence. These patients will have received the best treatment*

available in light of medical knowledge at the time. We have no plans to compensate those who may have been infected with Hepatitis C"

90.12. On 1 February 1995, Mr Scofield minuted Mr Shaw (not copied to Sir Kenneth) [WITN3430326]. He referred to Mr Heppell's minute of 23 December 1994 (see §90.17, above) in regard to responsibility for litigation matters. The minute said:

"HEPATITIS C AND HIV LITIGATION MATTERS

In his minute of 23 December Mr Heppell asked if the time had come for him to hand over responsibility for HIV litigation matters to you. I said that in principle this seemed right but there might be vote accounting implications. Mike Brownlee has since minuted me, copy to you.

Firstly Strachan Heppell is retiring shortly and there will not be a direct replacement. The options of leaving it with Strachan or his successor are not available.

It is also generally agreed that CA OPU should look after these matters on a day to day basis. You are our main board director and we would normally see our reporting line being through you to Alan Langlands as CE of the Executive.

Recent changes have sought to regularise the organisational and Accounting Officer positions so that Vote 1 reflects the work for which the CE has responsibility and conversely he has the staff to advise him on the work for which he is held responsible.

In the case of HIV litigation (or more precisely the payment of funds to discretionary trusts for onward payment to those infected with HIV through blood or blood products) the money is currently paid out from Vote 3 for which Perm Sec has AO responsibility. Mike Brownlee says that it would be technically difficult to transfer this to Vote 1. We have no such vote entry for corresponding payments in respect of HCV. I

think there must be a possibility that some sort of payments may be made at some stage in the future.

Payments of this kind are to some extent an outcome of the running of the NHS and may be argued to be part of CE's responsibility. He certainly would be the AO for normal clinical negligence claims. But there is also a very strong political element including the impact on OGDs etc. For this reason I see no strong argument against it staying on vote 3 under Perm Sec.

Perm Sec has, as you know, maintained a personal interest in the development of the hepatitis C policy which constantly looks back to the way in which HIV was handled.

*My conclusion is that responsibility for litigation on HIV and HCV should be with CA OPU reporting through you to Perm Sec who has vote accounting (AO) responsibility for the money concerned. Alan Langlands (**and indeed Dr Calman***) would of course need to be kept fully informed of developments.*

Although this is an unorthodox arrangement I think it reflects and regularises current practice.

If you agree you may wish to drop Strachan Heppell a line."

[*emphasis added]

90.13. On 5 March 1995, Mr Blake of the Solicitors Division minuted Mr Scofield [DHSC0016646]. The minute was not copied to Sir Kenneth's Office but was copied to Dr Metters. In the minute, titled *"Hepatitis C"*, Mr Blake set out his views on the look back exercise and considered the question of liability. In the latter section of the minute and on the question of compensation, he stated (§7):

> *"… Ultimately, ministers will have to decide who is to be favoured and who is not. I see great worth in Dr Metter's algorithm precisely because he recognises that it will be a political choice as to who is included."*

90.14. A document titled *"DRAFT… HEPATITIS C – PAYMENTS SCHEME"* [DHSC0042258_069] and dated 5 April 1995 has been located. It is not clear who authored the document, nor is there anything to suggest that it was sent to Sir Kenneth's Office. It has been included here to assist the Inquiry, as it sets out the position and development of thinking on the topic of payments / compensation and includes an Annex ('Annex B') at p. 16-17, written by Dr Metters on 17 February 1995 on the features of a comprehensive scheme.

On 21 September 1995, Dr Rejman minuted Ms L French [DHSC0006307_062]. The minute was on the topic of the Irish Hepatitis C Compensation Scheme and gave a 'line to take' whilst a minute was beingprepared for Ministers. The line to take was as follows (§9):

> *"The UK is aware of the announcement from the Republic of Ireland Minister of Health. The UK lookback exercise was announced in January and was put into action at the beginning of April. This is similar in many respects to that being used in Ireland, except that in the UK mothers did not become infected with hepatitis C following the use of anti-D immunoglobin. It is unfortunate that some individuals became infected with hepatitis C following blood transfusion or treatment with blood products. There was no negligence and treatment was given in accordance with the best medical and scientific knowledge at the time. The UK Government does not intend to make any payments to individual infected in this way."*

90.15. On 27 November 1995, the Private Secretary to the Secretary of State (by then Mr Stephen Dorrell) minuted Mr Mark Adams (Private Secretary at 10 Downing Street) [WITN3430327]. He attached a briefing note on Haemophiliacs and Hepatitis C for the Prime Minister.

90.16. On 1 December 1995, the Interim Report on the Hepatitis C look back exercise was sent by Dr Rejman to the Private Secretary to Mr John Horam, (who had succeeded Mr Thomas Sackville as Parliamentary Under Secretary of State for Health, a few days before) [WITN3430328]. The report included a

paragraph (§2.10) which commented on the increased media interest in, and pressure for, a compensation scheme to be provided.

1996

90.17. On 12 January 1996, the Private Secretary to Mr Horam sent a memorandum to Mr Guinness [DHSC0003883_123]. The memorandum set out that Mr Horam wished to explore (against a backdrop of mounting political pressure) the options for offering compensation. Costed options were requested by 6 February 1996.

90.18. On 17 April 1996, a Draft Paper to the NHS Executive Board *"Hepatitis C: Issues for the NHS"* was circulated [DHSC0003534_016 and DHSC0002419_015]. It considered the look back exercise, and issues of treatment and counselling (and mentioned Sir Kenneth by title in his role in considering the clinical guidance for the handling of new drugs (§16) and in respect of a GP letter about counselling sent in April 1995 (§19). It also included at "Annex E" two paragraphs on the subject of compensation:

> *"1. The main pressure for compensation has come from the Haemophilia Society with significant political support (200 + MPs have signed an EDM calling for compensation and the subject is regularly debated in the house). The principle [principal] claim is on behalf of haemophiliacs who were infected with HCV through the use of blood products prior to 1985 (when measures were introduced to destroy viruses in Factor VIII products). Best estimates suggest that some there are around 3,000, who are not already covered by the HIV compensation scheme, are involved. The Society is also seeking extra compensation for the latter group bringing the total nearer to 4,000. Additionally, if compensation were conceded, it would also be very difficult to exclude those infected through blood transfusion. The Lookback exercise is expected to identify some 3,000 such cases but it is likely that the true number is very much higher.*
>
> *2. Ministers have held the line that the Government is opposed to any form of no-fault compensation but in recent times the Society have been encouraged by what they see as a softening of*

Ministers' position. Confidentially, Ministers have been considering the possibility of limiting compensation to those most severely affected by HCV infection (eg using cirrhosis as a marker). Official advice has been that (a) objective clinical markers are not easily identifiable or workable and (b) a scheme that was reasonably "'cheap'" would be unlikely to satisfy the compensation lobby. Estimates based on the Haemophilia Society's own expectation put the cost at over £300m over the next ten years. This takes no account of the administration costs nor the likely knock-on effect in terms of potential claims in respect of other iatrogenic disorders."

90.19. Included within the documents is an undated briefing to the CMO on the legal implications of Hepatitis C [WITN3430329] and two additional versions of the briefing [WITN3430330], (the final page, a covering minute from Dr Graham Winyard, Medical Director of the NHS Executive, appears to be addressed to the Board of the NHS Executive, and not to directly relate to the briefing to the CMO).

90.20. On 31 May 1996, Mr Robb emailed Ms French. He attached lines to take, a question-and-answer briefing and background document for Hepatitis Awareness Week (3-7 June 1996) [WITN3430331].

90.21. On 25 July 1996, Mr Ieuan Jones minuted Ms Towner (CA-OPU2) with a Hansard extract from a debate on the motion for the Summer Adjournment [WITN3430332]. The extract featured an exchange between Mr Alfred Morris MP and Mr Tony Newton MP (then Leader of the House of Commons) on the topic of the campaign for compensation for haemophiliacs suffering with Hepatitis C.

90.22. On 3 October 1996, The Rev Prebendary Tanner of the Haemophilia Society wrote to Mr John Horam on the subject of the needs of those haemophiliacs infected with Hepatitis C through NHS treatment [HSOC0014299]. The Rev Tanner expressed disappointment at a letter received by him from Mr Horam on 1 October 1996. He made the distinction between compensation (not sought by the Society) and ex gratia payments and funding (sought by the

Society) and pointed out that the Society had not alleged negligence. On 21 October 1996, Ms Corrigan minuted a Private Secretary to Mr Horam with a draft reply to be sent to The Rev Tanner [DHSC0041255_034]. The reply to The Rev Tanner was sent on 25 October 1996 [HSOC0003918].

90.23. On 23 December 1996, Mrs Phillips minuted Mr Horam's Private Office [DHSC0004203_013]. She attached a submission to Ministers about Hepatitis C, its impact on the NHS and the proposed way forward. It noted the approach had been agreed with the Executive Board. The paper considered various matters, such as the objectives of the Department and NHS in handling Hepatitis C, public health, public confidence in the NHS, implications for the NHS et cetera. At Annex A (§e) it noted:

> *"…**There is pressure for compensation from the Haemophilia Society for those infected through blood products prior to 1985.** Approximately 3000 haemophiliac are thought to be infected who are not covered by the HIV Payment scheme. Ministers have recently written to the Haemophilia Society to reiterate that compensation will not be paid since no negligence was involved. Ministers have given commitments to help, including investigating alleged problems of access to Alpha Interferon for these patients. So far the few cases identified have been readily resolved."*

1998

90.24. On 16 February 1998, Ms Corrigan of the Health Services Directorate minuted the Secretary of State, (by then, Mr Frank Dobson) [DHSC0006917_078]. She noted that the Secretary of State had met with the Haemophilia Society in September 1997 to discuss funding for recombinant Factor VIII and special payments and had agreed to write to them. Ms Corrigan goes on to note that the Department had been *"largely preoccupied with the nvCJD issue".* Under the heading of 'Special Payments', she wrote (§3):

> *"In view of the very little time available I have assumed on the hepatitis C "compensation" issue, given the considerable implications to the wider NHS of agreeing to any such scheme, that you would wish to continue with the policy line which the Government has so far taken in*

response to representations from other groups ie to refuse such requests on the grounds that:

"Compensation in respect of any NHS treatment should only be made where it can be shown that the NHS owed a duty of care to the victim, that there had been negligence by act or omission, and that harm was caused by the act of negligence. This is in line with the Department's longstanding policy. based on the common law, and consistent with practice in the public sector generally.""

Section 16: Other Issues

Q.91 The 1997 Guidance on communication of Risks

91.1. See Personal Statement.

Q.92 The "Better use of blood in the NHS" initiative

92.1. This Annex to Section 16 in relation to the 1998 paper for the NHS Executive Board on blood services and the seminar held at St Thomas' Hospital on 6 July 1998 on the better use of blood sets out what appears, on the face of the documentary record, to be the more significant developments and information in the considerations surrounding this work on blood services undertaken in 1998.

92.2. Events leading to (i) the product recalls of 30 October 1997 and (ii) SEAC's recommendation in favour of planning to introduce leucodepletion are outlined in Section 13: see Question 79 – Question 81 in particular. This section gives further detail in respect of the period from November 1997 (leading up to the January 1998 paper) to the period after the seminar shortly after Sir Kenneth Calman stood down from the role of CMO for England in September 1998.

Events from November to December 1997: blood services

92.3. The financial consequences of decisions relating to sourcing non-UK plasma can be seen from a letter dated 26 November 1997 from Sir Colin Walker, Chairman of the NBA to Baroness Jay. He highlighted '[…] *the possible ramifications of the United Kingdom Haemophilia Centre Director's Organisation Executive Committee recommendation that any risk of transmission of nv CJD would be reduced by using products prepared from donor plasma collected in countries free from reduced cases of nv CJD and BSE.'* The issues highlighted by Sir Collin to Baroness Jay included that BPL could be financially impacted: *'Plasma products bought overseas will be at the expense of plasma products sold by BPL. BPL assesses that they could lose at least £30m worth of business in the next calendar year'.* There were further concerns as to '[…] *adverse publicity on the safety of red blood cell components'* [WITN3430273].

92.4. In a minute from DH officials to Baroness Jay's Private Office [WITN3430333], it was noted that Dr Winyard, Medical Director of the NHS Executive, had responded to Sir Colin Walker [WITN3430334]. Dr Winyard noted that many of the issues that Sir Colin raised '[…] *have considerable financial implications'* and asked that Sir Colin estimate the associated costs.

92.5. In December 1997, the Health Services Directorate prepared a paper for the NHS Executive Board on CJD [DHSC0014941_005]. The paper noted that:

> *'3.3 In view of the possibility of the involvement of white blood cells in the pathogeneiss of nvCJD, following its meeting on 24 October 1997 SEAC recommended that Ministers consider a precautionary policy of extending the use of leucodepleted blood "as far as is practicable". They also recommended a risk assessment of the transmission of nvCJD by blood or blood products, and that this assessment should inform any decision on what further action should be taken to protect patients. Government has accepted this advice.*
>
> *3.4 The National Blood Authority (NBA) are preparing a strategy for leucodepletion. This work is being carried out in parallel with the assessment of the potential risk of the transmission of nvCJD by blood or blood products, so that leucodepletion can go ahead with the minimum of delay. The strategy will include an assessment of the additional costs involved. These will undoubtedly be substantial; the NBA's working assessment is some £75 million, which will substantially impact on red blood cell prices. The NBA are also examining the scope for increased use of autologous transfusion. CMO will discuss with the JCC the possible scope for reducing "unnecessary" blood transfusion – in particular, the use of single unit – as well as the potential for the recovery of blood during surgery and autologous transfusion.'*

92.6. The paper also highlighted the CPMP recommendation that '[…] *implicated products where the donor developed nvCJD should be withdrawn. This approach has been agreed by SEAC and MSBT.'*

92.7. In the section on *'Emerging issues for health and social care'*, in respect of blood and blood products, the paper noted:

> *'4.7 Clinicians will need to reduce unnecessary blood transfusion as far as possible and there is likely to be an increase in autologous transfusion. Scientific advances, such as the development of validated nvCJD diagnostic/screening tests, could severely reduce the UK donor pool and threaten hospital and blood supplies.*
>
> *4.8 The UK Haemophilia Centre Directors' Organisation (UKHCDO) have already used the nvCJD risk to call for a move to recombinant products where possible, and non UK plasma derived products in all other cases. Some overseas purchasers are already starting to buy elsewhere (France and Portugal have both cancelled all BLP contracts). Further recalls, or a significant rise in the incidence of nvCJD cases, could increase pressure from both patients and clinicians for outsourcing of both blood and blood products and ultimately threaten BPL's viability. Such developments could have huge implications for the NHS, in terms of both costs and blood product availability, but are not recommended by SEAC on the basis of present evidence.'*

92.8. In a minute dated 19 December 1997 from Gwen Skinner of DH to Dr McGovern, Dr Metters and Julia Gale (Baroness Jay's Diary Secretary), it was noted that Colonel Thomas of the Autologous Transfusion Special Interest Group of the British Blood Transfusion Society had requested a meeting with MS (L) '[…] *to explain the benefits of intraoperative salvage (ICS) of blood, a process whereby the patient's own blood, lost during surgery, is retrieved, cleaned and returned to the patient.'* In light of the CMO's future discussions with the JCC on '[…] *the possible scope for reducing "unnecessary" blood transfusion, for example by more limited amounts, patient donation of own blood prior to surgery, recovery of blood during surgery'* it was suggested by DH that CMO or Dr Metters meet with the Autologous Transfusion Special Interest Group [DHSC0004055_022].

The draft Cash Report

92.9. In December 1997, Professor Cash, former Medical Director at the Scottish National Blood Transfusion Service sent his draft report on the NBA to SoS and Dr Winyard [WITN3430335; WITN3430336].

92.10. On 5 December 1997 Dr Winyard sent a minute to SoS on the subject of the draft Cash Report [WITN3430337]. Dr Winyard noted that:

> *'The need to introduce a range of new screening tests, the impact of nvCJD and the possible collapse in the market for BPL products have combined financial implications for DH/NHS which could exceed £100m per annum. It is clearly essential to maintain managerial and financial control of this service and prevent any further deterioration in staff morale. I suggest we need to act decisively and avoid further long periods of organisational uncertainty.'*

92.11. On 9 December 1997, the draft Cash Report was circulated more widely to the CMO, Chief Executive of the NHS Executive and David Hewlett at DH [DHSC0046954_037].

92.12. In a submission dated 10 December 1997 from David Hewlett to SoS [WITN3430338], David Hewlett noted that the Report's list of recommendations fell into two broad categories:

> *'i. those where immediate action is required to restore confidence and safeguard the future of the Liverpool Centre;*
> *ii. more fundamental issues about the organisation and structure of the NBA and the National Blood Service, and relationships with the wider NHS, which will require a more considered response.'*

92.13. In terms of the draft Cash Report's wider recommendations for the NBA, the submission outlined that Professor Cash recommended the following:

> *'b) The wider / more fundamental issues which would best be worked through with the new Chief Executive / Chairman*
> *Replacing the functional management structure*

Review of the financial and wider relationship to the wider NHS

Board performance (other than the Chairman)

Review of User Group structure

Improved links with Welsh/Scottish Blood Services'

January 1998 paper for the NHS Executive Board on blood services

92.14. In January 1998, a paper was produced by the Health Services Directorate for the NHS Executive Board on blood services [DHSC0041280_038; DHSC0041433_132].

92.15. The paper addressed the following particular issues:

i) Financial and operational challenges as a result of possible transmission of nvCJD through blood and blood products:

- *'In the shorter term, the NBA is already having to divert resources into working out a strategy for the possible introduction of leucodepletion (removal of white blood cells). If, as a result of the assessment of the potential risk of transmission of nvCJD through blood or blood products, this strategy is implemented, this will require significant operational changes involving substantial and recurring financial costs. The NBA's initial working assessment is that full implementation would take a minimum of 12 months and would cost some £75 million per annum.'*
- *'As a result of the concerns about nvCJD transmission…a number of overseas purchasers have already cancelled BPL contracts (to the value of £3 million) and some countries have introduced a ban on UK derived blood products.'*
- The UKHCDO recommendation '[…] *for a move to recombinant blood products where possible and non UK plasma derived products in all other cases'* putting further pressures on the BPL. *'Factor 8 is BPL's main product and currently represents some 43% of its sales income (c£24.5 million per annum). Hence any significant decline in this market could quickly threaten BPL's viability.'*

ii) Autologous donation:

- '[…] *the strategy to maximise the use of autologous donation (the preoperative donation by patients of their own blood prior to elective medical treatment or surgery) would require operational change at the NBS and is more expensive (because of the need for donations to be labelled, recorded and stored separately). According to the NBA's estimate, maximising autologous donation could add up to a further £4 million per annum to costs.'*

iii) New screening tests:

- Expected announcement of NAT (nucleic acid testing) for HIV and Hepatitis C by the EU by August 1998 presents '[…] *huge practical and logistical problems for the NHA and they anticipate some slippage in the timetable. There are also very high associated costs (£2.7 million per annum).'*
- Potential introduction of HTLV1 testing could result in costs of around £15 million.
- The prospective introduction of diagnostic nvCJD testing would '[…] *require considerable operational changes within the NBS.'*

iv) Impact on NBS:

- *'The introduction of each new process or screening test poses a significant new operational challenge to the service and increases the potential risks to quality standards while these new procedures are introduced and bedded in.'*
- *'The current cost of the service is approximately £158 million. The additional costs of leucodepletion along (c£75 million) would increase the cost of the service by around 50 per cent. The NBS recoups its running costs…through charges to Trusts. It is already running into negotiating difficulties with Trusts for 1998/99 because of the 2.5 per cent increase associated with the introduction of NAT testing. Trusts are indicating that they are reluctant to pay significant price increases for what they perceive to be very limited health benefit.'*
- Need to strengthen relationships between the NBS and NHS.

v) Impact on NHS:

- Increasing demands for blood: *'The NHS and the NHS need to work together to encourage and enable the NHS to pursue strategies aimed at optimising the clinical use of blood.'*

92.16. A further paper prepared by the Health Services Directorate for the NHS Executive Board on the clinical use of blood transfusion [NHBT0015864_002; NHBT0015863_003] addressed the following:

i) The safety of blood:
   - Need to assure the public and take measures to mitigate against the risk of the transmission of HIV, hepatitis B, hepatitis C and nvCJD through blood and blood products.
   - *'While the absolute safety of blood cannot be guaranteed, the goal is brought closer through:*
     i. *rigorous donor selection and scrupulous attention to quality control of blood collection programmes;*
     ii. *effective and efficient screening of all donated blood in line with good laboratory practice (GLP);*
     iii. *the preparation of blood components according to good manufacturing practice (GMP);*
     iv. *appropriate storage and record keeping of blood components; and*
     v. *audited of transfusion practice against agreed guidelines.'*

ii) Making better use of blood, a re-appraisal of the clinical approach to blood and alternative strategies:
   - *'Studies from other European countries, Australia and the US show similar results and indicate that there is still scope for making better use of blood and blood components in clinical practice. There is general support in the literature for the concept that an avoided transfusion is a good outcome.'*
   - *'For the present there is much that can be done to ensure the efficient and best use of blood and its components by clinicians through the development of clinical guidelines and protocols:*

i. *to avoid unnecessary transfusions; eg. There is good evidence that some blood is still given as single unit transfusions to adults;*
ii. *to explore how autologous blood transfusion might be extended;*
iii. *to look at the possibility of greater use of intraoperative salvage of blood;…*
iv. *to evaluate the extension of the use of stimulating factors and*
v. *to review clinical outcomes in patients having blood transfusion.'*

Seminar on the better use of blood in the NHS

92.17. A submission from Sir Kenneth Calman's Private Office to SoS dated 20 April 1998 outlined the proposal to hold a one day seminar on the better use of blood in the NHS [WITN3430339].

92.18. On 18 May 1998, an email was sent from Dr McGovern to William Connon outlining the aims of the seminar as follows [WITN3430340]:

> *'Baroness Jay may be interest in taking part / attending the seminar in view of the important ongoing issues in relation to the better use of blood, making blood transfusion safer, strengthening the Blood Transfusion Practice amongst the wider swathe of doctors including surgeons, physicians, anaesthetists, and regaining the confidence of NHS users in the blood services.*
>
> *The aim of the seminar will be to give a higher profile to the increasing need for blood, to promote the better use of blood in the NHS, to provide advice to clinicians and managers about getting better value from the Blood Services as well as looking at trends in transfusion practice.'*

92.19. The seminar took place at St Thomas' Hospital on 6 July 1998 [DHSC0004467_008].

Further recommendations and decisions on blood services issues

92.20. In a minute dated 14 August 1998, Mike McGovern at DH sent to CMO a draft of the Health Services Circular based on the recommendations of the CMOs' seminar on 6 July 1998 [WITN3430097].

92.21. In a minute dated 18 August 1998, Dr Pat Troop, Regional Director of Public Health, provided his comments on the draft Health Services Circular [WITN3430341]. On 25 August 1998, Dr Bill Kirkup, Acting Regional Director of Public Health, provided his comments [DHSC0020756_077] and Dr Metters provided further comments on 4 September 1998 [WITN3430342].

92.22. In a submission from Mike McGovern to Lady Hayman (the new MS (L)) dated 3 December 1998, the latest draft of the Health Services Circular was sent to MS (L) with the following comments [DHSC0004055_007]:

> *'3. The circular encourages collaboration between health commissioners, NHS Trust management and clinicians on the development of good blood transfusion practice. It outlines the action required in the short and medium term to set up hospital transfusion committees, to implement guidelines and protocols for blood transfusion, and to support the development of autologous blood transfusion. It also advises all NHS Trusts to take part in the UK wide Serious Hazards of Transfusion enquiry as a commitment to blood safety and clinical governance. The HSC recognises that there is a clear way forward in these areas and that early action is required.*
>
> *4. The HSC also recognises that other recommendations to the CMOs at the seminar require more thought and work. The last section of the circular lists these and we intend to follow them up with subgroups of those who attended the CMOs' seminar. We will consult the larger group and the relevant constituencies on any action recommended after which we will come formally to Ministers.'*

92.23. The final Health Services Circular was published on 11 December 1998 [NHBT0083701_002], outlining actions for clinicians, NHS Trusts and health commissioners to implement in respect of blood services.

Q.93 Other Issues

93.1. See Personal Statement.