

Dr Harold Hastings Gunson will state:

From 1st October 1988 I have held the post of National Director of the Blood Transfusion Service for England and Wales. From September 1975 until April 1980 I was the Regional Transfusion Director for the Oxford region and from April 1980 to 30th September 1988 I was the Director of the N.W. Regional Blood Transfusion Service and based in Manchester.

As Regional Director, I was responsible for the provision of the Blood Transfusion Services to the District Hospitals in the Oxford and N.W. regions. In both Oxford and in Manchester there was a Regional Haemophilia Service. While haemophiliacs are treated in hospitals, their management is under the auspices of the Regional Haemophilia Services. Another function in Manchester, but not in Oxford, was the purchase of commercial materials within the RTC budget for the treatment of haemophilia patients. It was my responsibility, in conjunction with the Directors of the Haemophilia Service, to negotiate the provision of the commercial factor VIII concentrates to supplement supplies from within the NHS. The Regional Team of Officers who subsequently became the Regional Management Team, allocated a specific budget for this purpose to the Blood Transfusion Service, which was finally

approved by the RHA. From this, we purchased supplies to fulfill the diverging gap between NHS supplies and demand. In general, the Regional Health Authority allocated sufficient finance, and I am not aware of under treatment for the lack of Factor VIII supplies, although some non-urgent surgical procedures were deferred.

Demand certainly increased over this period. However, the N.W. region, in general, used less Factor VIII per patient per year than other regions.

The N.W. Regional Supplies Department were involved with the negotiations with the companies. From 1982/83 the regional standing financial instructions demanded that for contracts over £100,000.00, tenders had to be sought. The Regional Supplies Department devolved its duties to several District Supplies Departments. The tendering procedures for commercial Factor VIII concentrates were carried out by the Supplies Department of the Tameside Health Authority under the management of Stephen Rhodes. The procedure adopted was to inform the Supplies Department of the number of units of Factor VIII required, the available budget and a list of approved firms.

A meeting was held with Dr. R.T. Wensley and Dr. D.

Lee after the tenders were in and before the final order was placed. The ordering process occurred approximately once a year, normally February/March. However, in the last five years, because of increased usage, it was necessary to supplement supplies of commercial Factor VIII in December/January.

Dr. Wensley was very much involved in the purchase of Factor VIII and was the person responsible for the distribution of both commercial and NHS products from the RTC. Dr. Lee, then Consultant-in-Charge at the Lancaster Centre, managed the supplies of Factor VIII allocated to that Centre and Dr. Evans those supplied to the Manchester Children's Hospital. Until September 1986, Mr. W.B. Mawson was the Administrative Officer at the Manchester RTC. He was succeeded by Mr. P. Hynes, Administrative and Donor Services Manager. Both these Officers were responsible for preparing tenders for the purchase of commercial Factor VIII concentrates in conjunction with the Supplies Department.

In October 1981, I was appointed Consultant Adviser to the Chief Medical Officer, DHSS. I was closely involved with developments at a national level. I was one of approximately 50 advisers to the Chief Medical Officer in diverse specialities, whose role

it is to give his staff advice on professional matters on a personal basis. I am giving this statement in my capacity as Regional Director, and not as Consultant Adviser to the Chief Medical Officer, although reference will be made to national matters concerning the NBTS when these are factual.

I was also a member of the Central Blood Laboratories Authority, the Authority responsible for the Blood Products Laboratory from December, 1982, when it was created, to 1st October, 1988.

I have read the statement of claim in the HIV Haemophiliacs litigation and would make the following comments:

Para. 91 My responsibilities within the blood transfusion service have been stated above.

I have not treated any haemophilia patients, having no direct clinical responsibilities in this regard. Neither have I carried out any research into the care, management or medication of haemophiliacs, other than statistical analyses, the results of which have been published from time to time.

I used to hold regular meetings with the physicians who treated the haemophilia patients concerning

supplies - how much, preferred products etc. These meetings were ad hoc about twice a year from 1980/81 onwards. They continued until I resigned as Director of the N.W. Regional Transfusion Service in 1988. Some were attended by the Officers of the RHA, the RMO and the AGM Personnel - the transfusion service is his responsibility within the RHA and I reported to him.

Para. 91(b) As far as the special regard I had for haemophiliacs is concerned, their vulnerability was principally a lack of treatment and I did all I could to secure the provision of cryoprecipitate and Factor VIII concentrates from the NHS and other sources to facilitate this.

Para. 92(a) The Regional Transfusion Directors (RTDs) held informal meetings regularly between 1946 and 1988. In these meetings, attempts were made to formulate national policies. It is true that, with the regional management of the Regional Transfusion Centres, divergent policies emerged, although certain core functions, such as the medical selection of donors, remained uniform on a national basis.

A Working Party of the RTD Committee presented a report to the Medical Advisory Committee of DHSS in 1973, advocating that the NBTS was reorganised as a

national service with a unified central administration. As a result of this the DHSS constituted a Committee, known as the Reid Committee, to consider whether any changes should be made in the present organisation of the blood transfusion services in England and Wales.

In the 1974 reorganisation of the NHS, the management of RTCs was transferred from the existing Regional Health Boards to the newly created Regional Health Authorities (RHAs). The DHSS considered, after deliberations by the Reid Committee, that the proposals in the White Paper entailed a scrutiny by the DHSS of operations and planning by RHAs. Therefore, it was not considered that central funding or management of the NBTS was necessary to increase its effectiveness. It was recognised, however, that central co-ordination of the Service would be advantageous and constituted a DHSS Central Committee for the NBTS. This Committee was chaired by a senior doctor at DHSS and its members comprised representatives from DHSS, the NBTS and the clinical specialities for which the NBTS provided a service. The terms of reference of the Committee were "to keep under review the operation of the National Blood Transfusion Service, including the Blood Products Laboratory and the Blood Group Reference Laboratory in England and Wales and advise DHSS and the Welsh

Office on the development of the Service."

The Committee met on several occasions, but was not effective in materially changing the priorities afforded by RHAs to their regional services.

In 1976, the RTDs, to improve communications within and between RTCs, formed themselves into three Divisions, viz:

Eastern: E. Anglia, N.E. Thames, N.W. Thames,
SE/SW Thames

Western: Oxford, S. Western, Wales, Wessex, W.
Midlands

Northern: Mersey, Northern, N. Western, Trent,
Yorkshire

Membership of the Divisions comprised all consultant medical staff working in the respective RTCs. The Divisional Chairman was elected from RTD members of each Division. Meetings were held quarterly prior to meetings of the RTD Committee.

The Central Committee for the NBTS was dissolved in the late 1970s and replaced by the Advisory Committee on the NBTS with similar terms of reference. This was chaired by a Deputy Chief Medical Officer of the DHSS and its membership comprised the Chairmen of the NBTS Divisions, the

Consultant Adviser to the CMO, the Director of the Blood Products Laboratory, a Regional Medical Officer, Regional Treasurer, a Regional Administrator and a Regional Nurse. Observers from SHHD, the Welsh and Northern Ireland Offices, attended the meetings.

This Committee performed three major tasks:

- (i) Determined the quantity of plasma required to provide 100 iu Factor VIII concentrates per year, this being the quantity estimated by the Haemophilia Directors for national self-sufficiency by 1990.
- (ii) A survey of record keeping in RTCs and hospital blood transfusion departments.
- (iii) A method for determining the cost of preparing products at RTCs.

Although these were matters of National importance, the Committee was not able to address detailed matters on the national aspects of the Service. Consequently, in 1985/6, the RTDs Committee submitted proposals to the DHSS for the creation of a national service. The DHSS commissioned a study of the NBTS by the NHS Management Services Branch of the DHSS. Field work began in September 1986 and the report was available towards the end of

1987. Deficiencies were identified in the organisation and management of RTCs, particularly with respect to the lack of management information and co-ordination of the work of RTCs.

In July 1988 the DHSS announced in the House of Commons the formation of the National Directorate and my appointment as National Director. The RTCs continue to be regionally managed, but it is my job to formulate national policies and co-ordinate the work of RTCs. I report to the Director of Operations of the Management Board (now the National Executive) and a National Co-ordinating Committee of the National Executive has been created.

Certain aspects of the Service are undoubtedly national. Blood collection and distribution, plasma collection for fractionation, management information, are all service matters which have major national implications. We have links nationwide, with particular hospitals of excellence for the provision of specific treatments, to maintain regional targets to cover such national commitments which would be difficult for the population in specific regions.

It is difficult, for instance in the London regions, who treat patients from other parts of the

country, to maintain blood supplies for all these patients, particularly those undergoing specialised treatment such as liver transplantation.

However, not every aspect is national. Some things must remain at regional level, for example ante-natal testing, consultant services and post graduate medical training. These are regional functions because of the essential direct contact between hospital and BTS staff. The human contact element is most important in my speciality. It is the local contact between the donors and Centres which encourages a regular blood supply of blood from a core of regular donors.

Para. 92(b) The changing pattern of haemophilia care during the 1970s necessitated a change in fractionation policy with the introduction of Factor VIII as a fractionated product from freshly collected plasma.

In 1973 it was estimated that approximately 230,000 donations per year were being used as a source of plasma or cryoprecipitate for the treatment of haemophilia. At this time, 20,000 donations per year were being sent to BPL for the preparation of Factor VIII concentrate. For total haemophilia care at that time, the RTD Committee estimated that products from between 400,000 and 700,000 donations per year were required.

RTCs began to increase plasma supplies to the Blood Products Laboratory and in December 1974, the DHSS provided ~~£~~^f0.5M to provide 275,000 donations of plasma for fractionation into Factor VIII concentrate. RTCs were given annual targets for plasma collection based on their collection of blood donations.

In 1981 a system of pro-rata return of fractionated plasma products was introduced to encourage RTCs to increase plasma production, i.e. the region received products equivalent to the quantity of plasma supplied. In some instances, the products were fractionated from the actual plasma sent from a particular region, but this did not always apply and a region could have received products derived from another region's plasma.

The haemophilia directors assessed nationally the future needs and advised the Department of Health. In fact, in 1981 they assessed accurately that by 1990 they would need 100 million units of Factor VIII per year. We have reached a demand of 95 million units in 1988.

Within the N.W. region, we worked on a year to year basis with the local knowledge of consultants in the Regional Haemophilia Service. This was based on the number of corrective surgical operations

needed in the following year, together with the numbers of patients able to pursue a home treatment regime, with an added percentage added for emergencies. Home treatment involves extra supplies of Factor VIII in that a haemophiliac would inject Factor VIII at the commencement of a bleed without waiting to see if the bleed was serious enough for him to attend hospital for treatment.

Para. 92(c) The regional centres were all given plasma targets agreed by the Directors and the Director of the Blood Products Laboratory (BPL) and generally from 1978 these were in proportion to the region's population. In order to monitor the targets we received monthly statements of the amount of plasma sent to the BPL and the quantities of products returned. Mr. P. Howell, the Principal Scientist and Laboratory Manager of the Manchester RTC, maintained these records at Plymouth Grove. Additionally, the DHSS statistical department at Blackpool received quarterly reports on a range of blood and plasma collection data from all RTCs and the results collated for all regions were returned.

A national summary of regional statistics for the financial year 1987/88, by way of example of the quarterly and annual figures, is appended to this statement and marked Appendix 1.

In the N.W. Region, plasma ^{Supply} groups comprising all staff concerned with plasma production, were established in the RTC and the Lancaster Centre in December 1985, and these groups met regularly to review the plasma supplied to the Blood Products Laboratory.

Para. 92(d) From 1974, RTCs removed part of the plasma from donations of whole blood shortly after its collection and this was used, in addition to general clinical requirements, for the preparation of cryoprecipitate and for issue to BPL for fractionation into products. Nationally and also in the N.W. region, the number of donations from which plasma was removed increased in numbers. In the latter part of 1983 a nutrient solution became available so that it could be placed on the red cells after removal of all the plasma from the donation. This allowed a 50% increase of plasma to be obtained from each donation.

Although the use of cryoprecipitate declined nationally between 1975 and 1985, the usage in the N.W. region remained high as a result of the policies adopted by the Regional Haemophilia Service. Cryoprecipitate competed with plasma sent for fractionation so that the latter targets were not achieved. However, Factor VIII from cryoprecipitates was used to treat haemophilia

patients and this supplemented the supplies of NHS and commercial Factor VIII concentrates. Details of the production of cryoprecipitate and plasma for fractionation are available at the RTC, Plymouth Grove, and at the Lancaster Centre, although for some years the RTC supplied Lancaster with cryoprecipitate.

Between 1982 and 1984, the N.W.R.H.A. financed the alterations to the former ICL computer factory to provide a new RTC. Co-incidentally, they responded to my arguments to increase the plasma supply with additional financial allocations for this purpose. In 1985/6, funding was provided for a plasmapheresis centre at Plymouth Grove and somewhat earlier, a similar, but smaller, plasmapheresis centre was established in Lancaster. In general, the production of plasma was divided in the proportions of two-thirds from Manchester and one-third from Lancaster.

Between 1975 and 1980, the BPL met with difficulties in meeting an ever increasing demand for Factor VIII concentrate, and by 1978 the production had reached 15 million iu per year, which was approximately one-third of the total usage of this product. The existing BPL was upgraded and the construction of a new plant was commenced in 1982.

Para. 92(e) and (f) It was not within my remit to have contact with the Scottish Blood Transfusion Service for the production and distribution of Factor VIII in England and Wales.

Para. 92(g) and (h) Do not apply.

Para. 92(i) The production of home-produced Factor VIII increased during the 1970s. This is evident from the data presented in my article entitled "Trends in blood transfusion practice in England and Wales" published in Health Trends, November 1986, volume 18. This is a statement and marked Appendix 2.

Para. 92(j) The level of home produced Factor VIII did indeed fall during the beginning of 1985. The standard product produced by the BPL was at that time an intermediate purity Factor VIII concentrate. Up to the end of 1984 it was not heat treated. This product withstood the heat treatment poorly and in the first half of 1985 the BPL changed the product to one which could be heat-treated. The level of output fell while this changeover took place. During this time, it was necessary to make up the shortfall of BPL Factor VIII with cryoprecipitate and commercial heat-treated products. In January 1985, this region commenced the use of a commercially heat-treated product. This had financial consequences in that the heat treated product was almost double the price of the previous

product which was not heat treated. However, the regional ~~provided~~ provided the extra funding upon my advice that to provide products to treat haemophiliacs which were not heat-treated, was no longer acceptable.

Para. 92(k) The decision to change to a heat treated product was made at a meeting between the Regional Transfusion Directors and Regional Haemophilia Directors and the Director of the BPL on 9th December 1984. At this meeting, evidence of the transmittability of AIDS to haemophiliacs was reviewed and a decision was made that haemophiliacs should receive only heat treated Factor VIII as soon as possible. I advised the N.W.R.H.A. of this decision soon after that meeting and it was implemented on about 14th January, 1985. The manufacturers took back supplies of unheated products and replaced them with the heated Factor VIII concentrate. There may have been un-heated Factor VIII concentrate still in the supply chain and Dr. Wensley will have records concerning the disposal of this material.

As far as Factor IX is concerned, the decision to use heat-treated products in the N.W. region was made at a meeting with the Consultants in the regional haemophilia service in, I think, July 1985. BPL did not, at this time, have sufficient

heat treated Factor IX and the RHA provided funds to buy commercial products for approximately six months. We reverted back to BPL sources of Factor IX in December 1985 when their heated product became available in sufficient quantities. This necessitated yet another allocation of cash from regional funds.

The pros and cons of heat treatment are fully documented in scientific papers. Experiments had started in 1984 in the USA, where it was shown that heat could kill the AIDS virus. In general, the heat treatment is effective, although there have been some batch failures. In 1986 there was a paper presented at a meeting on AIDS in 1986 by Dr. P. Jones of the Newcastle Haemophilia Centre, who said there had been four possible failures of heat-treated Factor VIII, three in the USA and one in the Netherlands.

Albumin is pasteurised for ten hours at 60°C¹⁰⁰ and has been produced in this way for the past 20 years. In so far as hepatitis is concerned, hepatitis B is a virus resistant to heat treatment, but tests for hepatitis B have been routinely performed on blood donations since 1971/2. It is possible that hepatitis non A, non B, for which a specific test has only become available in 1989, may have been eliminated in the heat-treated Factor VIII

concentrate currently produced at the BPL.

During 1982 it was not, in my view, proven conclusively that Factor VIII concentrates were the cause of AIDS contracted by haemophiliacs. Again, to quote Dr. Peter Jones, in his presentation at the meeting in 1986, reported "however, when in July 1982, the Centres for Disease Control (USA - my brackets) reported unusual opportunistic infections in three men with haemophilia, the possibility of a viral aetiology was thought less likely than an immune response to the constant barrage of extraneous denatured protein involved in treatment."

The first case of transfusion-associated AIDS was reported in 1983 in an infant transfused in December 1982 and this will be referred to later in the statement.

Para. 92(1) I did not conduct such research personally into the products used to treat haemophiliacs. Dr. Wensley, a Consultant at the RTC and Co-Director of the Regional Haemophilia Service, however, was involved in research in this area over a number of years.

Para. 92(m) I am unaware of the use of heat-treated products for the treatment of haemophilia in 1980.

Para. 92(n) Heat-treated products were not a particularly effective means of eliminating the risk of hepatitis. The most effective means of reducing transmission of hepatitis B was the routine screening of blood donations which commenced in 1971/2 and the introduction of more sensitive tests for this purpose as they became available.

There are several reports in the scientific literature that indicated that the transmission of non A, non B hepatitis occurred with heated Factor VIII concentrates, although with the present BPL heated product, this may have been overcome, as mentioned previously.

Para. 92(q) During 1982, the correlation between the transfusion of blood and blood products was not proven, nor was it known at that time that a virus caused AIDS, although investigations were being undertaken in this regard. The first proven case of transfusion-transmitted AIDS was reported in 1983 in an infant given a transfusion of blood and products in December 1982.

The Regional Transfusion Directors at their meeting in May 1983 decided to prepare a leaflet asking donors to self-exclude if they belonged to certain categories of activities which increased the risk of contracting AIDS. The leaflet was issued in

September 1983 and in the N.W. region this was distributed to prospective donors with their call-up letters for donation and was distributed to factory donors on recruitment.

It must be recognised that details of the self-exclusion categories were those which were considered pertinent at the time. The leaflets have been updated on four further occasions and a summary of the exclusion clauses is given for the various leaflets in Appendix 3.

On 20th June 1983 I wrote to sessional medical officers updating them on the situation with respect to the transfusion transmission of AIDS and subsequently they reported to me any donors who may be at risk.

Advice to clinicians came from the Department of Health and Social Security by a document known as the Blue Book. I discussed specific cases with clinicians either by telephone or directly and kept them informed, but in 1982/3 there was little more that could be done.

Dr Martlew, following her appointment as a Consultant at the RTC in January 1984, and now Director at Mersey RTC, worked with the gay sector to explain our policy with respect to the self-

exclusion of blood donors and fostered a good relationship with the gay groups in this region. She attended meetings of the Manchester AIDS Forum as RTC representative.

We did not do any non-specific tests which were being investigated in the USA. There was an AIDS Sub-Committee of the National Research Committee which I chaired, and the possible use of these tests were discussed in detail. It was agreed that the value of the non-specific tests could not be determined. Proposals were considered for a research product, but were not put forward because by mid-1984 the test for antibody to the AIDS virus had been discovered in the USA.

Para. 92(r) I did indeed adopt a policy of destroying or marking for non-use blood offered by donors who on enquiry revealed or gave the impression of being homosexuals, bisexuals, intravenous drug abusers or other high risk donors. This was part of the standing operative procedure. The majority of such donors were rejected on sessions, but of those who donated, the resulting donation was withdrawn from use and destroyed. This was done in conjunction with Mr. P. Howell. The policy was instituted in 1983. A system was arranged so that when sessions were completed and blood returned to the regional transfusion centre, any comments that a particular

donation came from an at risk person were reported by the sessional doctor to me in confidence and this to the donation being removed from those prepared for issue. This was co-ordinated with the sending of the leaflet. The system was maintained until the test was instituted, when a new set of operating procedures based on the test results was instituted, whilst still maintaining the previous reporting arrangements.

Para. 92(s) I received 50,000 copies of the DHSS leaflet on 1st September 1983. I also received the Department of Health's advice in January 1985 with respect to circulation of the leaflet, but by then we were already using the policy they recommended and had been since 1983, when we had initiated the distribution of the leaflet. I received no other DHSS advice on this matter. On 31st January 1985 I reinforced the system locally by sending a memorandum to the staff at the BTS, giving instructions for handling at risk donors. Appended to my statement and marked Appendix 4 is an analysis of the various regions' methods for disseminating the first AIDS leaflet, entitled "AIDS Leaflets - First ³ months Experience".

Para. 92(t) The test for AIDS antibody, now known as the anti-HIV test, was discovered in the USA in mid-1984. However, the test went through a necessary period

of development by a number of commercial companies and was eventually licenced by the FDA in March 1985.

In the N.W. region, we followed the national policy and the test was introduced routinely for the screening of donations on 14th October 1985 in common with all other transfusion centres in the U.K.

Several factors were important before commencing routine tests on blood donations in the U.K. The test must be reliable. There were reports from the USA that it gave a high percentage of false positive results and centres who could perform confirmatory tests were required. Very importantly, since the test had received wide publicity, it was feared that some persons would come to give blood as a convenient way of finding out their anti-HIV status. False negative results may occur because the test detects the antibody to the virus and not the virus itself. There is a period of several weeks or months before an infected person becomes anti-HIV positive. Persons of high risk donating blood in this "window period" could be infectious and would have made testing counter-productive and the blood supply less secure. It was essential that alternative venues for the tests for persons other than blood donors

were established. Finally, since the test only became available in this country after March 1985, staff had to be trained in its use. We had previously used the radioimmune assay (RIA) test in Manchester and Lancaster for the detection of hepatitis B antigen. The test for anti-HIV was an enzyme linked immunoabsorbent assay (ELISA) which was more sensitive than RIA. Tests using this system were carried out in June and July 1985 in order to assess the test in the working routine of the transfusion centre and the results were reported nationally.

We still recommend self-exclusion of donors because of the "window period" mentioned above. Testing for the viral antigen can be performed, but its complexity is such that it is not applicable to the screening of blood donations. Moreover, it takes 24 hours to complete the tests and within that period it is essential that the previous day's blood collection is processed and available for issue. Also, the antigen test is not always a reliable indication of infection.

When anti-HIV screening was commenced on 14th October 1985, all other donations held in the RTC and Lancaster Centre were tested, so that all blood issued from that day had been screened for anti-HIV.

There was still blood in hospitals which was untested on this date, but the hospitals usually had only 2-3 days supply and so we were sure that tested blood would soon become exclusively available in this region.

Thereafter, national monitoring of the anti-HIV testing of blood donations has been done monthly by Miss V.I. Rawlinson, Principal Scientific Officer at the Manchester RTC. She and I wrote up the results of the first two years of the tests in a paper entitled "HIV antibody screening of blood donations in the United Kingdom", and marked Appendix 5. *EZ.*

The policy with respect to handling of anti-HIV positive ^{na E} donations was documented fully and Mr. P. Howell will have all details.

Reliable tests have been in use for some time and they have improved in sensitivity and specificity over the past four years. The early tests were made from human antigen and were less specific than the recombinant antigen now used.

In March 1985, tests from several USA companies were licensed by the FDA. The test manufactured by Wellcome was not on the market until June 1985. This test is now in common use in this country.

The Central Laboratory of the Public Health Laboratory Service, Colindale, evaluated all the tests available and concluded that the Wellcome test and the Organon-Teknika test, developed by a company in the Netherlands, were the most useful for blood donor screening.

Screening of blood donations in European countries were instituted during 1985 and 1986. I collected this data as the U.K. representative of the Council of Europe Committee of Experts in Blood Transfusion and Immuno-haematology and a table showing the commencement of routine donor screening in various European countries is appended (Appendix 6).

Para. 92(u) The Department of Health itself did not give any advice on the reliability of the tests, but commissioned a study of the available tests by the PH Laboratory Services in March/April 1985. Their report was published in the Lancet.

Para. 92(w) I appreciated the risks of hepatitis to haemophiliacs as long ago as the late 1960s. In 1972, we started screening for hepatitis B. We were then able to remove from the system those donations with detectable hepatitis B surface antigens, but haemophiliacs still contracted hepatitis. Some instances were still caused by hepatitis B due to the sensitivity of the tests

available and it was recognised that a virus or viruses, called non A, non B, were the cause, since hepatitis A is rarely transmitted by blood products. Studies on haemophiliacs treated with Factor VIII showed non A, non B hepatitis to be prevalent. There was no specific test for this virus until June 1989. In 1990 we hope to introduce screening of blood donations for the antibody to this virus. Many haemophiliacs are vaccinated against hepatitis B now that a safe vaccine is available.

Para. 92(x) It was known from investigations performed by Dr. C. Rizza that Factor VIII made from the NHS plasma transmitted non A, non B hepatitis to haemophilia patients. It is arguable whether the reduction of imported commercial Factor VIII would have altered the situation in this respect.

Para. 92(y) I first became aware of the emergence of HIV/AIDS from the information in the Scientific literature from the USA.

The first reports were of the finding of Kaposi sarcoma in homosexuals. No-one knew what the implications were at that time for the BTS. As the reports began to accumulate, it was clear that the immune deficiency related to this disease was a major problem. The medical staff in the RTC

discussed each new development as any department would discuss such major developments in another field. In 1983, as soon as we knew that this virus was transmissible by blood products, we were aware that the disease would have a major impact on the work of the Blood Transfusion Service.

Para. 92(z) I kept myself informed by reading scientific literature, by attending meetings, by talking to experts and being a member also of the DHSS Expert Advisory Group on AIDS. We had staff meetings within the RTC. I held seminars and teaching sessions for the scientific and other non-medical staff, particularly those working on the blood collection teams, since the media publicity had caused alarm.

Para. 92(aa) I first suspected the link between haemophiliacs and AIDS during 1982, when there were instances of haemophiliacs contracting immune deficiency. However, it was not known at that time that AIDS was caused by a virus and when this was established, it was thought initially that the AIDS virus was not so virulent in haemophiliacs and only one per cent of those who had HIV seroconverted would develop AIDS. This, of course, has now been found to be entirely wrong. There were times, until the proof that AIDS was a viral infection and that it could be transmitted by blood products,

that I doubted the link with haemophiliacs; other colleagues also had these doubts.

Before the emergence of its cause by a transmissable virus, other theories were put forward for the origin of AIDS in homosexuals, e.g. pep pills, nitrates, etc. Until proof was available that blood transfusion could be a cause of AIDS, it was difficult to take specific action within the BTS. From that time, I held no doubts concerning the significance of blood transfusion in relation to AIDS and acted accordingly.

Any literature which I have published on this subject has been on the testing of blood donations and the safety of the blood supply.

I am sure I was aware of the articles in the Lancet on 15th, 22nd and 29th January, 1983, since I made a point of keeping up to date with the literature on this subject.

GRO-C

11 Jan 1989