HIV/AIDS
INS/RBS/435245(692)

STATEMENT

ANNE KIRKMAN COLLINS can say:

I am a Consultant Haemotologist employed by the Northern Regional Health Authority at the Regional Blood Transfusion Centre, Newcastle upon Tyne. I have held my present position since the appointment of Dr Lloyd as Director and General Manager of the Regional Blood Transfusion Service. Prior to Dr Lloyd's appointment, I was the Medical Director of the Regional Blood Transfusion Service. I hold the LRCP, MRCS, MBBS and MRCP Path qualifications. I qualified from the University of London in 1962 with the MBBS, LRCP, MRCS qualifications.

I succeeded Dr Shelagh Murray as Medical Director with effect from September 1979. In 1979 the Haemophilia Centre at Newcastle upon Tyne had already been established for a number of years, and the Director the Centre had been Dr Peter Jones for some time. I believe that the general arrangements which were in force in 1979, as between the Haemophilia Centre and the Blood Transfusion Service, had been negotiated at some time in the past between Dr Jones, Dr Murray and the Regional Medical Officer, Dr Mark Sackwood, but I do not know if these arrangements were set out in writing.

The practice in 1979 was for commercial blood products for haemophiliac patients to be ordered by the Pharmacy Department at the Royal Victoria Infirmary. As far as I was aware, payment for commercial blood products was arranged for by the Regional Health Authority. At no point was the financing of the purchase of commercial blood products debited to the blood transfusion service budget. The treatment of haemophiliac patients

themselves was entirely a matter for Dr Jones and his colleagues. Dr Jones was responsible for the selection of a suitable commercial blood product.

In the 1970's, treatment of haemophiliacs was largely carried out with cryoprecipitate and fresh frozen plasma. At this time, I was the Senior Registrar at the Blood Transfusion Service, (having started work in the Regional Blood Transfusion Service in 1970).

Although it was sometimes a struggle because of the poor facilities we then had at Newcastle General Hospital, we usually managed to meet the demands of the Haemophilia Centre for cryoprecipitate and fresh frozen plasma. There was a gradual improvement in our facilities at Newcastle General Hospital, prior to our transfer to the present purpose built premises at Barrack Road, Newcastle upon Tyne in September 1985. For example, whilst we were still at Newcastle General Hospital a new laboratory was provided for the production of cryoprecipitate. I cannot recall precisely when the new laboratory was completed, but it would have been about the time when hepatitis testing became a common practice.

I would say that the demand for cryoprecipitate and fresh frozen plasma for haemophiliac patients continued until Factor VIII blood product became available. Until then, the agreement between the Blood Transfusion Service and the Haemophilia Centre was to the effect that the Regional Blood Transfusion Service would produce up to 10,000 units per annum of cryoprecipitate and fresh frozen plasma.

Dr Jones became an advocate of home therapy for haemophiliacs, and I believe it was in the late 1970's, or early 1980's, that

Factor VIII blood products became available, as a result of which the demand for cryoprecipitate and fresh frozen plasma started to fall. One of the perceived advantages at that time of Factor VIII blood product was that it could be used in the home situation. It was generally felt that Factor VIII was more acceptable to haemophiliacs and I believe that the Haemophilia Society pressed strongly for its introduction and use. At that time, Factor VIII blood product seemed to answer the search for a means to enable haemophiliacs to lead a relatively "normal" life.

The Regional Blood Transfusion Service in Newcastle upon Tyne has never had the ability to produce Factor VIII product. The production process for this material is called fractionation, which requires the employment of production engineers as well as scientists and sophisticated. Fractionation is, in fact, a factory process.

With regard to the blood plasma produced by the Regional Blood Transfusion Centre, some of this would be used for direct clinical purposes unconnected with the treatment of haemophiliac patients. Some of the blood plasma would be sent as fresh frozen plasma to the haemophilia centre, and a proportion of plasma would be turned into cryoprecipitate. The blood plasma for the central blood products laboratory at Elstree had to be separated from whole blood within a short time (not more than 18 hours at most) after collection of the whole blood, to avoid a deterioration in the Factor VIII level in the whole blood. This meant that to send more blood plasma to Elstree would mean extra costs in the shape of additional blood packs and staffing facilities. Throughout this period (ie, during the whole time when I have been employed at the Regional Blood Transfusion Service), the Regional BTS has had a definite budget fixed by the Regional Health Authority, which could not be exceeded.

The problems associated with obtaining additional blood packs and the obtaining of extra staff were not the only limiting factors in the production of blood plasma. Another limiting factor was the outdated premises occupied for much of the relevant time by the central blood products laboratory at Elstree. For example, in 1983 even if we had sent more blood plasma to Elstree for fractionation, the Elstree plant would not have been able to carry out the necessary processing to enable more Factor VIII to be returned to the Northern Regional Health Authority.

There was another blood products laboratory at Oxford during this time, but to the best of my belief, this laboratory (which was much smaller than the Elstree laboratory) had no facility for the manufacture of Factor VIII, and was largely responsible for the manufacture of Factor IX.

A further difficulty arose from the arrangements which were made from about 1980 onwards for the distribution of Factor VIII. The system introduced at that time was known as the "pro rata" arrangement, by which Regional Transfusion Centres were intended to receive back amounts of blood products in proportion to the amount of blood plasma sent by Regional Transfusion Centres throughout England and Wales. Because some Regional Transfusion Centres, such as the Leeds Centre, sent a disproportionately large amount of blood plasma, the northern transfusion service "lost out", even when the amount of blood plasma sent to Elstree increased.

Although there was a shortfall in meeting the production targets for blood plasma by the Northern Regional Transfusion Centre, nevertheless this did not appear adversely to effect the operation of the haemophilia centre in Newcastle upon Tyne. In particular, I recall writing to Dr Jones as the Director of the

Haemophilia Centre in August 1983 informing him that there was a large supply of Factor VIII from the Central Blood Products Laboratory, which was awaiting use at the Northern Regional Transfusion Centre. I recall that I had previously spoken to nursing staff and to Dr Jones about the existence of this surplus, and because there was no reaction to my conversations, I eventually wrote to Dr Jones on 26th August 1983.

It became apparent that there was a preference at the Haemophilia Centre for commercially produced Factor VIII blood product, for the following reasons:

(a) commercial Factor VIII was more easily soluble.

(b) Some patients tended to have allergic reactions to NHS produced Factor VIII. For example, some patients had shivering attacks, presumably because NHS Factor VIII had more impurities, (ie, substances other than pure Factor VIII).

(c) The presentation of commercial Factor VIII was more attractive to the Haemophilia Centre. At that time, commercial Factor VIII was sold with a bottle of water and a needle, so that the dried Factor VIII could be infused.

The anticipated completion of the present Regional Transfusion Centre premises in 1985 was referred to in my letter of 21st September 1983 to Dr Laine of the Blood Products Laboratory in Elstree. My letter was written in response to a questionnaire from Dr Laine. I refer to the fact that there had been no response to my proposals to the Regional Health Authority regarding an increased supply of blood plasma to the blood products laboratory, and I foresaw little possible change until after the new Regional Transfusion Centre premises were open. My

correspondence also refers to the fact that although the Regional Health Authority had approved the new development and the revenue consequences of the move, the Authority had not approved an expansion in the blood transfusion service.

It was my practice as Medical Director of the Blood Transfusion Service, prior to the reorganisation of the Service under the leadership of Dr Lloyd, to submit Annual Reports to the Regional Health Authority describing the services which we had provided during the preceding year, and making proposals for the following year. In effect, the Transfusion Service had to "compete" for funding with other services provided by the Regional Health Authority.

I have had the opportunity to study the questionnaire which has been circulated to NHS staff involved in the HIV/AIDS litigation, and would make the following comments.

In answer to the question as to what arrangements I made for the care and treatment of haemophiliacs within the Northern Region, I would repeat that the care, etc, of haemophiliacs was not a responsibility of the Regional Transfusion Centre. The care and medication of haemophiliacs was entirely the responsibility of Dr Jones and his colleagues.

In answer to the question as to whether any research was carried out by me into Hepatitis, HIV and haemophiliacs, again this was not a responsibility of the Regional Transfusion Centre. In fact, we had very limited research facilities at the old Regional Transfusion Centre premises at Newcastle General Hospital. Such research as was carried out was into the field of tissue typing. This research was carried out by the principal scientific officer, Mr Dewar, until Mr Dewar's death in 1985. No successor

was appointed to Mr Dewar.

In connection with the question about the form of coordination or cooperation with other Regional Health Authorities or District Health Authorities, I refer to my comments above. By way of amplification, I would point out that we had no dealings with District Health Authorities other than the Newcastle District Health Authority in connection with haemophiliac patients. The reason for this was that other District Health Authorities in the Northern Regional Health Area possessed sub centres for haemophiliac patients, the main Reference Centre being based at Newcastle upon Tyne. It was very much Dr Jones' policy to ensure a central control for the treatment of haemophiliac patients. As I have already explained, the purchase use of Factor VIII blood products was entirely a matter for Dr Jones and his staff.

With regard to contacts with other Regional Health Authorities, from time to time, we would have regular, but informal, contacts with the Directors of other Regional Blood Transfusion Services, and their staff. For example, I would attend at symposia or meetings to discuss particular problems, for example, a patient with a very rare blood group. The Scottish Blood Transfusion Service was an entirely separate organisation concerned with the provision of a service to Scotland as a whole. Representatives from the Scottish BTS would attend the regular meetings of the Regional Blood Transfusion Directors. The meetings of BTS Directors were of an informal nature, in the sense that the meetings did not of themselves have executive authority to implement any agreed decision.

In answer to the question as to what "special regard" I had for haemophiliac patients, these were simply regarded as patients who needed blood products. There was nevery any reason for

haemophiliac patients to come to the Regional Transfusion Centre. For obvious reasons, they could not be considered as blood donors. There was never any facility for the treatment of haemophiliacs at the Regional Transfusion Centre, and indeed, this was never the purpose of the Transfusion Centre at any point.

With regard to the question as to whether consideration was given to the formation of a National Blood Transfusion Service, I would say that there were discussions on this subject within the meetings of Regional Transfusion Service Directors. In favour of a "national" blood transfusion service, it was felt that such a Service would release the local blood transfusion services from the need to refer to the parent Regional Health Authorities, before decisions could be made about future planning, etc. To this extent, the blood transfusion services in England and Wales would be placed on the same footing as the Scottish Blood Transfusion Service. As against that, however, there was concern that the Blood Transfusion Service would end up as a "second class" blood factory and would lose interesting work in the areas of tissue typing and ante natal care. On balance, the Regional Transfusion Directors seem to think that the establishment of a National Blood Transfusion Service would not be a bad idea, subject to reservations.

In answer to the question as to assessments made by me about the need for Factor VIII and Factor IX blood products, I would say first of all that the Regional Transfusion Service did not make such assessments. We were simply given targets to meet. The targets were formulated as a result of assessments made by the Central Blood Products Laboratory at Elstree, and the Haemophilia Directors. I would then calculate the amount of blood plasma required to meet a particular target, and would ask the Regional

Health Authority for the necessary funding to enable the target to be met. As I have explained above, planning was done an annual basis, and was the subject of my Annual Report to the Regional Health Authority.

In answer to the question of setting of targets, as I have explained these were set by the Central Blood Products Laboratory at Elstree and the actual targets are referred to in the report by Dr Lloyd dated 3rd October 1986. In 1983/84, the target was 9,300 kgs of fresh frozen plasma. This gradually increased, as follows:

1984/85	11,500 kgs
1985/86	14,570 kgs
1986/87	20,150 kgs
1987/88	25,730 kgs
1988/89	28,000 kgs.

As to the question "who monitored the targets?", I do not think that an individual stood on one side and estimated whether a particular target was too high or too low. For the reasons I have mentioned, the Northern Regional Transfusion Centre was not able to meet the production targets set for it, and this was particularly true of the time when we were transferring from the old to the new premises, when there was a disruption in production for obvious reasons.

In connection with the question as to whether there were targets set for the collection of blood, the position was that the Northern Blood Transfusion Service used to set its own targets for blood collection and generally, we were able to meet those targets. The setting of targets for the collection of blood was mentioned in the Annual Reports to the Northern Regional Health

Authority, which summarised what had happened in the preceding year and what was needed for the following year by way of service developments, etc. I believe that the Annual Reports will be held by the Regional Health Authority, if they have not now been destroyed.

With regard to the question about a target in June 1978 of 15 million international units, I have no idea who set this target, nor who advised that the target was too low. At that time, I would not have been involved with such matters since my predecessor, Dr Murray, was the Director of the Northern Regional Transfusion Service.

With regard to the question about additional money for increased Factor VIII production from 1975 onwards, I believe that the Regional Health Authority would have details about such funding. I think it must have been the case that additional funding was given, because the basement at Newcastle General Hospital was converted to a blood products department, equipped with refridgerated centrifuges. The intention was to increase blood plasma production and platelets production. Apart from this, not a great deal was done from 1980 onwards to increase blood plasma production because of the restrictions imposed by the old premises. I should emphasise, in addition that Factor VIII was something which was only dealt with at the Central Blood Products Laboratory.

With regard to contacts with the Scottish Blood Transfusion Service, our contacts were on a purely informal basis and I did not obtain any blood or blood products from the Scottish BTS at any stage.

With regard to the question about the size of donor pools for

the production of Factor VIII and Factor IX from 1977 onwards, I cannot comment. The Northern BTS used to pool fresh plasma into 5 litre bags which would comprise 20 or so individual blood donations. These bags were then frozen and sent to the Central Blood Products Laboratory. I cannot say if there were any changes in the size of the donor pools and it was not a matter for the Blood Transfusion Service to give consideration to changing the size of the donor pools. I do not know if NHS donor pools ranged from 200 to 760 and cannot say if the comparable figure for a donor pool for commercial Factor VIII was in the order of 2500 or more.

In answer to the question about home production of Factor VIII, I would reiterate that all of this was done at the Central Blood Products Laboratory and the question as to whether an attempt was made to increase Factor VII production is not therefore applicable to the Northern BTS. I can, however, point out that in October 1980, the Government approved a figure of £1.3 million for the short term upgrading of the then Blood Products Laboratory, and a modest increase in production. At the same time, the DHSS was encouraging RHAs to increase the supplies of blood plasma to the Blood Products Laboratory. There was discussion with a view to collaboration between commercial and industrial organisations and the Blood Transfusion Service, with a view to the provision of more fractionation facilities.

So far as concerns the question of consideration given to the use of heat treated blood products, I would point out that I had no part in deciding what material was to be used. As to the merits of heat treatment, I would add that this can change the structure of some molecules with the result that preparations of Factor VIII could be reduced in an activity. Clinical trial were therefore essential to measure any change in clinical

effectiveness, antigenicity and sollubility.

With regard to the success of heat treatment of Factor VIII in removing the risks of hepatitis or HIV, I would say that the HIV virus is more susceptible to heat than are the hepatitis viruses. Different forms of treatment/purification are being evaluated.

So far as concerns the heat treatment of albumen, I confirm that this substance is heat treated. Albumen is produced at the Central Blood Products Laboratory. I cannot say when the heat treatment of albumen started. I would add that albumen is a very stable material, and it is recognised that these solutions do not transmit active viral agents.

In answer to the question as to whether consideration was given from mid-1982 to the risk of HIV contamination, I would confirm that consideration was indeed given to this risk.

In answer to the question "Is clotting concentrate the same as Factor VIII or Factor IX?", I would say that this is not so.

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In answer to the question "Is clotting concentrate the same as Factor VIII or Factor IX?", I would say that this is not so.

With regard to the availability in West Germany of heat treated concentrate from 1980, I am unable to say if this was so, nor can I say if heat treated clotting concentrate was available in the United States from 1982.

I did not commission, encourage, or take part in any research into the development of heat treatment of Factor VIII or Factor IX. I did no use heat treated Factor VIII of Factor IX from 1980 (because of the risk of hepatitis), for reason that I had no direct clinical involvement with haemophiliac patients - for the reasons already mentioned above.

In answer to the question as to when I appreciated that some people were higher risk blood donors than others, I would say that high risk groups became apparent in the early part of the 1980's, as AIDS became clinically defined. The categoris of donors who are in the higher risk group comprised homosexuals, intravenous drug abusers, persons who have lived in sub-Sahara Africa, prostitutes (male and female), men and women who have had sex with anyone in these groups, and the sexual partners of haemophiliacs. With regard to the risk of contracting hepatitis from Factor VIII, as alleged in paragraph 23 of the Main Statement of Claim, I have no information on this subject.

Signed : .....

Dated : .....