

Dr Lee of

will state:

I am the Regional Director of the North Western Regional Blood Transfusion Service, and have been since April 1989 (acting Director since October 1988). From the 1st January 1976 until that time, I had been appointed to Lancaster Transfusion Centre as Consultant in Charge which was the equivalent of sub-director. This is a largely autonomous Centre operating within regional targets for blood and plasma collections. This appointment included sessions at the Royal Lancaster Infirmary as a Consultant Haematologist and this statement is concerned mainly with this clinical role and only occasionally, where appropriate, with my Blood Transfusion duties as Regional Transfusion policy was established by the Regional Transfusion Director.

On appointment at Lancaster, I was asked to organise the treatment of haemophiliacs which was at that time fragmented. This has been divided between three physicians and there was no unifying consultant. There were five or six severely affected patients in the District requiring regular treatment.

Because there was always the doctor on call at the Transfusion Centre, I arranged for the haemophiliacs to attend the Centre if they needed treatment. I organised a roster for the treatment of the patients and I also saw them periodically for a review of their general health, the state of their joints, etc, in an Outpatients appointment. Initially almost all the treatment was based on cryoprecipitate. As Factor VIII Concentrate became available, the patients were trained in home treatment. I still saw these patients in Outpatients approximately once a year or when they came in to pick up Factor VIII or alternatively came in for treatment either for a bad bleed or for some other reason so that despite there being only occasional formal appointments, there was in fact regular contact. I severed my links with the patients when

my present appointment was ratified in April 1989. Therefore, in all, I knew these patients very well from approximately 1977 until 1989.

Lancaster is an associate centre which deals primarily with treating haemophilia at a basic level. For most other problems the patients are referred to the haemophiliac reference centre. In this region Manchester is the haemophiliac centre at which all aspects of haemophiliac care can be undertaken.

I have read the statement of claim compiled and served in the HIV Haemophiliacs litigation and would answer the questionnaire based on this approved by the consortium for common proofs as follows: (It should be borne in mind that I shall answer questions directed to the Blood Transfusion Service where appropriate as well as those directed to haemologists treating patients with Haemophilia.)

Paragraph 91

I carried out no research with reference to HIV or hepatitis with haemophiliacs.

As far as co-ordination/co-operation with other RHA's or DHA's within my region was concerned, the main link I had was with the Manchester Haemophilia Reference Centre though we had one patient who was referred to Oxford. I attended periodic meetings which Dr Wensley would organise, perhaps annually, which provided an update. More recently, Dr Gunson held meetings concerning the purchase of heat-treated Factor VIII through the budget held at the Regional Transfusion Centre. I also had the opportunity to attend the annual meetings of the Haemophiliac Directors.

In 1980 the new haematologist at the Royal Lancaster Infirmary joined in the roster for emergency treatment, but I retained my earlier role and remained in frequent and direct touch with the haemophiliacs in the District. Although the patients would normally ring the Transfusion Centre when needing treatment, and the Centre would then divert the call to whoever was on duty that night or weekend, some patients did in fact have my home telephone number and they knew that I was available to advise and care for them.

By comparison to my other patients, I had a more intimate knowledge of my haemophiliacs' personal circumstances, and I used to spend much more time with them. I was committed to them as people as well as patients. The total number of patients between 1977 and 1989 would be approximately 10.

An additional commitment was to provide treatment for visiting haemophilia patients. Several years ago, the North West branch of the Haemophilia Society purchased a static caravan sited close to Lancaster and I agreed to receive advance information about visiting haemophiliacs and to provide treatment if necessary.

Paragraph 91(b)

See above

Paragraph 92(b)

Since 1975 I have not seen the assessment of the Regional need for Factor VIII or Factor IX as my role since the amount that was

used in Lancaster was small compared to Manchester. We received as much Factor VIII as was required for treatment on demand and later for home treatment.

Paragraph 92(e)

See 92(b)

Paragraph 92(k)

I was in the hands of Dr Wensley for the consideration given to the use of heat treated Factor VIII and IX. The supply of NHS Factor VIII and the purchase of commercial Factor VIII was channelled through Manchester. Most of the material used in Lancaster was from NHS sources. We believed that this NHS product was less likely to be contaminated than imported products. One positive step which I took was to try to make sure that individual patients were exposed to as few batches as possible.

Albumin has been heat treated since around 1973. It has been well recognised that heat treatment could be used to kill viruses. However, Factor VIII is a labile protein and was until recently believed very difficult to heat successfully.

I have no ideas as to what was available by way of blood products in West Germany.

I do not know whether heat treated clotting concentrate was available in America in 1982.

Paragraph 92(l)

I carried out no such research.

Paragraph 92(m)

Heat treated Factor VIII and Factor IX concentrate were used as soon as these were available to me.

Paragraph 92(n)

We used NHS Factor VIII for all my patients except one or two. That reflects the privileged position that Lancaster was in in being able to get almost all our supplies as BPL Factor VIII.

Paragraph 92(o)

We had had occasion to treat two patients with commercial concentrates who in the past who had received large quantities of Factor VIII. For example, one patient broke his leg and he was on daily doses of Factor VIII. So when commercial concentrates had to be used again it was offered to those two patients if we needed to give it to anyone.

I relied completely on Dr Wensley's decisions in so far as steps taken to ensure the use of heat treated Factor VIII or IX in place of non-heat treated factors.

The only commercial advantage of using NHS Factor VIII at that time was that it was provided free of charge.

Paragraph 92(p)

I think I started using small amounts of imported heat treated Factor VIII from late 1984. The supply came from Dr Wensley. This can be verified from the relevant stock inventory records which are available. Another book entitled "The Cryo Pooling Book" records the batch number of Factor VIII concentrate (originally recorded the serial number of the cryoprecipitate) used for each treatment episode.

Paragraph 92(w)

I have been aware that haemophiliacs were at risk of acute hepatitis since 1966 when I first became involved with them. I do not know when I became aware that commercial Factor VIII had a higher risk. This was a risk faced by anyone who received blood or a blood product.

I believe that I first appreciated the risk of chronic hepatitis to haemophiliacs from Factor VIII and IX in the mid 70's because a colleague in Sheffield was interested in liver damage to haemophiliacs. Any treatment with blood products carried the risk of hepatitis. It could have been obtained from the cryoprecipitate and was indeed passed on in this way.

Paragraph 92(x)

I was not directly involved in treating haemophiliacs in the early 1970's so I did not know how much imported Factor VIII was used. At this time I was mainly a transfusionist and remained so until

I commenced my post at Lancaster. From 1977 the imported Factor VIII and its path from Manchester to my patients is fully documented. I obtained the Factor VIII from Manchester.

I determined its use (only occasionally when necessary) when supplies of NHS Factor VIII were not available in sufficient quantity, for example a particularly severe bleeding episode in a particular patient.

In so far as the extent which I used non-heat treated Factor VIII is concerned, I used it exclusively until late 1984 and then used the commercial heat treated product as it became available in Manchester. From April 1985 I believe that I used exclusively the heat treated product.

I can certainly now tell whether a patient received non-heat treated products or not from the two books which I have mentioned above during this period.

Concerning advice which I gave to colleagues, I would have discussed arrangements with but not advised David Gorst, the haematologist in Lancaster.

There was a swing back to cryoprecipitate being administered to children and mildly affected adults in the early 1980's because of the risk of hepatitis. Dr Wensley has indeed always been a powerful advocate of cryoprecipitate,. It is a harder product to make and to administer than Factor VIII, but his thoughts were that yields of cryoprecipitate over those of concentrate are

roughly 70% compared to 20%, and the risk of transfused viruses are certainly less. He would advise this constantly at haemophiliac directors's meetings, and I remember that he was very much alone on this point at one time.

Paragraph 92(y)

I became aware of the emergence of HIV/AIDS when the virus was identified as HTLV III when those papers were published concerning strange illnesses amongst homosexuals. I cannot remember what the papers were called.

I cannot exactly recall when I became aware of AIDS; my recollection is of an evolving story from 1981 onwards.

Paragraph 92(z)

I kept myself informed by journals and discussions with colleagues, transfusion directors' meetings and minutes of Haemophilia Directors Meetings.

Paragraph 92 (aa)

I did become aware of the connection between AIDS and blood products but I cannot remember when. I relied on the meetings of the haemophiliac directors and contact with Dr Wensley for new information since my role was to treat Haemophilia patients rather than to make policy.

I try to read the leading articles in The Lancet every week, and believe that I would therefore have read articles on 15th, 22nd and 29th January 1983.

Paragraph 92(ac)

We only used imported non-heat treated Factor VIII as a second line of treatment - it was never the treatment of choice. It was not used for children and mildly affected patients.

I have already given full details of the treatment with cryoprecipitate above.

I can remember advising patients who received either of these products that whatever the risk of the treatment was, it was less than the risk of non-treatment.

Paragraph 92(ag)

Both my patients who sero converted at Haemophilia of such severity as to make Factor VIII concentrate the only appropriate treatment.

I started using commercial heat treated Factor VIII in Lancaster in November 1984 and started using home produced heat treated Factor VIII in April 1985 as soon as it was available.

I cannot remember receiving any advice in November 1983 from the Department of Health.

The Haemophilia Reference Centre Directors indeed gave advice on 13th May 1982 on the use of Desmopressin for mildly affected patients and for the use of British products for children on which I acted.

Paragraph 92(ag)

Cryoprecipitate was used for children and mildly affected haemophiliacs. I have not used Desmopressin.

Paragraph 92(ak)

Patients were advised of the risk of HIV infection when it was agreed by the Haemophilia Directors that this was appropriate.

Paragraph 92(am)

Such advice was not appropriate to the patients under my care. These people were seriously crippled. Amongst the patients I had then were one or two children and other than that they were all people with long experience of their problems who had lived their lives against a constant background of advice concerning behaving sensibly.

Paragraph 92(an)

I have never prescribed Factor VIII prophylactically.

Paragraph 92(bh)

All my haemophiliac patients were tested for HIV infection after appropriate counselling, and that included a full discussion culminating in the patient deciding whether or not they wished to know the results. We were encouraged to test each patient by the Haemophiliac Directors.

Paragraph 92(bi)

Two patients proved to be HIV positive. One did not wish to know and I saw the other personally and explained the full implications.

Paragraph 92(bj)

One patient was unmarried and celebateg. I tested the wife of the patient who was married, preceded by joint counselling with her husband.

Paragraph 92(bm)

I undertook the counselling of these patients personally. The counselling was in the form of a full and frank discussion.

Paragraph 92(bp)

As I said above, appropriate counselling was carried out.

Paragraph 92(bg)

I have already included the patient's intimate (wife) in my answers.

Paragraph 92(bt)

None of the children were tested positive. Only one severely affected patient was a child and I counselled the father fully. I remember getting involved with and talking to the headmaster in order to provide the appropriate reassurance when public understanding of the virus was causing worry in the school.

Signed

Dated