IRISH HAEMOPHILIA SOCIETY

TRIBUNAL NEWSLETTER

ISSUE 36

CONTENTS:

18.7.01

TRIBUNAL OF INQUIRY

(Into the Infection with HIV and Hepatitis C of Persons with Haemophilia and Related Matters)

PROCEEDINGS: Monday 18th June 2001 - Day 146

Dr. Morris, senior pharmacist for the NDAB since 1987, continued his evidence. He was asked whether or not he thought freeze-dried cryoprecipitate, fractionated from small pool donors by the BTSB, would have required a product authorisation. He said it was his understanding that it would not. However, he agreed that there was nothing in the legislation from which he could draw this conclusion.

Dr. Morris was then cross examined by Mr. Giblin for the I.H.S. Dr. Morris agreed that there was a breakdown of communications and a poor relationship between the NDAB and the BTSB; the BTSB were unwilling to submit themselves to the jurisdiction of the NDAB.

Mr. Clarke for the BTSB asked Dr. Morris, what steps would have had to be taken by the BTSB if they were seeking a product authorisation for a heat treated product. Dr. Morris agreed that the BTSB would have had to carry out clinical studies and provide the NDAB with the results of these clinical studies to show the efficacy of the heat treatment that was proposed. Dr. Morris said if the application was urgent the NDAB speeded up the process, but that it would take several months at least.

Mr. Aston for the NDAB then examined Dr. Morris. Dr. Morris told him that the NDAB was reactive; they waited for product authorisations to come in and generally didn't pursue companies or bodies to ensure that they had the relevant product authorisations. Dr. Morris agreed that while dry heat treatment didn't necessarily entirely inactivate NANB hepatitis, it did have the effect of reducing the clinical symptoms.

In relation to the solvent detergent viral inactivation process, Dr. Morris agreed that a product authorisation had been granted for a product using this method in 1984. In relation to viral inactivation of NANB by heat treatment, Dr. Morris was asked whether the super heat treating at 80 degrees Centigrade for 72 hours was well known in the 1980s. Dr. Morris said that prior to 1988 it was not; in 1988 an article was published in The Lancet explaining super heat treatment. Dr. Morris said that the NDAB would normally implement some regular quality control as a result of scientific information published in medical journals. Dr. Morris said that after 1988 there was no further application by any party for a heat treated product, and the only product authorisations that were granted after this date were for the product which used the pasteurisation viral inactivation or solvent detergent method.

In the afternoon, Brendan Murphy of the NDAB was examined. He was the secretary of the NDAB from April 1974. Mr. Murphy described the issue of the product authorisation for the non-heat treated Koate in 1985 as an administrative error. He said he could give no other explanation for how the product authorisation was issued. Mr. Murphy then went on to describe in general how the NDAB was under funded and under resourced. He also described how the volume of work increased rapidly through the 1980s, and how the personal load of work adopted by Dr. Scott was enormous.

The Tribunal then adjourned until Thursday 21st June. This concluded the hearing of evidence from witnesses from the NDAB.

PROCEEDINGS: Thursday 21st June 2001 - Day 147

Expert evidence began today. Prof. Keith Hoots, Professor of Paediatrics at the University of Texas, gave evidence. His specialty was Paediatric Haematology. Prof. Hoots said that he had been treating people with haemophilia in the United States between 1979 and 1986. By the end of the 1970s, NANB Hepatitis had clearly been identified as a condition, however the virus had not been identified at this stage.

Some time around the turn of the 1980s fractionators began to look for ways to inactivate the NANB virus and prevent its transmission in factor concentrates. One of the difficulties in attempting to do this, Prof. Hoots said, was trying to ascertain whether the virus had actually been eliminated, since it could not be tested for. The only way to tell whether it had been eliminated was to do clinical studies. One way to do this was by giving the product to primates to see if they subsequently developed the symptoms of Non-A, Non-B Hepatitis.

Prof. Hoots described how in July 1982, the CDC (Center for Disease Control) in the U.S., reported cases of three people with haemophilia who were thought to have contracted AIDS. By the end of 1982 there was a total of eight reported cases. Prof. Hoots said that people with haemophilia at this time were like canaries in the mine shaft. Because they were using factor concentrates over and over again, they were being exposed to literally tens of thousands, and even hundreds of thousands, of individuals in the population whose donations had been obtained. If there was something in the blood supply that was potentially infectious, they would be the first to suffer the effects of that infection. At the same time, Baxter Pharmaceutical Co. had developed a heat treatment method which they claimed would inactivate or greatly reduce the Hepatitis B virus in factor concentrates. They made these claims on the grounds that treated factor concentrate given to chimpanzees did not cause the primates to develop Hepatitis B as quickly as it would normally have done. At this stage, of course, there was no way of knowing whether heat treatment would be effective against HIV, since the HIV virus had not been isolated and the cause of AIDS wasn't known at that time.

Prof. Hoots said he became aware in March 1983 that a licence had been granted to Baxter to market their heat treated factor concentrate product, Hemofil T. One of the main difficulties in using the heat treated factor concentrate was that there was an increased cost. Prof. Hoots described how he looked at the risk/benefit ratio in relation to using the heat treated product. Firstly, he considered there was a danger that inhibitors could develop in patients using heat treated product. Secondly, there was increased cost. However, on the other hand he said that there was a suspicion that AIDS was caused by a virus, and it was now believed that certain viruses could be inactivated by heat treatment. Taking that information into account, Prof. Hoots decided to give his patients heat treated factor concentrates. He said he didn't want to be the one who would look back and say, "well, if only I had done that then I might have been able to prevent some cases of AIDS".

With the introduction of the heat treated product, Prof. Hoots said that he didn't recall the non-heat treated product. He said he didn't do this, because he didn't know whether or not there was going to be any benefit from using heat treated product, so the transition was gradual rather than instant.

In relation to young children who had not been exposed to factor VIII, Prof. Hoots said that he made a conscious effort to try and treat them with cryoprecipitate only. The reason this was done was because cryoprecipitate was made from a single donor as opposed to large donor populations, and he believed that this would reduce the risk of viral infection. For Haemophilia B patients, he said that he tried to use fresh frozen plasma as opposed to factor IX concentrate.

Prof. Hoots said that he began making the switches in Autumn 1982. He said he gave his patients an informed choice as to whether they wanted to use cryoprecipitate or heat treated product as opposed to the unheat treated product. He said in relation to children it wouldn't always be possible to treat them with cryoprecipitate only. In certain circumstances the amount of factor VIII required to stop bleeding would be greater than that would be permissible to get from cryoprecipitate. Prof. Hoots described one unfortunate episode where a small boy began to develop a target joint, when his knee began to bleed. He was afraid the little boy would lose the use of his leg, so severe was his condition. He said that they decided to perform surgery on him and switched him to cryoprecipitate. In February 1983 they successfully carried out the surgery and treated him post-operatively with cryoprecipitate for five days. However, on the sixth day the boy fell into a life-threatening situation when the cryoprecipitate failed to work, and he was forced to change back to factor concentrate. However, tragically, the child became infected with HIV as a result of this change to factor concentrate.

Prof. Hoots said that they were aware of the risk of increased thrombogenicity by heat treating the factor IX. However, he said that by that time in 1983, the risk of AIDS had become so profoundly manifest that the risk benefit for heating seemed to far exceed some theoretical risk of extra clotting.

Prof. Hoots described how clinical assessment of patients was carried out. They examined the lymph node enlargement which might occur in the neck, under the arms, above the clavicle and in the groin; they examined whether there was an enlargement of the liver or spleen, and looked for clinical symptoms such as fever or night sweats. Prof. Hoots also took blood samples at this stage; those samples were subsequently used to do a retrospective study in 1984. Some of the samples were used to help develop the ELISA test, which was manufactured or developed by Abbott Laboratories. The results of the retrospective study showed that there was little evidence that any patient had seroconverted after they had received a heat treated product.

In relation to the pool size for manufacturing factor concentrate, Prof. Hoots said that there was an economy of scales issue. If you decrease the pool size you increase the cost. On the other hand, if you increase the pool size there is a greater safety risk.

Prof. Hoots described the precautionary principle to the Tribunal. This is the principle that is used when you are dealing with an unknown risk for a medication. If there is a known array of strategies to potentially reduce that risk then you should, if you apply the precautionary principles, employ them in order to reduce, if not eliminate, the risk. If you have a germ in a product or a medicine that is theoretically there, and you have a series of steps you can take which theoretically would reduce the risk for that germ, then you should not delay in employing those steps.

Prof. Hoots was then examined by Mr. Frank Clarke for the BTSB. Prof. Hoots agreed that it was only in October 1984 that consensus was reached that heat treated factor VIII should be used instead of non-heat treated factor VIII. In 1982/1983, when Prof. Hoots started using heat treated factor VIII, his activities went against the general consensus in the U.S. at the time. Prof. Hoots also said that there was no general recall by him on non-heat treated product when he introduced the heat treated product.

Prof. Hoots was then examined by Mr. Bradley for the Irish Haemophilia Society. Prof. Hoots agreed that freeze dried cryoprecipitate would be much safer than commercially manufactured concentrates, because the donor pool size would be greatly reduced. He said that freeze dried cryoprecipitate would have been convenient to use. The use of freeze dried cryoprecipitate, had it been available in the U.S. in 1983, would have been a very attractive treatment option.

Looking at epidemiological studies, it was fair to say that a high incidence of Hepatitis B in the population would allow a link to be made between Hepatitis B and AIDS. The high incidence of

Hepatitis B could well indicate that there was a strong risk of AIDS as well. It would have made sense to exclude donors who tested positive for Hepatitis B in the early 1980s, because you would also then be excluding donors who would probably test positive for HIV.

After Prof. Hoots had completed his evidence Mr. Hayden, for the I.H.S., made an application. The application was based on a submission which was delivered on the previous date of the Tribunal. The basis of this submission was that the I.H.S. and other parties had only been furnished with statements and supporting documents that expert witnesses were going to rely on in the course of their evidence over the coming weeks, at the very last minute. Statements had been delivered on Monday prior to the beginning of Prof. Hoots' evidence on Thursday, however it was clear from many of these statements that the Tribunal had had them in its possession for many months, in some cases as early as May 2000. The I.H.S. said that it was at a grave disadvantage in being in a position to cross-examine witnesses, having only received the statements a couple of days before the expert witnesses began, especially in circumstances where the statements had been in the possession of the Tribunal for many months. Mr. Hayden said the lack of ability to prepare adequately for the expert witnesses was made worse by virtue of the nature of the evidence to be given; it was of a highly technical nature and the I.H.S. should be given an opportunity to get expert advice on it.

The application was refused by the Chairperson. She said that the I.H..S. had been given over a month's notice of this section of evidence. She said that there was a schedule that had to be kept to, and she could not accommodate the I.H.S. by adjourning any of the witnesses. The Tribunal then adjourned.

Dr. Albert Prince, virologist and head of the Lindsley F. Kimball Research Institute in New York, gave evidence. Dr Prince has a huge amount of experience in dealing with Hepatitis C and other Hepatitis viruses. Dr. Prince described tests he had carried out on patients who had been transfused with coagulation factor concentrates. He identified the existence in these patients of Non-A, Non-B Hepatitis by examining raised ALT levels. He also said that serious long-term difficulties could not be ruled out from infection with Non-A, Non-B Hepatitis. Dr. Prince said that from the information that was available from the early 1980s, it was clear that there was almost 100% infection with NANB Hepatitis by using commercially developed coagulation factor concentrates.

Dr. Prince was asked whether he agreed that there was no way of screening donors, either by their blood or plasma, to ascertain whether they might be infected with NANB virus in the early 1980s. Dr. Prince said while there was no specific way of doing that, there was the means of testing for ALT, which he thought was a useful way of essentially testing for liver abnormality and was a surrogate test for infection by Non-A, Non-B. Dr. Prince advocated at the time in the early 1980s using ALT tests as a surrogate test for donors.

Dr. Prince said that 1983 was the year that solid information became available that there was a serious risk of infection with AIDS by the use of coagulation factor concentrates. Dr. Prince said while he favoured the ALT testing as the surrogate test for Non-A, Non-B infection, he did not agree that there was any suitable surrogate test available for HIV in the early 1980s. Dr. Prince was asked about tests which were done on chimpanzees who had been given heat treated factor concentrates. The results of the tests suggested that heat treatment of factor concentrates reduced the dangers of hepatitis viral infection post transfusion. However, no claim was made about the viral inactivation of the virus which was thought to cause AIDS.

Dr. Prince was then asked about a subsequent trial and the publication in the Lancet in July 1985 which shows that the original tests done on chimpanzees were not conclusive. In clinical trials, patients given heat treated factor concentrates still went on to develop NANB Hepatitis. Dr. Prince said that the reason the chimpanzee study was inaccurate was because of a design flaw in the study, in that the amount of virus that was used to spike the factor concentrates given to the chimpanzees was too low. The level of NANB infection in factor concentrates commercially produced was much greater; heating at 60 degrees Centigrade did not appear to be effective against transmission of Non-A, Non-B Hepatitis.

Dr. Prince was then asked about tests carried out for CDC (Centers for Disease Control) in the US, by McDougal in 1984. These tests were measuring the effect of heat treating factor concentrates and the inactivation of the HIV virus. These tests showed that heat treating at 60 degrees for one hour inactivated 90% of the virus in the factor concentrates. However, Dr. Prince said that unfortunately the results of these tests were extrapolated in a linear way; it was presumed that if 90% of the virus was inactivated in one hour, that 100% at least would be inactivated in two hours. However, Dr. Prince said what they didn't realise was that the first hour of heat treatment was by far the most effective, and that there was a diminishing return in every hour subsequently. Dr. Prince said that this is what is called the resistant fraction, and that unfortunately McDougal didn't keep that in mind when he extrapolated his data. Dr. Prince said that the McDougal study influenced the commercial companies so that they believed that this heat treatment method, 60 degrees, was safe.

Dr. Prince said that he was asked to do some tests in respect of dry heat treatment of factor concentrates by Armour. He said he began in January 1985 and worked on Armour's commercial factor VIII products.

He said they spiked the factor concentrates with the HIV virus and then exposed it to heat for different periods of time, and measured the residual infectivity of the virus. He said that the results of the test show that heat treating at 60 degrees Centigrade for 30 hours was ineffectual. In fact heat treating at 60 degrees Centigrade for any number of hours was ineffectual in completely removing or inactivating the virus. Dr. Prince said that he submitted the results to Armour, but that Armour would not permit Prince to publish his results. It should be remembered that Prince has carried out tests proving out that the viral inactivation method used by Armour was clearly ineffectual. However, Armour refused to allow Dr. Prince to publish his results. Dr. Prince, in order to get around this obstacle, went off and carried out the same tests himself in his own laboratory, and was then able to publish the results in the Lancet in 1986. The publication of his results coincided with the seroconversion of patients who were using heat treated Armour factor VIII product.

In relation to NANB Hepatitis, Dr. Prince agreed that during the 1980s and between 1979 and 1986, the knowledge was building up about the potential seriousness of the infection. Dr. Prince said that the discovery of a test to identify the Hepatitis C virus was not significant or crucial in relation to virally inactivating the virus. He said that it was possible always to do studies on chimpanzees to assess the effectiveness of viral inactivation of NANB Hepatitis, without having a specific test.

Dr. Prince then described the solvent detergent method of viral inactivation which he developed. He said that the solvent detergent viral inactivation method was discovered by chance. Some viruses have lipid envelopes and others have a protein envelope. A classic way to test whether the virus has a lipid envelope or a protein envelope, is to expose it to detergent. This was done, and the material which had been treated with detergent was given to chimpanzees and subsequent studies showed that the chimpanzees did not develop, or were not infected with, NANB Hepatitis. Having made this discovery, they then went on to test its effectiveness at inactivating Hepatitis B and HIV virus, and were delighted to discover that solvent detergent worked. It was also interesting to note that the yield remained essentially 100% throughout all solvent detergent treatment. The licence for this solvent detergent process was granted by the FDA in June of 1985. Dr. Prince said that articles he published in 1987 and 1988, outlining the different methods of viral inacivation for coagulation factor concentrates, were aimed at, and should have been seen by, haemophilia treaters and regulatory bodies. He said that the time lag between the publication of such an article and the dissemination of the information into the scientific committee, would be very short, a matter of weeks he said.

Dr. Prince was then examined by Mr. Bradley for the I.H.S. Dr. Prince was asked about an information leaflet issued by Armour in 1986, which attempted to state that viral inactivation in the factor concentrates was achieved by heating at 60 degrees for 30 hours. Dr. Prince said that this information was not consistent with the discoveries he made in his own tests, or with the discoveries made by McDougal in similar tests carried out.

Dr. Prince was then given information about a letter written from Armour to Prof. Temperley, again stating that the viral inactivation method used by Armour was sufficient to kill the virus, and advocating the safety of the product. Dr. Prince agreed that there was nothing in the correspondence which should have caused Prof. Temperley to have concern in relation to the safety of the Armour product. Dr. Prince said that the information in this letter would be largely at variance with the perceived knowledge of the day. Dr. Prince then agreed that creating products from small pools of donors would drastically reduce the risk of infection from Non-A, Non-B Hepatitis. Dr. Prince said, if they had stuck with cryoprecipitate we would not be meeting here today. Dr. Prince said that, from the day it was realised that untreated factor VIII pool preparations were highly infectious, a change should have been made to cryoprecipitate.

The Tribunal then adjourned to the following day.

PROCEEDINGS: Wednesday 27th June 2001 - Day 149

Mr. Bradley for the I.H.S. continued his cross examination of Dr. Prince. Mr. Bradley asked Dr. Prince whether there was reason for concern about the development of cirrhosis and hepatocellular carcinoma arising from the contraction of Non-A, Non-B Hepatitis between 1980 and 1985. Dr. Prince said that there was a paucity of clear reports on the matter. There were some letters to the Lancet but overall it wasn't considered seriously. However, Dr. Prince did say that the state of knowledge in relation to the risks associated with NANB Hepatitis such as it was, would certainly encourage the use of virally inactivated concentrate.

Dr. Prince went on to say that they decided to licence the solvent detergent process around the world at a very modest rate. They did so in order to allow volunteer blood banks and small fractionators to use it. He said that there was a large take up by fractionators of the process.

Dr. Prince was then examined by Mr. Michael McGrath for the BTSB. He agreed that prior to 1984, and even prior to 1986, that the major concern was HIV. Mr. McGrath asked Dr. Prince whether or not the super heat treating method 80 degrees Centigrade for 72 hours was approved by the FDA. He said that he was almost certain that it was not approved by the FDA because there was no application for a licence. It wasn't intended to sell a product in the States which was virally inactivated using a solvent detergent method. So therefore there would be no need for it to have a licence, and it would not then be approved by the FDA.

Dr. Prince was then examined by Mr Aston for the National Drugs Advisory Board. Mr. Aston asked Dr. Prince about the original tests which were done on chimpanzees when they were given heat treated factor concentrates. The chimpanzees developed Hepatitis B but not NANB Hepatitis. He then asked him about clinical trials on humans who had been given heat treated factor concentrates; conversely, they didn't develop Hepatitis B, but did develop NANB Hepatitis. When he was asked about this, Dr. Prince replied, "Don't blame the chimpanzees, blame the designer of the study". He said you could easily get a positive inactivation result if you don't use very much virus in the chimp studies. It is a question of how much virus you evaluate and what level of kill you can demonstrate. He pointed out that, while the chimpanzees received a limited amount of material, patients receive huge amounts of material in their everyday use of factor concentrates. Dr. Prince agreed that when AIDS was perceived in 1983 it did become a major concern. He also agreed that it was only when the AIDS problem settled down that the treaters and other professionals turned their mind as a priority to the question of Non-A, Non-B Hepatitis.

Dr. Prince was then examined by Mr. Nicholas Butler for Prof. Temperley. Dr. Prince said that the articles he had been referred to yesterday were articles which were published in scientific journals. These articles contained the results of his studies on the efficacy of heat treatment of factor concentrates. He said that not only were these articles aimed at medical professionals and treaters, they were also aimed at manufacturers. Not only were they aimed at the manufacturers, they were also aimed at all the staff employed by the manufacturers; microbiologists, virologists and specialists. He said they were also aimed at fractionators and distributors of product, such as the BTSB. Dr. Prince agreed that any one article that was published could not be taken as a blueprint for a treating method for a treater; any treater would have to take a whole range of issues into account.

Dr. Prince then concluded his evidence and the tribunal was adjourned to Thursday 28th June.

Prof. Leikola from the Finnish Red Cross Blood Transfusion Service, gave evidence today. Prof. Leikola described how in Finland the Blood Transfusion Service is run by the Red Cross. He said that it was a budgetarily independent operation. It has its own fractionation unit in Helsinki. He said the population of Finland is about 5 million, and prior to the 1980s he said that Finland was entirely self sufficient in producing its own plasma products. He explained how, in the fractionation process, they introduced a solution called SAG towards the beginning of the 1980s. He said that by using this additive you could increase the yield in your plasma fractionation process by 15% - 20%. He said that there were 106 patients with severe haemophilia A, 26 patients with moderate haemophilia A and 34 patients with mild haemophilia A. There were approximately 20 patients with haemophilia B. He said in Finland in the 1970s they had used freeze dried cryoprecipitate. This cryoprecipitate was manufactured from small pools of donors. Certainly there were never any donor pools larger than eight.

Prof. Leikola said that from January 1982 to August 1986, he worked for the League of Red Cross Society in Geneva. However, he said he has examined the documents in relation to Finland at that time, and he is in a position to give evidence based on those documents and based on his contacts with Finland.

He said that spring 1983 was really a decisive time. He said that in March or April there had been a meeting on AIDS in the United States, and it emerged from this meeting that blood could transmit the AIDS disease. It was at this time that he himself first became convinced that AIDS could be a real threat to the blood supply. He said on his return from his meeting from the US, a committee of experts for the Council of Europe put together a recommendation on how to deal with a threat of AIDS to the blood supply. He said he was a member of the group that drafted the recommendation. This recommendation ultimately became known as R80. He said there was a sense of urgency about the situation, and that the Council of Europe approved the recommendation very quickly in the circumstances. The thinking behind the recommendations was that the exposure of patients to the risk of a large number of donors should be reduced. Self sufficiency was seen to be a key to prevent that risk. He also said that the recommendations stated that it was important to inform physicians, and for physicians to inform people with haemophilia of the risks.

The first reaction in Finland was to organise meetings with groups which may contain high risk donors. They decided that this was a better method than producing a leaflet because the effectiveness of leaflets in discouraging donors was dubious. It would be very difficult for a donor arriving at a donor clinic having read a leaflet, then to leave.

Freeze dried cryoprecipitate made from small pools of donors was the product that was used in Finland to treat haemophilia A between 1980 and 1985. The Finnish Red Cross had started developing its own intermediate purity factor concentrate in the early 1980s. There was a growing demand for the use of factor concentrates, and although commercial factor concentrates could easily be imported from the US, there was a serious fear about the risks associated with the commercial factor concentrates from the US. This was because there was generally good knowledge about the risks. The Finnish medical community and the people with haemophilia refrained from using US factor concentrates. Prof. Leikola agreed that AIDS was not considered to be a problem for Finland in general at this stage. Like other European countries, the problem of AIDS was seen to be limited to North America, and in particular high risk areas like San Francisco and New York. He said that all information about the fear of AIDS was freely distributed to people, and in particular to people with haemophilia. He said that there was a very good relationship between physicians, treaters and people with haemophilia in Finland. The Finnish factor concentrate became available in April or May of 1984. There was a knowledge that there was a risk of infection even from Finnish generated factor concentrates. A very small group of patients were put on the

intermediate concentrate. It was limited to only those most severe haemophilia A patients. In that year, 1984, 17 patients in all were treated with the intermediate factor concentrate. The Finnish factor concentrates were generated from pools of about 800 donors, so the pools were nearly 100 times bigger than those for cryoprecipitate.

Towards the end of 1984 and the start of 1985, after the discovery of the virus by Gallo and Montagnier et al, the Fins started to heat treat their intermediate purity factor concentrate. Towards the end of 1984 they stopped distributing the unheat treated product. There was no recall of the product because of the fear that there wouldn't be sufficient product to go around. In Finland at this time roughly 90% of people with haemophilia would have been using cryoprecipitate. The use of cryoprecipitate continued right into 1987 and 1988 in Finland. Cryoprecipitate in Finland wasn't heat treated until about 1987. It was very difficult to heat treat cryoprecipitate, and although the CLB in Holland had developed a method of doing it, it was some time before the Fins managed to implement it. Overall, throughout the entire patients, only two patients in Finland became infected with HIV; both were haemophilia A patients. One infection occurred in 1983 and the other occurred some time in 1985. Retrospectively, the rate of infection with HIV in Finland is extremely low in comparison to other countries. The reason that it was low was that first of all, the Fins took measures very early on to reduce the risk factors by insisting on the use of cryoprecipitate rather than the use of coagulation factor concentrates. Secondly, the epidemiological situation in Finland was favourable at the time; the indigenous population had a very low incidence of HIV infection because there were very few intravenous drug users. Since Finland had a policy of self sufficiency, any infection that was going to come into the blood system and into the blood products, came in through the indigenous population. Prof. Leikola said that the low incidence of HIV infection in the Finnish people with haemophilia was largely due to the policies implemented which were prompted by the Council of Europe recommendations in 9183. There was about a 60% infection of people with haemophilia with Hepatitis C in Finland. There was concern about Non-B, Non-B Hepatitis at the time, but Prof. Leikola said they didn't know how dangerous the disease really was. He said the general policy was to try and avoid this type of infections, but they didn't realise to what extent the Finnish population were infected with Hepatitis C.

In 1991 the Fins moved to applying the solvent detergent method of viral inactivation.

Mr. Bradley for the I.H.S. examined Prof. Leikola. Prof. Leikola said that mutual trust between people with haemophilia and their treaters in Finland was very important. Prof. Leikola said there was no difficulty in meeting self sufficiency requirements;.he said that Finland had the lowest rate of HIV infection in Europe, followed by Belgium; Holland also had a low rate of infection. He said that, however, Holland could have had an extremely low rate of infection if it had not been for the high incidence of HIV infecion in the population at large..

The Tribunal then adjourned before lunch, to sit again on Tuesday 3rd July.