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TRIBUNAL OF INQUIRY

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

PROCEEDINGS: Monday 23rd July 2001 - Day 164

Today, Prof. Eric Preston was examined by Ms. Clohessy on behalf of the Tribunal. Prof. Preston was Professor of Haematology in Sheffield until January 2000, when he retired.

NANB Hepatitis

Prof. Preston worked in the Sheffield Haemophilia Centre, where he was assisted by Dr. Trigger, a Hepatologist. Prof. Preston said it was quite unusual at the time for a haematologist to have the backup of a professional hepatologist in the same unit. He said that this backup gave him a greater insight into what was occurring in terms of liver disease with people with haemophilia. He said that they studied abnormalities in liver function. He said that most people didn't really understand the effects of these abnormalities. Prof. Preston said that many people with haemophilia who were being treated with factor concentrates in the 1970s and early 1980s were showing abnormal liver function. However, that the abnormality in liver function didn't necessarily correlate directly with the underlying liver histology. He said it was known in the 1970s that chronic active hepatitis would probably lead to cirrhosis of the liver. Increased transaminitis in people with haemophilia was a small price to pay for the advantages of clotting factor concentrate. Prof. Preston said that it became clear in the early 1980s that there was an almost 100% chance of being infected with NANB Hepatitis by using factor concentrate. The general consensus in the very early 1980s was that, while NANB Hepatitis was persistent and chronic, it was not something that was considered to be very dangerous.

Heat Treatment

Prof. Preston said that in 1985 they used the National Health product 8Y as much as possible. They were aware that this product was likely to virally inactivate NANB Hepatitis. He said, however, that there was a shortfall of supply in 8Y product, and that in Sheffield they used an Immuno product which was made in Austria. Prof. Preston said that he had only treated adults in 1985 and it was impossible to tell whether or not the new heat treated products inactivated NANB Hepatitis. He said he didn't contemplate changing to treatment with cryoprecipitate in 1985. This was because he was only treating adults and most of them were severe haemophilia A patients. He said there was no guarantee that for those severe patients, cryoprecipitate would be sufficient.

Is NANB Hepatitis Progressive?

Ms. Clohessy asked Prof. Preston about a paper that was published by Prof. Mannucci in 1982. This paper suggested that NANB Hepatitis was not a progressive disease. Mannucci's paper indicated that NANB Hepatitis would not necessarily lead to chronic or severe liver disease. Prof. Preston said he was surprised at the conclusions drawn in this paper. He said that the paper was only based on a small group of patients, and then on only one biopsy taken from each patient. Prof. Preston said that he was aware in his own patients that there was a broad spectrum of chronic liver disease. Prof. Preston said that in Sheffield, by carrying out biopsies, they had demonstrated the progressive nature of NANB Hepatitis; the progression could be associated with cirrhosis and also hepatocellular failure. Prof. Preston said that certain factors influenced the rate of progression; alcohol accelerated the rate, as did co-infection with HIV.

Prof. Preston was then examined by Mr. McGovern on behalf of Prof. Temperley. Prof. Preston said that, to say that the scientific state of knowledge in 1985 was that NANB Hepatitis was not progressive was wrong. He said that that was one view held by some people. Prof. Preston said that it was in his own knowledge in 1978 that NANB Hepatitis was associated with a broad spectrum of liver disease, including cirrhosis. He said by 1982, he was aware that there could be a rapid progression of NANB Hepatitis to cirrhosis in patients with von Willebrand disease following a single exposure to clotting factor concentrates.

Prof. Preston was then examined by Mr. Bradley on behalf of the I.H.S. Prof. Preston reiterated his belief that in the late 1970s and early 1980s, it was known that NANB Hepatitis could progress. He accepted that there may have been two views, but it had always been his view that NANB was progressive. Prof. Preston said that his views about the progressive nature of NANB Hepatitis would have been known to treaters of people with haemophilia and would have been discussed.

Mr. Bradley asked Prof. Preston about the difference between his views and the views of Prof. Mannucci, and in particular the difference in results of studies carried out by both himself and Prof. Mannucci. Prof. Preston said that the results of the studies of Prof. Mannucci were based on very young patients. Prof. Preston said that they now know (but didn't know then) that the rate of progression is much slower in those that are infected with NANB Hepatitis in early childhood. Those who are affected in later life do not deal with the infection of NANB Hepatitis so well, and the progression is faster. The patients used in the Mannucci study were of a much younger age profile. Prof. Preston said that he believed this was why there was a difference in the results of the studies.

Super Heat Treatment

Prof. Preston said that in July 1985, he published an article in the Lancet. In that letter, he pointed out that in studies there was no transmission of NANB Hepatitis following use of the NHS factor concentrate product 8Y. This product, which had been super heat treated, did not transmit NANB hepatitis. Prof. Preston said it was clear from studies by Fletcher and others, that there was a 95%-100% chance of transmission of NANB Hepatitis using other factor concentrates.

Prof. Preston said that by 1987 he was aware that approximately 15 years after infection with Hepatitis C, 2% of patients rapidly developed cirrhosis. Prof. Preston said that in his view, it could be estimated that approximately half of those people who were affected with Hepatitis C would go on to develop cirrhosis of the liver. Prof. Preston then commented on studies undertaken by Prof. Lee, who was a haematologist working at the Royal Free Hospital in London. Prof. Lee's views were that only those people who were co-infected with HCV and HIV would go on to develop chronic liver disease. Prof. Preston said that he didn't agree with this view. He said that it was clear that HIV does accelerate the rate of progress from Hepatitis C infection to chronic liver disease, but he said the risk of liver failure and hepatocellular carcinoma was also present in those who were not co-infected.

The Tribunal then adjourned to Tuesday 24th July 2001, at 10.00am.

PROCEEDINGS: Tuesday 24th July 2001 - Day 165

Today, the Tribunal heard evidence from three witnesses. First was Dr. Terence Walsh from the BTSB. Dr. Walsh had previously given evidence and had been recalled to clarify part of that evidence.

BTSB

Dr. Walsh was asked to comment on the transcript of evidence given by Prof. Egan from Galway. Prof. Egan had given evidence on the 118th day of the Tribunal and Mr. Durcan, Counsel for the Tribunal, read out a portion of that transcript to the Tribunal. The portion of the transcript dealt with correspondence which had passed between Prof. Egan and Dr. Walsh. Prof. Egan had been asked whether or not he had indicated to Dr. Terence Walsh that one of his patients had become infected with HIV at the beginning of 1985 or at the end of 1986. Prof. Egan had said that it was inconceivable that he did not tell Dr. Walsh about this seroconversion. Mr. Durcan then asked Dr. Walsh, could he remember, in light of the evidence that had been given by Prof. Egan, whether or not he had had a conversation with Prof. Egan on 13th January 1986, during which he had been informed by Prof. Egan that one of his patients had been infected with HIV following the use of cryoprecipitate. Dr. Walsh said that he did not remember any conversation on those grounds.

Mr. Durcan then put the question in more general terms, and asked whether Dr. Walsh remembered being informed of any patient who had seroconverted following the use of cryoprecipitate. Dr. Walsh said that he had been made aware that a patient had seroconverted having used cryoprecipitate, and that he became aware of this information at the start of 1986. He did say, however, that this information was obtained from the National Haemophilia Treatment Centre. Mr. Durcan asked Dr. Walsh where at the National Haemophilia Treatment Centre he would have got this information. Dr. Walsh said that he probably would have phoned Prof. Temperley or his secretary and asked for information.

Mr. Durcan then referred Dr. Walsh to a letter which had been written by Prof. Egan to Dr. Walsh dated 14 January 1986. The letter began, "Further to our conversation on Monday 13 January, I would wish to have the following organised: Mary Kearney in our Blood Bank will be onto your staff about these matters, our present stock of non-HTLV-III screened cryoprecipitate to be replaced by HTLV-III screened cryoprecipitate. Mr. Durcan put it to Dr. Walsh that Prof. Egan had felt that it was inconceivable in the context of this letter, that he would not have informed Dr. Walsh that one of his patients who was using cryoprecipitate, had been found to be positive for HTLV-III. Dr. Walsh said that he felt it wasn't clear from the letter that Prof. Egan was certain that the patient who seroconverted had done so following the use of cryoprecipitate. He said that it was a reasonable request at this time to seek to have his stock of cryoprecipitate replaced with stock which had been screened for HLTV-III. Prof. Egan said that he would not have known at this point about the seroconversion of the boy who had used cryoprecipitate nor he would not have been informed of this by Prof. Egan. If he had been informed and if he did know, he would have informed the Chief Medical Consultant. Mr. Durcan went on to say that the discovery that cryoprecipitate had caused seroconversion had further implications, because the cryo supernatant which might have come out of the plasma could have been used to manufacture factor IX. Dr Walsh agreed that this was a possibility. Mr. Durcan put it to Dr. Walsh that the knowledge that cryoprecipitate had caused a seroconversion would make it all the more important to make sure that there was an effective withdrawal of non-heat treated factor IX from the market. Dr. Walsh agreed and said that it was difficult to put oneself back in the mindset of the mid 1980s; he said it would have been hard to try and identify where the infection came from and whether that blood had been used in the manufacture of factor IX.

Mr. Durcan then put it to Dr. Walsh that Prof. Egan's evidence was quite clear: He had informed Dr. Walsh of a seroconversion, Prof. Egan was only using cryoprecipitate to treat his patients at that time and

therefore he had effectively informed Dr. Walsh that there had been a seroconversion in a patient following the use of cryoprecipitate. Dr. Walsh said that he had no recollection of having been told that.

Mr. Durcan then asked Dr. Walsh whether it was a case that he did subsequently become aware of the seroconversion due to cryoprecipitate use. Dr. Walsh said that he had, and that this was the information he had got from the Haemophilia Treatment Centre. Mr. Durcan asked Dr. Walsh to explain what steps he took following his discovery that there had been a seroconversion following the use of cryoprecipitate. Dr. Walsh said that of course he wasn't certain whether or not the seroconversion had been caused by the use of cryoprecipitate; he thought that it may have been caused by the patient going away on holiday and becoming infected by some other cause. Mr. Durcan referred him back to the original question. Dr. Walsh said that they had asked for information ,and the information that he got at the time was that there was a probability that a patient had seroconverted due to the use of cryoprecipitate. Mr. Durcan asked him did he report that to the Medical Director. Dr. Walsh said that he did not.

Mr. Durcan asked Dr. Walsh was it not appropriate for him to have taken several steps when he learned that there had been a seroconversion due to the use of cryoprecipitate. Mr. Durcan said, was it not the case that these steps should have been taken, particularly in circumstances where plasma used to manufacture the cryoprecipitate may also have been used to manufacture cryo supernatant for factor IX. Dr. Walsh said that he had done nothing, but again stated that he may not have been sure whether or not the seroconversions were caused by cryoprecipitate, and that the main concern at the time was not what had caused the infection in people with haemophilia, but how to prevent infections in the future. Mr. Durcan put it to Dr. Walsh that it must have been important to know whether or not people had been infected using BTSB product. Dr. Walsh said in June 1986 when he became aware that people had been infected with BTSB factor IX it was extremely upsetting. Mr. Durcan suggested that the best way to ensure that infections wouldn't happen again was to find out what the cause of the seroconversion was.

Dr. Walsh was then examined by Mr. McCullough on behalf of the I.H.S. Dr. Walsh said that he did accept that the report of a seroconversion in a patient following the use of cryoprecipitate had been made to the Council of Europe in 1986. Mr. McCullough put the transcript of day 73 to Dr. Walsh. On this day, Dr. Walsh had given his evidence in relation to the information he had supplied to the Council of Europe. In the course of that evidence given on that day, Dr. Walsh said that he had reported one seroconversion in 1986, but that he had not reported the fact that it was related to cryoprecipitate. Mr. McCullough put it to Dr. Walsh that on the previous occasion in his evidence, he had suggested that the seroconversion he had reported was a seroconversion of a patient who was using both factor VIII and cryoprecipitate. Mr. McCullough asked Dr. Walsh whether or not he was now saying that the seroconversion reported was one caused solely by cryoprecipitate. Dr. Walsh agreed. Mr. McCullough attempted to ask Dr. Walsh about certain other areas of BTSB policy which related to the answers he had given in evidence today. However, the Chairperson of the Tribunal interjected and refused to allow questions other than those already put to Dr. Walsh, to be dealt with. She said that Dr. Walsh had been asked to come back and give evidence on a very specific area, and that questions would be limited to that area.

Department of Health and Self Sufficiency

The next witness to be examined today was Michael Kelly. Mr. Kelly is the Secretary General of the Department of Health and Children. He was appointed to that position in January 2000. He had been working in the Department of Finance between February 1982 and February 1984. He said that when he moved to the Department of Health he did have involvement in establishing the National Haemophilia Services Co-ordinating Committee, although his memory of this period was vague. Mr. Kelly accepted that the Department had adopted a policy of self sufficiency in line with the Council of Europe directions and recommendations. In or around 1981 the Department of Health had requested information from the

BTSB as to what the likely cost of moving to full self sufficiency would be. The BTSB responded that it was attempting to develop high purity factor VIII concentrate in 1981, and that as soon as clinical trials had proved the efficacy of these products they would revert to the Department indicating the cost of producing sufficient factor VIII product to supply the entire needs of the country. However, no response appears to have been received by the Department. Mr. Durcan asked Mr. Kelly whether it was the case that self sufficiency was Department policy. Mr. Kelly agreed. Mr. Durcan then asked Mr. Kelly what steps were taken, if any, to ensure that self sufficiency was achieved. Mr. Kelly said that the request had been made to the BTSB to indicate the cost of achieving self sufficiency.

Mr. Durcan put it to Mr. Kelly that the Department, in line with its policy, had requested the BTSB to do something; the BTSB had failed to do this, and Mr. Durcan wondered why the Department had not done anything further to ensure that progress was made towards self sufficiency. Mr. Kelly wondered what else he would have done, having already contacted the BTSB seeking information about the likely cost, and not having received a response. Mr. Durcan suggested the most obvious thing to do would be to contact BTSB again, and subsequently until the relevant and necessary information was supplied. Mr. Durcan suggested that the Department ought to have played a more practical role in ensuring that its policy of self sufficiency was achieved. Mr. Durcan pressed Mr. Kelly on why a second follow-up letter wasn't written to the BTSB seeking the information that had originally been sought. Mr. Kelly accepted that this probably should have been done.

Mr. Kelly was then examined by Mr. Bradley on behalf of the I.H.S. Mr. Bradley put it to Mr. Kelly that the Department knew that the increased cost of self sufficiency meant that it was an unattractive option. Mr. Bradley suggested that it was never indicated to the BTSB that the appropriate resources would have been available to achieve self sufficiency. Mr. Bradley also suggested to Mr. Kelly that the Department was in an invidious position of on the one hand realising that the BTSB was not in a position to move to self sufficiency because of financial restraints, and on the other hand recognising that the only way in which the BTSB could move to self sufficiency was to increase prices. The Department was loathe to sanction an increase on prices of blood products, since the cost of that increase would be borne by other State agencies.

Government Policy and Compensation

Mr. Collins, the third witness of the day, was then examined by Mr. Durcan. Mr. Collins was asked about two areas: first, his involvement in regard to compensation arrangements for people with haemophilia and secondly, a product authorisation application. Mr. Collins was employed at the Department of Health and Children. At the time, in the 1980s, Mr. Collins worked in the Public Health Division of the Department of Health. Mr. Collins described his involvement in meetings with the Irish Haemophilia Society in July and November of 1987. He said the Haemophilia Society had found itself in a situation where a large number of its members were HIV positive, and they were seeking support for those members. Mr. Collins said that from his recollection, three key areas emerged. The first was that there was a need for social workers for psychological support. The second was that there was a need for funding for self help support groups for people with haemophilia, and the third was that there was a serious issue of fear of discrimination against people with haemophilia who had become infected with HIV. Mr. Collins remembered that a small grant had been made to the Haemophilia Society. Mr. Collins described how he had worked on developing a document in order to brief the Minister for Health to assist him in making a response to the demand by people with haemophilia and the I.H.S.for some form of compensation. In the document developed, it was suggested that only heat treated products were being used since January 1985. Mr. Durcan asked Mr. Collins where he would have got this information from. Mr. Collins said he would have got it from a leaflet that was produced by the I.H.S. itself, which stated that:- "all products now used are heat treated". Mr. Durcan put it to Dr. Collins that this leaflet didn't specifically say that all products used since 1985 were heat treated. Mr. Collins agreed with that. Mr. Durcan went on to point

out to Mr. Collins that in fact non heat treated factor IX was still being used from 1985 onwards. Mr. Collins accepted that this was the case.

Mr. Durcan then asked Mr. Collins whether or not the Department viewed the claim being made by people with haemophilia at this time as being a legal claim, or simply a claim based on humanitarian grounds. Mr. Collins said that the view was that at this time it was a humanitarian claim. Mr. Collins also agreed that the Department considered that claims for negligence against prescribing doctors, health authorities and manufacturing companies who played a role in the infection of people with haemophilia through the use of blood products, are unlikely to succeed. Mr. Collins stated that in 1988 it was suggested to the Minister that £1 million should be offered to people with haemophilia to establish a fund to assist them. Mr. Durcan asked Mr. Collins whether the figure of £1 million which was mentioned, was raised in order to suggest to the Minister that this amount should be offered. Mr. Collins said that it was really an estimate of what money ought to be granted, and that this was based on the amount of compensation that had been paid in the UK to people with haemophilia.

Mr. McCullough then examined Mr. Collins on behalf of the I.H.S. Mr. McCullough asked Mr. Collins about the outcome of a meeting in 1989 when the Government offered people with haemophilia the sum of £50,000 to establish a support fund. Mr. McCullough asked Mr. Collins whether he thought that the I.H.S. had been disappointed with this offer. Mr. Collins agreed that they would have been.

The Tribunal then adjourned to Wednesday 25th July 2001 at 10.30am.

PROCEEDINGS: Wednesday 25th July 2001 - Day 166

Today, Prof. Christine Lee gave evidence. Prof. Lee is a Haematologist at the Royal Free Hospital in London, and she worked during the 1980s with people with haemophilia who became infected with HIV and Hepatitis C.

Prof. Lee described how people with haemophilia treated by the Royal Free Hospital, were using cryoprecipitate for home treatment up until 1978. Prof. Lee said that there was a sufficient amount of UK made factor IX concentrate to supply all patients with haemophilia B. This was because there were in total in the UK about 300 people with factor IX deficiency. This was not the case with factor VIII deficiency: the total number of these patients was somewhere in the region of 1800. The majority of haemophilia B patients used factor IX made by the National Health Service.

AIDS Awareness

In June 1982, Prof. Lee said that awareness began to emerge about cases of pneumocystis carinii pneumonia in patients with haemophilia A. In December 1982, the Royal Free Hospital began to study the T4/T8 ratios in patients with haemophilia. In 1983 and 1984, the results of the studies were published in the Lancets. The results of the study show that patients with haemophilia A who have been treated with factor VIII concentrate, had low T4/T8 cell ratios which indicated that they had contracted AIDS (or at least, at that time, it indicated that they had immunodeficiency). However, patients with haemophilia B who had been treated with factor IX concentrate, had normal T4/T8 cell ratios. Prof. Lee said that the results were perplexing; it was first suggested that factor IX did not affect the immune system in the same way as factor VIII might because of the way that it was prepared. However, Prof. Lee said that they subsequently discovered that the patients with haemophilia B were not suffering from low T4/T8 cell ratios because they had been treated with factor IX which was prepared by the National Health Service, whereas people with haemophilia A had received commercial factor VIII concentrate and had been infected with HIV.

Prof. Lee described how she attended the World Federation of Hemophilia meeting in Stockholm in 1983, and in an informal meeting presented the results of her study. The purpose of the meeting was to discuss immunodeficiency problems in people with haemophilia. Prof. Lee mentioned an article which was published in the New England Journal of Medicine in January 1984 which provided, she said, definite proof that the causative agent of AIDS was transmitted through blood transfusions and blood products. Prof. Lee then went onto comment about a paper she herself had published in 1989, entitled *The Natural History of Human Immunodeficiency Virus Infection in a Haemophilia Cohort*. It was a study of 112 haemophilia patients who were infected with HIV, who had been treated at the Royal Free Hospital in London. The data supplied in this study indicated the date of infection of these patients. This was calculated using stored serum samples. The first infection was actually in 1979. The greatest number of people appear to have been infected sometime in 1983.

NANB Hepatitis

Prof. Lee said that it was clear in the late 1970s that NANB Hepatitis was a sequelae of transfusion of blood products. Prof. Lee said that in her view, 100% of people got hepatitis following a first infusion and it made no difference whether or not they were treated with American factor concentrates or National Health product. She said the vast majority of patients who were first infected were completely asymptomatic. The only way to determine that they had been infected with NANB Hepatitis was to monitor the transaminase levels. Prof. Lee said that HIV infection was a more serious problem in the mid 1980s than hepatitis infection.

Prof. Lee then went on to describe the treating policy at the Royal Free Hospital in London. She said that there was a very strict policy that DDAVP was reserved for those with mild haemophilia. Adults with severe haemophilia A were treated with both National Health Service product and commercial concentrate. Children, however, were always treated with National Health Service factor VIII. This is partly because in the beginning that was where factor VIII came from, and partly because parents preferred to have their children on a British product. There was never enough product to treat all adults exclusively with British factor VIII concentrate.

Supply of British Product

When the risk of AIDS emerged, a policy was adopted of postponing elective surgery. This policy continued until it became clear that heat treatment would inactivate the virus in factor concentrate. If there was emergency surgery which needed to be done, she said that the hospital had a policy of trying to stock up National Health Service concentrate for the operation. Prof. Lee said that by 17th July 1985, the National Health Service heat treated factor IX available. Before heat treated factor IX and factor VIII concentrates became available, there was some debate as to whether or not it was safer to use non-heat treated British product rather than heated American product. Prof. Lee said it was the view at the Royal Free Hospital that the greatest risk came from the donor source, and therefore it was likely that British made product would be safer.

Armour Product Withdrawn

Prof. Lee then spoke about the announcement by Armour Pharmaceuticals in 1986, when it was announced that the heat treated Armour product, which had been heated for 30 hours at 60 degrees centigrade, was being withdrawn from the market because of its connection with some seroconversions. Prof. Lee said that the reaction to this announcement was amazement: this was a pharmaceutical company which had a major involvement in providing clotting factor concentrate to the UK, and many UK haemophilia treaters used the product. She said that people had thought that heat treating rendered the product safe, and now they knew that it didn't, or at least now they feared that it didn't. Prof. Lee said that of 310 patients with haemophilia at the Royal Free, 125 were HIV positive. Prof. Lee said that of those infected with HIV, they must also have been infected with HCV. She said this was so because anybody treated with a factor concentrate would automatically be infected with Hepatitis C if the factor concentrate wasn't heat treated. So therefore if they were infected with HIV, they must have been infected with HCV. She said one of the significant findings of studies they carried out was that co-infection with HIV was a significant factor in speeding the progression of Hepatitis C infection.

Progression of Hepatitis C

Prof. Lee was asked about her views on the progression of Hepatitis C, and she said that it wasn't necessarily a progressive condition. She said that studies carried out by Prof. Preston from Sheffield showed that Hepatitis C was progressive. However, Prof. Lee distinguished her studies from those of Prof. Preston, by saying that Prof. Preston had carried out his studies based on biopsies of all patients. Prof. Lee said that she felt that Prof. Preston had been very selective in which patients he chose to biopsy. All of those biopsies had abnormal liver tests and therefore, Prof. Lee said, it was inevitable that he was going to pick up more cirrhosis in that group of patients studied. Prof. Lee also pointed out that Prof. Preston's study was based on a smaller group of patients, 138, while her studies were based on a larger group of patients. Prof. Lee maintained that the people who were co-infected with HIV and Hepatitis C faced serious difficulties with the progressive nature of Hepatitis C, and also older patients were more likely to develop cirrhosis or hepatocellular carcinoma.

Prof. Lee was then examined by Mr. Bradley for the I.H.S. Prof. Lee said that approximately 10% of all the patients at the Royal Free were infected with HIV. She said that of 1500 patients, 135 were infected. Prof. Lee said that no children who were treated with National Health Service factor concentrate became infected with HIV. Prof. Lee said that the rationale behind treating children with National Health product was purely because parents felt that British product was better. Mr. Bradley asked her, was there not a move among haemophilia treaters generally in 1983 to move to British factor concentrates because it was felt that the donor source would be safer. Prof. Lee agreed that that was the case in 1983, but before the 1983 the policy of using National Health product for children was purely based on the fact that people felt that British product was better.

The Tribunal then adjourned to Friday 27 July, 2001 at 11.00am.

PROCEEDINGS: Friday 27th July 2001 - Day 167

Today, the Chairperson of the Tribunal gave her ruling on an application which was brought by the I.H.S. on 10 July 2001. On that date, Counsel for the I.H.S. had made an application based on two submissions:

1. First, the Tribunal should investigate the activities of pharmaceutical companies who supplied into Ireland products which caused infection with HIV and HCV of people with haemophilia;

2. and secondly, the documents submitted by the witness Dr. Peter Jones should be admitted in evidence to the Tribunal.

The Chairperson dealt with the application to investigate the American pharmaceutical companies first. She considered the Terms of Reference under which the Tribunal had been established. She said it was clear from the Terms of Reference that the Tribunal was obliged to investigate all relevant matters which related to persons or bodies within the State. Those persons or bodies included the BTSB, the Department of Health, the National Drugs Advisory Board and physicians and treaters. The Chairperson said that the Terms of Reference were quite clear in excluding any investigation of any person or persons outside the State. She said that there were provisions in the Terms of Reference to carry on an investigation into matters arising outside the State if, but only if, that investigation was necessary in order to pursue full examination of the role played by parties within the State. She said that the Terms of Reference specified that this investigation of international matters should be carried out only if it was appropriate and reasonable, would not unduly delay the work of the Tribunal, and there was a substantial expectation of being able to attain necessary evidence by conducting such an investigation.

The Chairperson said that she had investigated relevant matters arising outside the State by means of hearing evidence from experts drawn from other countries. She said she had examined relevant medical and scientific provision and factors prevailing at relevant times outside the State. The Chairperson also said that the Tribunal had entered into correspondence with pharmaceutical companies. This correspondence, she said, had provided information to the Tribunal which was relevant. There was nothing in this correspondence to suggest that a body of evidence existed which had not yet been examined by the Tribunal which would be relevant to the matters the Tribunal was required to investigate under the Terms of Reference. The Chairperson said that it was her view that carrying out an inquiry into the actions of pharmaceutical companies would not assist her in reporting on the matters set out in the Terms of Reference.

Having reached this decision, the Chairperson said it was not necessary for her to consider the practicalities of the proposed means of investigation which had been suggested by Counsel for the I.H.S.

The Chairperson then considered whether or not the documents which had been submitted by the witness Dr. Peter Jones should be admitted into evidence. The documents that Dr. Jones wished to submit included an internal memorandum from Armour Pharmaceutical Company which indicated that it knew in 1985 that the heat treatment protocol it was applying to its factor VIII concentrate did not virally inactivate the product. The minute reveals the attitude of Armour Pharmaceuticals at the time: withdrawing this product from the market would have an adverse effect on profit and market share. The Chairperson of the Tribunal did not consider the content of this document, but said simply that it was not relevant to Dr. Jones' evidence. She said that it was admissible for Dr. Jones to give evidence about matters which were in his own knowledge in 1985 and 1986. Since this document (and other documents) had come into his possession after 1986, he was not able to give evidence in relation to them. In any event, the Chairperson said that she did not consider the state of knowledge of Armour Pharmaceuticals in 1985 to be relevant to the work of the Tribunal. She said what was relevant was what was communicated

to persons within the State, and what the state of knowledge of persons within the State was in 1985. The Chairperson said that Dr. Jones had no connection with the documents in question, and that she had serious reservations about the propriety of being allowed to produce the documents as evidence of the state of knowledge or state of mind of Armour. For these reasons, she refused the application of the I.H.S. that these documents be submitted in evidence.

The Tribunal then adjourned to September 17th 2001 at 10.30am.