IRISH HAEMOPHILIA SOCIETY

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TRIBUNAL OF INQUIRY

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

PROCEEDINGS: TUESDAY 3rd OCTOBER, 2000 – DAY 48

Mr John Trainor for the Irish Haemophilia Society cross-examined Mr Ted Keyes of the BTSB.

Mr Trainor took Mr Keyes through his early days with the BTSB and the circumstances of his appointment, firstly as executive consultant and subsequently as chief executive officer.

Mr Trainor asked Mr Keyes, had he been briefed about infection arising from the treatment of people with haemophilia A. Mr Keyes said he was not specifically briefed on this topic. This was a medical issue and medical staff of the board would have dealt with it. Mr Trainor asked Mr Keyes, was he aware of potential liability for the BTSB with regard to this issue. Mr Keyes said the Department had said it would ultimately deal with all claims. The possibility of claims had been mentioned to him briefly. Mr Keyes said that anything non-medical was his problem, so the issue of claims would have been discussed with him. He said that the claims were mentioned in passing. He was not involved in any settlement or negotiation concerning claims against the board.

Mr Keyes said his understanding of the board's liability was that it was liable for products it either supplied or manufactured. He did not see a difference in any duty arising from them. Mr Keyes said this was his personal point of view, and he hadn't discussed the matter with the board.

With respect to dealing with blood products, Mr Keyes said this aspect of the business was catered for by Dr Walsh, Mr Hanratty and Mr Keating, while the chief medical consultant, Dr Barry, had overall responsibility for this area. Up to the end of 1987 the *de facto* situation was that Dr Walsh, Mr Hanratty and Mr Keating took care of these matters. He said he presumed they consulted with Dr Barry. All information on blood products coming to Mr Keyes emanated from Dr Walsh or Mr Hanratty. Mr Keyes said they gave the information, which he took to the board.

Mr Trainor referred Mr Keyes to the situation which pertained at a meeting held in January 1986. Mr Keyes was not at the meeting, but it discussed stock and financial implications of the withdrawal of product made by the BTSB from donations which had not been tested. The board was looking for financial compensation. Mr Keyes said he had no input into this letter, or any subsequent notice which emanated from the meeting. He noted from the letter that some of the non-heat treated factor IX remained in the hospitals at this stage in 1986. Mr Trainor asked Mr Keyes was he aware that, at the

beginning of February 1986, some factor IX was being returned, re-heated and re-issued. Mr Keyes said he was not aware of this.

Mr Trainor referred Mr Keyes to Day 34 of the transcript (pages 63 and 64 and questions 342-347). This evidence was given by Dr Walsh on 24th July 2000. Mr Trainor asked Mr Keyes did he know, or had he been made aware of the fact that returned stock was being heated and re-issued. Mr Keyes said he was only aware that an £80,000 loss had been written off into the 1985 accounts, arising from the requirement to supply product from pre-tested material only.

Mr Trainor asked Mr Keyes who was responsible for this decision. Mr Keyes said that heating and the issue of stock was a matter for the technical staff. Mr Keyes said he was unaware of the issues surrounding factor IX until Dr Walsh educated him.

In early 1986 BTSB factor IX was being heated at 60 degrees for 20 hours. Mr Keyes agreed that this was the case. Mr Trainor referred Mr Keyes to a letter of 22nd April 1986, wherein Prof. Temperley informed Dr Walsh that BTSB factor IX had caused a problem, in that seroconversions had been reported from people using this particular product. Mr Trainor asked Mr Keyes, did alarm bells sound when this letter was received at the BTSB. Mr Keyes said that no alarm bells had sounded with him. Mr Keyes said he could not recall this letter giving rise to concern. In any event the letter would have been dealt with by Dr Walsh.

Mr Trainor referred Mr Keyes to a BTSB board meeting of 18th June 1986, at which it was reported that the factor IX situation was unsatisfactory. Arising from this situation a meeting of BTSB management was convened for 25th June 1986, at which heat treatment of factor IX was discussed. Subsequent to the meeting Dr Walsh wrote to the hospitals.

Mr Trainor directed Mr Keyes to a note of the meeting written by Mr Cann. Mr Keyes' memo of the meeting did not reflect the note taken by Mr Cann.

Mr Keyes said that the only decision taken at the meeting concerned the heat treatment of factor IX. Mr Keyes said the meeting decided to apply a new heat treating protocol to BTSB factor IX. Mr Keyes said that while the new heat treating protocol of 60 degrees for 72 hours was the protocol described by Mr Keating to the meeting upon his return from Paris, the meeting had not taken its instructions from Mr Keating because Mr Keating was not an expert in this area. It was also decided to use existing stock which had been heat treated. Mr Keyes said the committee which made these decisions was never reconvened.

Mr Trainor asked Mr Keyes why it was that there was no mention of factor IX infections at the meeting held to discuss the heat treatment requirements of factor IX. Mr Keyes indicated that it was simply not recorded. The meeting was discussing the heat treatment of factor IX, not infections caused by factor IX. In these circumstances, Mr Trainor asked Mr Keyes was it a fact that infections from factor IX were not recorded because of

the serious implications which would arise on liability if such information had been written down. Mr Keyes rejected this allegation.

Mr Trainor referred Mr Keyes to the BTSB's contract fractionation operations. Mr Trainor put it to Mr Keyes that contract fractionation was seen as a source of capital. Mr Keyes said that the BTSB was not in the profit business, but in the business of providing a service, however he accepted that contract fractionation was profitable. He said the sale of plasma and the mark-up on products was beneficial to patients. Mr Keyes said that contract fractionation was a better prospect for the BTSB than the direct sale of plasma as a commercial operation. He also said that the contract fractionation allowed the Government policy of self sufficiency to be satisfied.

In 1986 and 1987 Mr Keyes said that contract fractionation made a significant contribution to the BTSB. With regards to contract fractionation Mr Keyes said that the BTSB could not contemplate sending its plasma to the US as it was not ALT tested. For the plasma to be fractionated in the US it required to be ALT tested and Hepatitis B core tested.

Mr Keyes said that the Armour company was an option when Travenol, the BTSB's first contract fractionator, failed to make the yields which the BTSB expected. With respect to the Armour product and the Armour contract, Mr Keyes said he felt the BTSB had no choice but to continue with the Armour heat treated contract, given that monoclonal technology delivered a low yield and would therefore require more plasma and would lead to a doubling of the price of factor concentrates.

With regards to the Armour product, Mr Keyes said that the Armour contract returned a yield of around 20 per cent. This is what the BTSB expected. While Armour was offering monoclonal technology this particular product would not produce sufficient yield.

Mr Trainor put it to Mr Keyes that, if the BTSB had been able to obtain further supplies of plasma, it could have considered more advanced viral inactivation techniques such as the monoclonal product. Mr Keyes said in 1987 it was not possible to get extra plasma. Mr Keyes said that in 1987, when the Armour contract was being considered, the BTSB was under instruction to reduce staff. While it may have been possible to increase plasma production using methods such as SAG-M, these technologies had not been considered as the Armour contract could produce enough product on the quantity of plasma it was then possible to harvest.

Mr Keyes said he was not aware of other viral inactivation techniques available at this time such as pasteurisation. He agreed that it may have been Dr Lawlor's evidence that pasteurisation would virally inactivate product at this time.

Mr Trainor asked Mr Keyes why the BTSB had chosen Armour as a contract fractionator, at a time when Armour had no licence to produce factor IX, and just a few months after Armour had been involved in the HIV infection of people with haemophilia A. Mr Keyes

agreed that Armour's reputation at this time was poor. However, he said that the Armour contract and the Armour product was not going to be used unless it was validated by the National Drugs Advisory Board and expert advice from within the BTSB. Despite the cloud hanging over the Armour company's reputation at this stage, Mr Keyes said they could be relied upon to do what they said they were going to do.

Mr Keyes said that the Amour contract envisaged heat treating both factor VIII and factor IX. However when the BTSB learned that Armour could not product factor IX without a licence, it was suggested that the named patient basis be used as a way of allowing Armour to supply factor IX. Mr Trainor asked Mr Keyes, was the named patient basis used as a way of overcoming the licence difficulties. Mr Keyes said that Mr Trainor would have to ask his colleagues in the BTSB. Mr Keyes said that the Armour contract was pursued as a way of fulfilling the BTSB's obligation to observe the Government's policy of self sufficiency. Mr Keyes said he was being advised by Dr Walsh, Prof. Temperley, Mr Keating and Mr Hanratty in these matters.

Mr Trainor referred Mr Keyes to a letter from Armour in January of 1988, wherein Armour informed the BTSB that it intended to stop producing heat treated factor VIII in favour of its monoclate product. The letter advised that Armour required the BTSB to provide an indemnity if the BTSB wanted to avail of the arrangement it had just made with Armour. Mr Keyes said the letter came as something of a surprise, in that he had never come across a situation where a company had treated one of its customers in this way.

PROCEEDINGS: WEDNESDAY 4th OCTOBER, 2000 – DAY 49

Mr John Trainor S.C. continued his examination of Mr Ted Keyes, formerly of the BTSB.

With respect to self sufficiency, Mr Trainor asked Mr Keyes was it the case that the Board allowed its concern for self sufficiency to overcome its duty to provide safe product? Mr Keyes said no, this was not the case, that safety was paramount. In this regard, Mr Trainor asked Mr Keyes was it the case that once viral inactivation was available, a self sufficiency policy was no longer necessary? Mr Keyes said that the Armour contract was a way of satisfying the Government policy on self sufficiency. Prof. Temperley was happy with self sufficiency. Mr Keyes said that self sufficiency was the BTSB's first priority. Whatever decision it made the BTSB could not ignore Government policy. Mr Trainor asked Mr Keyes, did the BTSB ever revisit the policy of self sufficiency by going back to the Government and explaining, in the changed situation, that the policy of self sufficiency should be revised. Mr Keyes said the BTSB never sought a change in Government policy in self sufficiency.

Mr Trainor referred Mr Keyes to a BTSB board meeting of 27th April 1988, when the board approved the indemnity sought by the Armour Pharmaceutical Co. At this meeting it was noted that a full debate on self sufficiency would take place at the following meeting in May 1988. Mr Keyes said that the question of the Armour indemnity raised the issue of self sufficiency in the minds of the board. There was discussion on the indemnity, but without the Armour contract the board was of the opinion that it did not have the ability to provide factor VIII from Irish plasma. Mr Keyes said he was aware at the time that alternatives were available. The alternatives being factor VIII obtained from BPL or from the Scottish Blood Transfusion Service, or the monoclate product on offer by Armour.

Mr Keyes said the board was aware that the continuation of the Armour contract may present product liability problems for the board, but it signed the indemnity and the board's advisors were happy to proceed. Mr Keyes included among these advisors the NDAB.

The May 1988 board meeting of the BTSB did not discuss the issue of self sufficiency. Instead the board considered a letter from Prof. Temperley. Prof. Temperley's letter told the board that the hospitals could not bear a doubling of the price of factor VIII. The letter, said Mr Keyes, indicated that Prof. Temperley was prepared to balance the cost of treatment and the risk of infection. The Board approved the recommendations of Prof. Temperley, said Mr Keyes.

Mr Keyes acknowledged that the letter pointed out that heat treated factor VIII was unsafe for NANB hepatitis, yet the board was prepared to take the risk based on Prof. Temperley's treatment scheme as set out in his letter.

Mr Keyes agreed with Mr Trainor that the BTSB board had responsibility to those persons receiving the product. It was the board's duty, he said, to provide safe product.

Mr Trainor pointed out that there was no mention of factor IX in Prof. Temperley's letter. However, the Armour project did return factor IX. Mr Trainor put it to Mr Keyes that the factor IX element of the Armour contract represented a gross profit of £90,000 to the BTSB. Without the contribution of factor IX sales from the Armour contract, would factor VIII have been more expensive? Mr Keyes agreed that this was theoretically correct, but how much more the BTSB would have had to pay was, "another day's work".

Mr Keyes said that the primary consideration in negotiating with Armour was to obtain product for the patients. Mr Trainor put it to Mr Keyes that the BTSB would have foregone £90,000 profit if no factor IX had been returned on the contract, and on Mr Hanratty's projections of profit which had been put forward by Mr Keyes, ie. that the entire contract would return £124,000 to the board, £90,000 would represent about 75 per cent of this amount. Mr Keyes said the BTSB had problems with factor IX.

Mr Trainor put it to Mr Keyes that the BTSB had indicated in the minutes that the verbal agreement of Travenol had been obtained for the use of Travenol's viral inactivation protocol on the BTSB's factor IX. However, Mr Trainor put it to Mr Keyes that the Travenol protocol was not in fact used. At this point the Tribunal objected, saying the evidence so far was that the Travenol protocol was used. Mr Trainor put it to Mr Keyes that it would have been possible for the BTSB to obtain adequately heat treated factor IX on the world market. He put it to Mr Keyes that Elstree BPL could provide such a product. Mr Keyes said he could not answer this question.

Mr Trainor put it to Mr Keyes that the factor IX product heated for 152 hours by 60.6 degrees was responsible for infecting at least four children with Hepatitis C. Mr Keyes said this was the first time he had heard of this particular assertion. Mr Keyes vigorously rejected any connection between the profit made by the BTSB on factor IX, and Hepatitis C infections.

Mr Trainor referred Mr Keyes to Hepatitis C infections in 1990. These infections occurred at a time when individuals were being treated with Octapharma and BTSB product. Mr Trainor asked Mr Keyes, was the BTSB product recalled on the advent of the Octapharma product. Mr Keyes said he did not know if this was the case. Mr Keyes said he knew nothing about the circulation of BTSB batch No. 9885. He could not answer for medical matters and he agreed with Mr Trainor that the board's insurance company was notified.

With respect to the sale of dated plasma to Kabi, Mr Keyes agreed with Mr Trainor that this stock appeared to be ALT tested. Approximately 6000 litres of plasma per annum were sent to Kabi. This volume of plasma represented a third of the amount of BTSB's plasma required for factor VIII and factor IX production. Mr Trainor asked Mr Keyes if the BTSB could ALT test for Kabi, why could it not ALT test for Armour? Mr Keyes said that the BTSB was not in a position to ALT test the entire blood supply.

Mr Trainor referred Mr Keyes to correspondence from the Department of Health concerning Accuscience and Intrascience. In a letter to Ms Delores Moran, assistant principle officer at the Department of Health from Mr Frank Ahern of the Department of Health, it was noted by the writer that a middle man was receiving £150,000 for the supply of blood packs to the BTSB. The blood packs were supplied by NPBI. It is suggested in the letter that the chairman of the BTSB Mr Fox instruct Mr Keyes to travel to the Netherlands to scrap this arrangement. Mr Keyes said Mr Fox had discussed this matter with him. Mr Keyes re-negotiated the arrangement with NPBI, in that the company agreed on a price reduction for the blood packs from £7.90 per pack to £5.50. The revised price was made retrospective to the start of the project, which effectively gave the BTSB a refund of £150,000.

Mr Trainor referred Mr Keyes to the investigation carried out by him into the commercial connections between a senior member of the BTSB and Accuscience. The senior member of the BTSB concerned was Mr Sean Hanratty, who was recorded in Company's Office documentation as James Hanratty, a farmer of Co. Monaghan. Mr Keyes explained that Sean Hanratty's real name was in fact James, and that he had been left a farm by an uncle in Co. Monaghan, hence his description as farmer.

Mr Keyes said he could find no record of any discussions at BTSB board meetings of the board being informed of Mr Hanratty's connections with the company. Mr Keyes set out his understanding of the formation of Accuscience by Mr O'Donnell and Mr Hanratty. Mr Keyes said Mr Hanratty had informed him that he was an investor in the company. The company subsequently obtained an agency for Cutter blood concentrates. Cutter supplied the BTSB with factor VIII in 1984 and factor IX in 1985, and also dealt directly with St. James' Hospital. Mr Keyes said Mr Hanratty had no involvement in product choice for the BTSB. Such choice was made by Mr Cann.

Mr Keyes said it was estimated the 1.5 million units of factor IX were required annually. It was noted that in 1986 the treaters were reluctant to use BTSB factor IX. Communication ensued between Mr Keyes and Prof. Temperley, whereby it was pointed out that if BTSB factor IX was not used, the price of factor VIII would be affected. It was noted that by 1989 a tenfold increase in the use of BTSB factor IX had occurred, compared with the same period in the previous year. Mr Keyes said if people were satisfied with the product its use would increase.

Mr Trainor referred Mr Keyes to Cooper & Lybrand's internal control documents. The document indicated that the board could no longer expect to receive grants from the Department of Health. These documents were dated for the audit year of 1985. Mr Trainor put it to Mr Keyes that it appeared to be Cooper & Lybrand's view that the Department of Health would no longer make good the BTSB's losses. Mr Keyes said he did not agree with this particular viewpoint. If he needed help he would go to the Department for help and would generally get it.

Mr Trainor referred Mr Keyes to a document prepared by him on 30th December 1986 concerning monoclonal antibodies project in conjunction with Biocon Ltd. and the board. Mr Keyes said it was essential that the Board be involved in commercial activity, and pointed out that the sale of plasma was a commercial activity. Mr Keyes said these commercial enterprises were engaged upon in the interests of treating people. Mr Keyes said that these projects were commercial in the sense of providing funds for treating people. Mr Keyes said that this was especially the case with regards to factor VIII, where money was needed to fund the growth in demand in this area. There was a concern about using freely given blood to generate profit.

Mr Trainor referred Mr Keyes to a document produced by Mr Keyes in his examination by Mr Finlay. Mr Keyes said the document was prepared in and around 1988 by Mr Hanratty. Given that this was the case, asked Mr Trainor, what was the significance on the document of the code 57/321? Mr Keyes said he could not remember how he came by the document. He said he may have picked it up six months previously. Mr Trainor asked Mr Keyes was he certain the document was not prepared by Mr McStay. Mr Keyes said he was not aware that the document may have been prepared by Mr McStay. He had picked the document up somewhere on the file.

The document presented by Mr Keyes appears to be an analysis of figures prepared by Mr Hanratty in 1988. The figures in Mr Keyes' document are derived from that prepared by Mr Hanratty.

Mr Finlay interjected for the Tribunal. He said what the document seemed to say was that someone, perhaps Mr McStay, had taken the document of 5th May 1988 signed by Mr Hanratty, and produced the document that Mr Keyes referred to the Tribunal. Mr Keyes said it was likely he got the document from one of the bundles that Mr McStay had.

Mr Keyes was cross-examined by Mr Nicholas Butler for Prof. Temperley, and by Mr Ian Brennan of the Department of Health.

PROCEEDINGS: THURSDAY 5th OCTOBER, 2000 – DAY 50

Mr Ian Brennan cross-examined Mr Ted Keyes. Mr Brennan, for the Department of Health, questioned Mr Keyes on ALT testing, the provision of safe product vis-à-vis self sufficiency, the Armour contract and the indemnity thereon, and Prof. Temperley's letter to the BTSB Board Meeting of 15th June 1988.

Mr Keyes was further cross-examined by Mr Michael McGrath of the BTSB. Mr McGrath questioned Mr Keyes on Prof. Temperley's letter, the Armour contract and the supply of factor VIII in 1989.

Mr Gerry Durcan S.C. for the Tribunal then examined Prof. Ernest Egan of the Regional Hospital, Galway.

Prof. Egan is a Consultant Haematologist at Galway Regional Hospital and was a member of the BTSB Board from 21st July 1976 until the 25th May 1983. However, while Prof. Egan's term of office expired in May 1983, he continued to attend a number of board meeting thereafter. Prof. Egan was also a member of the NHSCC. He said he became disenchanted with this group when no services were forthcoming for the Galway region.

Prof. Egan recalled the introduction of factor concentrates and the advantages derived from them by home therapy. Home therapy increased through the late 1970's and while the risk of hepatitis from concentrates was recognised, Non-A, Non-B Hepatitis was not considered to be a significant problem at this time.

Prof. Egan recalled the 1981/82 period when Mr Hanratty's factor VIII project was being promoted by the BTSB, and at the NHSCC. Prof. Egan said that the project was more a subject of discussion at the NHSCC as the BTSB board was not a board of experts, whereas the NHSCC consisted mostly of medical professionals.

Prof. Egan said it was his understanding that the BTSB's objective of self sufficiency would be achieved through this project at the time. Prof. Egan said he did not know why the project was abandoned, but it continued to be presented as the BTSB's self sufficiency project up until May 1983. Prof. Egan said that upon inquiring at various meetings as to the progress of the factor VIII project being conducted by Mr Hanratty, he was told that things were going well, and that they were moving positively.

Mr Durcan referred Prof. Egan to a query from the NDAB in May 1984 concerning risks arising from the use of foreign factor VIII blood concentrates. Prof. Egan said it was known that imported concentrates carried an infection risk. He said, while the infection risk was small, the fact that people with haemophilia had to use large amounts of this product meant that the small risk was magnified and became a significant risk.

Prof. Egan was of the view that factor concentrates should be reserved for critical clinical situations, and should not be used as a matter of course for home therapy. However, Prof. Egan said that there was a lot of pressure from the I.H.S. to have factor concentrates made available. Prof. Egan said that the wish for more convenient products pushed the BTSB towards the use of pooled products.

Prof. Egan said that the NDAB letter was written at a time when the issue of blood products was in a state of flux. Prof. Egan said that the only real concern in the use of blood products in the early 1980's was the risk of Hepatitis. With the advent of HTLV-III, however, there was no change in practice. There was no re-discussion of the risk when HIV infections occurred, as there was no question of going back to cryo.

Mr Durcan then referred Prof. Egan to the events of 1986. Various communications from the BTSB were opened. The letters informed Prof Egan that the BTSB was experiencing some quality control problems with its factor IX and concern was expressed over the use of non-heat treated products.

Mr Durcan referred Prof. Egan to a report sheet on the use of BTSB factor IX batch number 90753. Prof. Egan said this report sheet was not completed in the Galway Regional Hospital, but would have been completed in Pelican House. Prof. Egan said at this time it appeared to be the case that different standards were applied in different parts of the country, in that heat treated and screened product was available in Dublin but not in the regional centres.

Prof. Egan said that the records at Galway Regional Hospital were not consistent with those of the BTSB. It would appear that a particular patient who was cited as having been treated in January 1986 with infected BTSB factor IX, was in fact treated in August or October 1985. Prof. Egan described his conversations with Dr Walsh concerning the availability of heat treated factor IX in Galway Regional Hospital. Mr Durcan pointed out to Prof. Egan that there was no record of a return of product from Galway in January of 1986. The first record of a return of product from Galway was in September of 1986. Prof. Egan insisted that product was returned in January of that year.

Mr Durcan asked Prof. Egan, did he treat persons with haemophilia with unheat-treated factor IX from the BTSB in 1986. Prof. Egan said that this was the case, that he had treated his own patients with infected product and looked to their seroconversion. However, fortunately none were infected.

On 16th September 1986, Prof. Egan discovered that the BTSB heat-treated product, which had replaced the non-heat treated product, was in fact non-screened product. This emerged from the fact that the BTSB recovered unheat treated and unscreened product from Galway and subjected the product to heat treatment. The product was then re-issued. However, while the product could be heated it could not be adequately screened. Prof. Egan said he felt it was the BTSB's responsibility to have provided the product he specified, and that he was disappointed that it had not done so. Prof. Egan said he appreciated the fact that a rapidly evolving situation had occurred with respect to BTSB

factor IX, but it was a pity that no updates or formal guidelines had been issued. He said information should have come from the BTSB and he felt let down on this matter during this period.

Prof. Egan was then cross-examined by Mr Martin Hayden for the Irish Haemophilia Society. He agreed that he had served on the board of the BTSB from 1976 until 1983, and that technical matters had been usually discussed elsewhere, on the Scientific Committee for instance.

Prof. Egan said the BTSB board was not competent to deal with technical matters. He agreed with Mr Hayden that Dr O'Riordan had held a very negative view of factor concentrates and was unhappy at the use of product from paid donor pools. Prof. Egan said that he shared this sentiment.

Prof. Egan said at this time the existing product, ie. cryoprecipitate, was safer but it was incredibly inconvenient to use and created major logistical difficulties. Prof. Egan said the change over to concentrates was facilitated by placing a lot of reliance on screening procedures used and in viral inactivation techniques. Prof. Egan said blood concentrates were screened for Hepatitis B up until the early 1980's and for HIV thereafter. Risk arising from these products was not seen as substantial, he said. Prof. Egan said that during all of this period home produced products were seen as safer.

Professor Egan stated that financial issues never arose for discussion at the BTSB board. He said the BTSB was part of the health service and part of a larger organisation, and while bizarre arrangements were in place to finance the BTSB, they could not be regarded as ever having been insolvent, because as far as he was concerned finance was not an issue.

PROCEEDINGS: FRIDAY 6th OCTOBER, 2000 – DAY 51

Mr Martin Hayden for the I.H.S. continued his cross-examination of Prof. Egan.

Mr Hayden referred Prof. Egan to his evidence of the previous day where he had said that the I.H.S. played an active role in choosing the products they used. Mr Hayden asked Prof. Egan, was it really the case that I.H.S. representatives on the NHSCC would have played an active role in product choice. Prof. Egan said he thought this may have been the mechanism by which the style of product was chosen. Mr Hayden asked Prof. Egan, was it therefore the case that it was Prof. Temperley and the Regional Directors who would select the actual products? This was the evidence as previously given by Prof. Egan. Prof. Egan said he would accept that this was the case.

Mr Hayden referred Prof. Egan to the National Haemophilia Service Co-ordinating Committee policy document contained at vol 44, page 72 of the Tribunal's core documents, wherein it states that the NHSCC would recommend to the Department of Health on an annual basis the products to be used, and the products that should be subsidised by the Department of Health during a specific year, and it sets out the procedures to be adopted. The procedure to be adopted was that the Director of the National Haemophilia Treatment Centre and the Regional Directors, in arriving at a recommendation, should evaluate all available products in consultation with the National Drugs Advisory Board and Blood Transfusion Service Board.

With respect to Prof. Egan's communication to the NDAB, Prof. Egan said his understanding of 'significant' was that as previously set out to Mr Durcan, ie. multiple exposure to a low risk product could result in a low risk becoming a significant risk.

With respect to who was responsible for telling Prof. Egan that he should use only heat treated and screened product, Prof. Egan said he was not personalising the issue to Dr Walsh, but he should have told Prof. Egan of the necessity to use heat treated product only, as he was the person dealing with the problem.

Mr Hayden then referred Dr Walsh to BTSB board minutes of June 1983 and September 1983, where Prof. Egan was present. Prof. Egan said he remembered nothing about these board minutes. The meeting in June 1983 debated the Council of Europe recommendations but did not debate the recommendations as far as they were concerned with the treatment of haemophilia. The meeting of June 1983 was also the first time that AIDS was mentioned at the board meeting. The meeting also discussed the BTSB strategy in face of the threat of AIDS in the summer of 1983, in that it would produce a leaflet to all blood donors. Mr Hayden asked Prof. Egan that, given his own area of expertise, and given the fact that in 1984 he had written to the NDAB talking about the dangers of factor concentrates, would he agree with the Council of Europe recommendations. Prof. Egan said that he would agree with what they were saying.

Mr Hayden noted that the Board had proceeded to produce the pamphlet, *Message to all Blood Donors*. He asked Prof. Egan, from a medical point of view, did he find it surprising that the other recommendations did not get equal attention. Prof. Egan said that the minute recorded that the Director briefly outlined action being taken by the BTSB, but he did not know what action had been outlined at that time.

The representatives of Prof. Temperley, Ms Cunningham, the NDAB and the Department of Health had no questions for the witness.

Prof. Egan was cross-examined by Mr Michael McGrath for the BTSB. Mr McGrath noted that the witness had two areas of criticism for the BTSB. One was in September 1986 when the product specifications as set out by him with respect to factor IX were not met. The other being that upon reports of contamination with HIV, Prof. Egan moved to a commercial factor IX, and when he indicated he wanted screened, heat treated product from the BTSB he got heat treated unscreened product. Prof. Egan also set out the difficulties encountered by using cryoprecipitate as opposed to factor concentrates.

Mr McGrath put it to Prof. Egan that in January 1986, when he had requested heat treated and screened product, that heat treated concentrate from tested donations was not available and did not become available for some time after that. Prof. Egan said he was aware of that fact now but wasn't aware of it then. His understanding then was that from October 1985 all product was screened, and he now accepts that there was product in the BTSB which was not screened or was in the process of manufacture from plasma which had not been screened.

The second area of criticism referred to by Mr McGrath was that Prof. Egan had said that he wasn't informed about the need to use heat treated product only in January of 1986. Further, he had not received the circular of 30th January 1986, and he did not receive a letter from the BTSB on 25th June 1986 in relation to the recall of non-heat treated factor IX concentrate. Prof. Egan said he did not receive the document of January 1986, nor had he received the document of 25th June 1986.

Mr McGrath then referred Mr Egan to his letter to the NDAB of May 9th, 1984. In the letter Prof. Egan notes that his practice in haemophilia is very small and that he had no patient in whom high potency factor VIII concentrate was required.

Mr McGrath asked, did that change between December and May of 1984, ie. did he have a patient requiring high potency factor VIII concentrate. Prof. Egan said this was not the case. He did not require high potency factor VIII concentrate, but he required factor VIII for his patients and administered cryoprecipitate. He had no patient requiring high potency factor VIII. Prof. Egan pointed out to Mr McGrath that cryoprecipitate was a low potency concentrate. Prof. Egan said he was not being kept out of the loop as regards the difference between using concentrate and cryo, but he was being kept out of the loop with respect to using heat treated and non-heat treated material.

Prof. Egan's counsel, Mr Meenan, had no questions for the witness. Mr Gerry Durcan S.C. referred briefly to the Council of Europe Committee of Minister's meeting on 23rd June 1983, which adopted the final Council of Europe recommendations. Mr Durcan pointed out that the final recommendations were slightly different from the draft recommendations referred to earlier by Mr Hayden.