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: Monday 3rd July, 2000 – DAY 19

John Trainor S.C. for the I.H.S. cross-examined Dr Emer Lawlor of the BTSB. Dr Lawlor outlined her professional qualifications and medical career. Her association with the BTSB started in 1975. In 1991 she became a permanent part-time employee of the Board, and by 1996 she was full time in the employment of the BTSB.

Dr Lawlor told the Tribunal that she had travelled to North Carolina, to Chapel Hill, to Los Angeles, to Washington on a number of separate occasions, and to Dartmouth, New Hampshire, in preparation for the Tribunal. She also travelled to Holland, Scotland and the U.K.

Dr Lawlor described Dr O'Riordan's role with the BTSB. As National Director, he controlled both the administrative end of the BTSB and the medical side, said Dr Lawlor. She said, however, that there was no job description or specification for the role of Chief Medical Officer, which was also filled by Dr O'Riordan at this time. Dr Lawlor said Dr O'Riordan had the final decision on everything, subject to Board approval, but in practice he ran the show.

Dr Lawlor agreed with Mr Trainor that the Board had enjoyed a reputation for safety over the years. She further agreed that the Board encouraged people who have received products from the Board to believe that the Board was standing over the safety of the products, and in providing them with safe products in general. Dr Lawlor agreed with this proposition but said there was never a zero risk with transfusion.

Dr Lawlor said she accepted that the Board had some responsibility for the safety of the products it distributed, but that the Board's position was that it had an obligation to ensure the products manufactured by it were safe. However, where products were licensed, an obligation for safety also falls on the Drugs Advisory Board and the FDA, said Dr Lawlor. With respect to licensed products which were regarded as unsafe, the only thing the Board could have done was to refuse to stock the products. Dr Lawlor said that the treating physicians and the patients were as aware of the risks regarding blood products, as was the BTSB.

Dr Lawlor said it was her view that Council of Europe Recommendations were largely aspirational. This was particularly so with regard to Factor VIII, she said.

Dr Lawlor agreed that the starting position for the debate on blood concentrates was the arrival of Hemofil from Travenol, at the end of March 1973. Dr Lawlor agreed that Dr O'Riordan had objected to the first application for a licence to import Hemofil. However, it was noted that the Board had no legal capacity to object under the Therapeutic Substances Act.

The Board based its objection on the fact that the licence would be granted contrary to the Council of Europe Recommendation that blood products be made from voluntary donations to distribute on a non-profit basis. Mr Trainor pointed out that now the Board seemed to be relying on the Council of Europe Recommendations to ground their objections to Travenol's licence application. In this sense, could it be said that the Council of Europe recommendations were purely aspirational? Dr Lawlor's reaction to this position generally is that, where the Council of Europe Recommendations could be fulfilled, they were fulfilled; but where they could not be fulfilled they were not binding, and other options were taken.

Mr Trainor went on to note Dr O'Riordan's continuing resistance to the importation of concentrates. He objected to the fact that concentrates would cost twice as much as the cryoprecipitate then available. He also objected to the fact that donors were not voluntary – blood was being taken from skid row types in the U.S. and native populations in the Caribbean. Dr Lawlor agreed that the reference to skid row types was reference to people who were in dire straits at the bottom of society, who were forced to sell their blood either to feed their addiction or relieve their poverty.

With regard to native populations of the Caribbean, Mr Trainor said that this was not some idle racist remark, but was derived from a concern that non-indigenous blood-borne diseases would be imported with these products. Dr Lawlor said that might have been an issue, but what was more in issue was the fact that there were ethical concerns about bleeding people for plasma for products that they themselves could not avail of. Dr O'Riordan was also concerned that high pressure sales techniques would result in decentralisation of blood concentrate distribution.

In March 1974, Travenol had obtained a licence for the distribution and use of Hemofil. Approaches had been made by Prof. Temperley to the Department of Health, to have the Hemofil distributed through the treatment centres, principally the NHTC. Dr Lawlor agreed with this summary of affairs.

If this situation had come about the BTSB would have been by-passed in the distribution of Hemofil. In March 1974, Travenol contacted Dr O'Riordan. The letter said that, in order to ensure a controlled distribution of Hemofil in the Republic, the BTSB could hold a stock of Hemofil at an agreed level to meet demands in the Republic, and give advice and guidance for its proper use, and in exchange for this service Travenol would offer a service fee amounting to 10% of the selling price of Hemofil. Travenol would invoice the BTSB at a rate of 12p per international unit, and the Board would invoice the hospitals for the product.

Alternatively, the Board could agree to hold an emergency stock of Hemofil. Travenol would ship the product directly to the hospital, invoice the hospital directly, and a service fee of 2.5% of the value of the order would accrue to the BTSB for its guidance and advice in the use of the product.

Mr Trainor then put it to Dr Lawlor that the BTSB would be able to invoice the hospitals and enjoy a mark-up on the product and additionally, it would also receive a 10% reimbursement or kick-back, by way of a fee in addition to the mark-up on the product. Dr Lawlor agreed with this proposition.

Dr Lawlor confirmed that the Board opted for the arrangement whereby it received 10 per cent of the selling price of Hemofil, and then go on to invoice the hospitals, enjoying a further mark-up on the product. Dr Lawlor said that the BTSB was not in a position to

produce any financial records which could assist the Tribunal in determining the exact nature of the relationship between Travenol and the Board at that time. She agreed that the Board would have had two opportunities for profiting from the distribution of the product:

1) The mark-up to the hospital, and
2) The reimbursement from Travenol of a certain percentage of the sale price to the Board.

By the summer of 1974, the BTSB had agreed to act as distributor for Hemofil. This arrangement was agreed on the basis that the BTSB would continue to develop its own freeze-dried concentrate. In or around this time, Dr Egan returned from the US. Dr Egan was in charge of the blood bank in Galway. He reported that in the U.S., considerable concern was being expressed publicly at a government level, about some of the plasma procurement methods being used by drug companies in America, particularly in relation to getting blood and plasma from the third world.

In April 1975 a report in the New England Journal of Medicine, dealt with the emergence of Non-A, Non-B Hepatitis in association with transfusion. It was estimated that the risk of Hepatitis from non-voluntary donations was ten times higher than that associated with the risk from voluntary donations, ie. non-paid donors.

In 1975 Hemofil was withdrawn as the product had been associated with causing Hepatitis B. By 1975 Hemofil had returned to the BTSB and was being distributed by it. Dr Lawlor agreed that at this stage, the BTSB in distributing Hemofil, was distributing a product made from donations of blood which had not been collected by the BTSB. She further agreed that it was proposing to distribute blood products for profit by virtue of the mark-up to the hospitals and the payment back from the drug company. However, she said that the Council of Europe Recommendations, which disapproved these activities, was aspirational and that she was not in a position to answer questions on financial arrangements.

Mr Trainor directed Dr Lawlor to a reference in her statement to a World in Action programme broadcast in 1985, and to a reference contained within that programme of another World in Action broadcast in 1975. The programmes warned of the dangers to people with haemophilia posed by blood concentrates – in 1975 the threat was hepatitis, in 1985 it was Aids.

Dr Lawlor said she had not seen the programme at the time, but reference to it was contained in the BTSB Discovery. Dr Lawlor agreed that, if this programme had an effect on British government policy at the time, it is likely that it would have come to the notice of the BTSB.

Mr Trainor went on to note the dangers posed by concentrates drawn from large pools of donors. The danger at this time being the transmission of Hepatitis. With regard to the risk of Hepatitis, Dr Lawlor said the risk was known, but the benefits of the product were deemed to outweigh the risk. Mr Trainor put it to Dr Lawlor that the picture coming across from her evidence, was that a decision was taken somewhere along the line by the Board, that the Board would not concern itself with the safety of the products, that there was a demand for them, and the Board could make a profit from the product which it could use to underwrite its other activities. It would do so in spite of the fact that it was exposing persons with haemophilia to a risk. Dr Lawlor said everyone involved knew of the risks. Notwithstanding the risk, they still wanted the product and the BTSB brought it in. I don't see anything wrong with that, she said.

The price charged for imported blood products by the Blood Transfusion Service Board to hospitals was lowered following representations from Prof. Temperley. Prof. Temperley was concerned that the NHTC was being charged 18p per unit for Hemofil, while the Board purchased it for 15p. From the year 1977 the 3p difference amounted to a total of £6,600.

Further, Dr Elizabeth Mayne in Northern Ireland, was being charged 10p per unit for commercial factor VIII. Cutter had told Prof. Temperley that it could supply factor VIII concentrate at substantially less than 15p per unit. Following Prof. Temperley's representations to Dr O'Riordan, which included an indication that he would seriously consider moving to another supplier such as Immuno which was offering factor VIII concentrate at 11.9p per unit for European plasma-derived factor VIII, the price was reduced. Hemofil was reduced to 14p per unit, with effect from 1st June 1979.

Dr Lawlor agreed that that the BTSB did not attempt to buy concentrate for a cheaper price elsewhere. The BTSB did not appear to be sensitive to price and when Prof Temeperly protested the BTSB dropped its price.

The final document put by Mr Trainor to Dr Lawlor, consisted of an invitation to Dr O'Riordan to attend the 32nd Annual American Meeting of the Association of Blood Banks, to be held in Las Vegas, Nevada, on 3rd August 1979. Dr O'Riordan was to attend the meeting on behalf of Travenol. Dr Lawlor said she did not know whether Dr O'Riordan had travelled to Las Vegas, but he went to practically all the AABB meetings. It was standard practice for commercial companies to fund clinicians and doctors to go to meetings.

Dr Lawlor said, while this is no longer the practice, it was once commonplace, and was all the more so when there was no budget for travel. Mr Trainor said this may be so, but that Las Vegas, Nevada was hardly the venue for an intellectual assessment of blood transfusion technology around the world. Dr Lawlor said the American Association of Blood Banks meeting was a very prestigious meeting, and this year it was being held in Washington, which also might not be an intellectual capital, but it goes to different places.

PROCEEDINGS: TUESDAY 4th JULY, 2000 – DAY 20

Mr Trainor continued his cross-examination of Dr Emer Lawlor of the BTSB.

1. The BTSB's records prior to 1986 were destroyed in bulk sometime in 1985, Dr Lawlor told the Tribunal. Dr Lawlor said there were no records available prior to 1986. These records had been destroyed in bulk by the BTSB.

2. Dr Lawlor said the BTSB was not responsible for the safety of products it distributed if these were licensed products.

3. Dr Lawlor said the BTSB was responsible only for products processed by the BTSB.

4. Dr Lawlor said the BTSB was self sufficient in factor VIII in 1977 / 1978 by using cryoprecipitate.

5. Dr Lawlor said it was not unusual for drug companies to sponsor the training of staff and to subsidise travel for BTSB Executives to conferences.

6. Mr Trainor put it to Dr Lawlor that the BTSB did not take the safety of factor concentrates into its consideration. The BTSB's policy was that it did not have direct responsibility for the safety of licensed products. It did not therefore address the issue of safety when it came to distributing commercial concentrates.

PROCEEDINGS: WEDNESDAY 5th JULY, 2000 – DAY 21

DESTRUCTION OF DOCUMENTS

Dr Lawlor opened proceedings with the clarification of evidence given on Tuesday, 4th July, concerning the destruction of documents by the BTSB. Dr Lawlor read from her Affidavit dated September 1999.

She said that by way of a letter to the BTSB solicitor in 1995, Mr Sean Hanratty, former Chief Technical Officer of the BTSB, stated that, other than order books from 1982 onwards, all other records of blood products were shredded and disposed of in 1993 by the Board. Mr Hanratty was Chief Technical Officer of the BTSB in 1993. He died in 1996. Dr Lawlor said she had been unable to ascertain why the documents were destroyed and disposed of in 1993. Documents held at the Cork Centre of the BTSB for the period concerned were not destroyed. Dr Lawlor said that other donor and medical records for the period in question had been kept. The chief target of the destruction of documents appeared to be records of blood products received and despatch documents connected thereto.

Despatch records, if available, would have been of assistance in the HIV and Hepatitis C look-back programmes. These records were the only way of determining which hospital received different batches of product. Dr Lawlor said from a medical point of view it was very unfortunate that the records were destroyed. Dr Lawlor said it appeared to be the case that documents were destroyed in 1993 following the conclusion of litigation against the BTSB, arising out of HIV infections. This litigation had terminated in the recompense scheme, established by the Government in respect of HIV.

John Trainor S.C. asked Dr Lawlor, was she aware that during the course of 1993 a body of litigation had commenced by persons with haemophilia against drug companies in respect of the supply of the products. Dr Lawlor said she was not aware of this. Mr Trainor asked, was it not the case that the despatch records destroyed in 1993 were in fact critical documents for the purposes of identifying which product from which drug company had been responsible for causing HIV infection in particular persons with haemophilia. Dr Lawlor said this was not totally correct as hospital records could be relied upon.

Mr Trainor asked, was it not the case that the destruction of despatch documents could have facilitated the defence by drug companies of the litigation brought against them in 1993. At this point the Chairwoman interjected and said she thought that was a very unfair question to ask.

Dr Lawlor said that the documents in question had been stored in a remote storage facility and there may be more than one remote storage facility.

Mr Trainor asked Dr Lawlor, who in the BTSB would have access to such documents? Dr Lawlor said there would be no problem in having access to the documents – they could be called up as required. Mr Trainor asked, was it the case that any person in the employment of the Board could have access to the documents. Dr Lawlor said that the Chief Technical Officer would have had access to the documents. Mr Trainor asked, was there a list of persons authorised by the BTSB to have access to the documents. Dr Lawlor said she made exhaustive searches in 1995 in preparing her affidavit, and she had no more information on the issue.

Mr Trainor asked, did the Board carry out any interview with the employees of the storage company to find out how it was that Mr Hanratty managed to get the documents. Dr Lawlor said that part of the problem was that there were two storage companies. Mr Trainor asked Dr Lawlor if she, at any stage, received a communication from Mr Keyes containing a direction to cease destruction of documentation? Dr Lawlor said there was one from1989. Dr Lawlor said that, because of pending litigation, the instruction issued that documentation should not be destroyed.

FINANCE

Dr Lawlor said she was unable to answer any questions about financial matters.

Dr Lawlor said she had already made her views known: i.e. financial matters were nothing to do with the issues under investigation by the Tribunal. Mr Trainor said that, as Dr Lawlor was testifying to the Tribunal for the BTSB, and she held a view that financial matters had no relevance to the decisions made by the Board, she presumably had a basis for giving such an opinion.

Presumably she had considered the financial matters and had concluded they were not relevant?

If so, was she not then in a position to discuss the papers in front of her?

If the witness had not considered financial matters, then she was not in a position to say that such matters had no part in the decision-making of the Board, and any evidence offered by Dr Lawlor to the effect that financial matters were not relevant to the Tribunal's investigations could not be allowed to stand, said Mr Trainor.,

The Chairperson said that Dr Lawlor was not a financial person and her observations on financial matters were by way of comment and not from a perusal from the financial documents. She was entitled to give her view of financial matters. The Chairperson said the BTSB had said they would produce a witness to deal with financial matters, and it would be more appropriate to put such matters to this witness.

TRAVENOL LETTER

Mr Trainor drew Dr Lawlor's attention to a letter from A.W. Barrell of Travenol. Among other things, the letter suggested that Mr Barrell and Dr O'Riordan should get together again about other matters. Mr Trainor replied that the letter in January in 1983 coincided with the advent of heat treated factor concentrate by Travenol in the U.S. The letter, however, does not mention relevance in the U.S., and Mr Trainor suggested Travenol may have been keeping Dr O'Riordan in the dark as to their new heat treated product. Dr Lawlor rejected this idea. Mr Trainor said that the letter suggested some sort of mutual relationship between Dr O'Riordan and Travenol, which may or may not be relevant to matters that the Tribunal has to consider.

CUT -BACKS

Mr Trainor directed Dr Lawlor to the Board Minutes of the BTSB of 16th February 1983. At this Board Meeting, a number of financial cut-backs were outlined, which it was proposed would be adopted by the Board. With regard to blood fractions it was decided that no cut-

back would be made. It was deemed economically prudent to continue the purchase of blood derivatives from abroad. The economic prudence of this course of action was determined by the BTSB's plan for home production of Factor VIII. The BTSB's plan was to produce its own brand of factor VIII, and in the meantime continue to import concentrates from abroad.

The Tribunal then considered draft recommendation number R(80)3 of the Committee of Ministers of the Member States of the Council of Europe on preventing the likely transmission of AIDS. The documentation recommended:

1. To avoid the use of coagulation factor products prepared from large plasma pools except when such product is specifically indicated for medical reasons.

2. To inform attending physicians and selected recipients, such as haemophiliacs, the potential health hazards of haemotherapy and the possibility of minimising these risks.

3. To provide all blood donors with information on AIDS so those in high risk groups will refrain from donating (example leaflet appended).

4. To pursue rapid and full implementation of Recommendation R(80) and R(81) (16).

A major step to be taken among these measures was the avoidance of the use of coagulation factor products prepared from large plasma pools, except when a product was specifically indicated for medical reasons. That is, do not use blood concentrates unless absolutely necessary. This was particularly important in countries where self sufficiency had not been achieved. Dr Lawlor agreed that this was an important measure.

Dr O'Riordan attended this Meeting of the Council of Europe.

At the BTSB Board Meeting of July 1983, the subject of AIDS was discussed for the first time. The recommendations of the Council of Europe with regard to haemophiliacs, were not mentioned. It was proposed to bring out a leaflet with a message to donors.

With the Board failing to discuss the recommendations, it was difficult to see how people with haemophilia would know of the risks involved in using factor concentrates, said Mr Trainor.

In a press statement of July 1993, Dr O'Riordan said the Board was actively pursuing the Council of Europe Recommendations, self sufficiency was at hand and a message to donors leaflet, with regard to AIDS, was in preparation. There is no mention of haemophilia.

At the July 1983 Board Meeting, Dr O'Riordan stated that there was a danger arising from the use of factor VIII, but that people with haemophilia wanted to use them. However, there is no record of the recipients being told of the risk of continuing to use factor products.

PROCEEDINGS: THURSDAY 6th JULY, 2000 – DAY 22

John Trainor S.C. continued his cross-examination of Dr Emer Lawlor of the BTSB.

Mr Trainor referred Dr Lawlor to her evidence of yesterday, 5th July 2000, wherein she said that by the start of 1983, 95 per cent of those people with haemophilia who would be infected with HIV had, in fact, become infected. Mr Trainor referred Dr Lawlor to a retrospective study of stored blood samples taken from persons with HIV prior to the end of 1984. Samples tested for 1982 showed that 14% of the samples were positive for HIV, and at the end of 1983, 58 per cent of the samples were positive. These figures were drawn from the evidence which will be given by Prof. Temperley.

Mr Trainor produced these statistics to disprove Dr Lawlor's assertion that, by 1983, 95 per cent of those who would have haemophilia-related HIV had already become infected. Dr Lawlor said she would have to refresh her memory on the figures. At this point the Chairwoman intervened, it was decided that Dr Lawlor would be given an opportunity to look at the figures concerned, and the issue was deferred until this could take place.

Mr Trainor then asked Dr Lawlor if she had been present for the evidence given by Mr Raymond Kelly on 2nd May, the opening day of personal testimony. Dr Lawlor agreed she was present but said, "I can't comment because I haven't seen the records. I don't think it would be appropriate for me to comment at this stage."

Mr Trainor asked Dr Lawlor, had she heard the evidence given by Mr Kelly that his son, John had died on 9th August 1984, and had initially received cryoprecipitate. He received his first factor VIII. Supplied by the Board in August of 1984. Mr Clarke, Counsel for the BTSB, objected to this line of questioning, saying the witness could not answer unless she had access to medical records. The Chairperson agreed that if the witness did not have access to the records, she couldn't possibly give an answer to the question.

The Chairperson said that to answer the question the witness would have to have an opportunity to refer to documents and the private or confidential personal records that exist in relation to a particular patient.

Mr Trainor said he would have to take instructions as to whether or not personal records could be made available to Dr Lawlor. Mr Trainor also said it was his understanding that Dr Lawlor had had access to medical records in the past. Mr Trainor said he would return to the subject when he had taken instructions.

Mr Trainor put it to Dr Lawlor that, of 126 persons with haemophilia in Northern Ireland, only 16 were infected with HIV because of the timely action taken with regard to contract fractionation.

Dr Lawlor said it was much more to do with the fact that Northern Ireland was using European sourced produced, in fact Northern Ireland was using European Immuno, she said. At this point, Mr Finlay objected. Mr Finlay said this topic was within the question of the consequences for the numbers of persons who became infected in 1983, and it has been agreed that documents are to be assembled, and that the matter is to be dealt with. Mr Finlay said he felt Mr Trainor should move onto some other topic.

The Chairperson said this issue had already been dealt with and documents were being assembled, and she could return to the subject when the books of documents had been put together. Mr Trainor said that Dr Lawlor clearly knew the relevant statistics with respect to Northern Ireland, and he also wanted to ask her about Finland and Belgium. The Chairperson directed that it would be better to wait until all the documents were assembled, and address the matter in issue.

A symposium held on 1st October 1983, addressed by Dr O'Riordan, it was noted that there was no discussion of heat treatment. Mr Trainor said that Dr O'Riordan could have warned people with haemophilia there and then that there was a risk in using factor concentrates. Dr Lawlor said that it was not his (Dr O'Riordan's) place to do so; he was not the treater. Furthermore, she said no-one was talking about heat treatment until October 1984.

Dr Lawlor said the issue of importation was a complex one. It belonged to the Department of Health and it belonged to the National Drugs Advisory Board. Dr Lawlor said it would have been helpful to her personally, if the decision to discontinue imports had been made at the time. But, said Dr Lawlor, unfortunately for the patients it would not have made any difference because the majority was already infected and importation was continuing.

Mr Trainor said that the I.H.S. and its representatives, in attendance at the Tribunal, would be grateful if Dr Lawlor refrained from saying ceasing the importation and distribution of contaminated factor products would have made no difference to the levels of infection suffered by the haemophilia community. Mr Trainor said this matter would be dealt with at the appropriate time. The Chairperson said to Mr Trainor that it was up to her (the Chairwoman) to decide how the witness should conduct herself.

Mr Trainor then referred Dr Lawlor to Prof. Temperley's treatment plan of December 1983. The programme set out a management plan for the treatment of haemophilia in view of the threat posed by HIV. Mr Trainor suggested that here was a firm opportunity for the BTSB to urge caution in the use of concentrates. Dr Lawlor said it would be impertinent of Dr O'Riordan, who was not directly responsible for the treatment of patients, to suggest to Prof. Temperley how he should look after his patients. Mr Trainor asked, did Dr O'Riordan consider the plan. Dr Lawlor said, "I don't know what he did or did not do". She suggested that Mr Trainor ask Prof. Temperley.

On considering the overall debate on the threat posed by AIDS to people with haemophilia, Mr Trainor suggested that the BTSB played no part in the debate. While it had been directly involved in the business of distributing blood products, the BTSB was a silent voice in the debate in this jurisdiction.

Dr Lawlor said the BTSB had to work with the scientific resources and funds available to it; if it had made wrong decisions, so had other, bigger and better-resourced services. She said the BTSB were pygmies in the sense that, they really didn't have very much to offer the on-going debate concerning the threat posed by AIDS. Dr Lawlor said the BTSB was unable to contribute to any debate, because it did not have the information with which to do so, and that the BTSB would have been following what was happening elsewhere, that it didn't have the ability to do scientific research, and was grossly under-funded. And additionally, it had a blood transfusion service to run. So therefore, said Dr Lawlor, she did not accept that the BTSB did not contribute to the debate.

Mr Trainor pointed out that under-funding had not hampered the BTSB's ability to contribute to scientific debate. Mr Trainor put it to Dr Lawlor that it was open to Dr O'Riordan when asked by Prof. Temperley for his opinion on the management of haemophilia and treatment for AIDS, Dr O'Riordan could have told Prof. Temperley that he had been saying for years that these products should not be distributed, and he was now making his position clear on that. Dr Lawlor agreed that he could have written that, and she agreed that he didn't do it. Mr Trainor put it to Dr Lawlor that the reality was that the Board had ceased to care about the safety of the products.

At NHSCC on 3rd February 1984, the issue of plasma procurement was discussed. This was an overture for the BTSB's new departure in self sufficiency and towards contract fractionation.

Mr Trainor drew Dr Lawlor's attention to a letter from Dr Egan to Dr McCartney, Medical Assessor of the NDAB of 9th May 1984. In the letter, Dr Egan urged restraint in the use of factor VIII concentrates, he was concerned about the origins of the plasma used to produce these concentrates. They should only be used when they were indicated by a serious medical condition, said Dr Egan.

Mr Trainor directed Dr Lawlor to a report by Dr Gunson, which assessed the BTSB on behalf of the Council of Europe. In the report, the BTSB informed Dr Gunson of the Council of Europe, that the BTSB had the power of reasoned refusal when it came to the supply of blood products. Mr Trainor referred Dr Lawlor back to some of her previous evidence, wherein she stated that the Board was compelled by statute to supply blood products.

Mr Trainor asked Dr Lawlor why Dr O'Riordan had the combined roles of Chief Medical Officer and National Director. Dr Lawlor said she did not know the reason for this, but that there were arguments both for and against.

At the BTSB Board Meeting of July 18th 1984, the current Cutter product recall is not discussed. Armour and Cutter were suppliers of the BTSB at this point.

In April 1984 heat treated products became available from Cutter and Travenol.

In November 1984, Mr J Walsh wrote to Dr Aboud about the first person in Ireland with haemophilia to be diagnosed with AIDS. In December 1984, at the first Board meeting to convene after this news had broken, the issue of Ireland's first person with haemophilia to have AIDS was not discussed by the Board. Dr Lawlor said that it was probably still being evaluated at that time.

The issue was not discussed at the next meeting. Mr Trainor asked, did this denote an indifference on the part of the Board. Dr Lawlor said that, in 1984, AIDS was being treated in a hush-hush manner. Dr Trainor said, now that the first AIDS case had become public, had the BTSB not then considered withdrawing imported factor concentrates. This did not appear to be the case.

The BTSB future development committee report of 130 pages contains hardly a mention of AIDS. There is no mention apart from a foot-note explanation as to the condition. On December 17th 1984, Prof. Temperley wrote to Dr O'Riordan, informing him that only heat treated product should be used in 1985. Dr O'Riordan said that urgent attention would be given to the issue of heat treating all product for the treatment of haemophilia.

Prof Temperley wrote to Dr Scott at the NDAB in January of 1985 saying, "This year, we will be using Cutter and Armour". Mr Trainor asked why Cutter and Armour had been chosen above other fractionation companies, to which Dr Lawlor responded by saying that treating physicians chose the supplier.

Mr Trainor put it to Dr Lawlor that in July 1982, that in an article in the MMWR it had been reported by the CDC that there were three cases of pneumocystis carinii pneumonia among patients with haemophilia. Was this the date upon which the risks of using factor concentrates for the treatment of haemophilia became apparent? Dr Lawlor said she did not agree with this date.

She said HIV, at this stage represented a small black cloud. There was no way that anybody could have realised that it was going to turn into the storm of AIDS.

Mr Trainor then asked Dr Lawlor, from the position of the BTSB, was the organisation satisfied with the response that it made to the emerging risk of AIDS. Mr Trainor said this could be from either July 1982 or, if Dr Lawlor preferred in the absence of having re-read her transcript of the previous day, January 1983.

Dr Lawlor said that she would not necessarily agree that the start of events was January 1983. Dr Lawlor said that it was a pity consideration hadn't been given to bringing in heat treated products. She understood why it had happened, and that within the international community heat treated products weren't believed to be safe. The introduction of heat treated products would have saved a number of people, but not very many, said Dr Lawlor. This was a pity, but otherwise she did not think there was anything else that could be done.

Mr Trainor asked Dr Lawlor that, with hindsight, were there any regrets within the Board, the fact that it never chose to withdraw the product or ceased to distribute them in the period. The Chairperson interjected and said that this would be a decision for her to make.

PROCEEDINGS: FRIDAY 7th JULY, 2000 – DAY 23

APPLICATION – ADMIT VIDEO EVIDENCE

Mr John Trainor S.C. made an application that the Tribunal receive into evidence, a video tape containing three World in Action programmes, which were referred to in the statement of Dr Lawlor. Two of the programmes were broadcast in 1975, and one programme was broadcast in 1985. The programmes are referred to at paragraph 79 of Dr Lawlor's supplemental statement.

Mr Trainor noted that the Discovery of the BTSB included a transcript of the programme, which was subsequently included in the core documents of the Tribunal of Inquiry. Mr Trainor said that it appeared that most of the parties to the Tribunal had no objection to the public showing of the video; the only objection being that of the Legal Team for the Tribunal of Inquiry, led by Mr Finlay. Mr Trainor noted that it was not appropriate to go into the detail of the programmes contained on the tape; it was sufficient to say that the 1975 programmes concerned the risk arising from the use of blood products - that risk being contracting hepatitis.

The first 1975 programme purported to show viewers the results of the visit by the World in Action team to 10 out of 24 Baxter donor clinics in the U.S. The programmes looked at donor screening and the whole issue of paid donations.

The second 1975 tape contained an interview with three haemophilia families and highlighted the concerns of the British Haemophilia Society. It traced the development of the blood fractionation facility at Elstree, and the UK Government's response to the threat of hepatitis arising from blood concentrates, and the unjustifiable risk of continuing the import of such concentrates.

Mr Trainor said the 1975 programmes, and the 1985 programme, were clearly relevant to what the Tribunal must consider. Mr Trainor said that in the light of what was in the programmes, it would have been an act of irresponsible madness for the BTSB to have continued to deal with Travenol without investigating the nature of the allegations contained in the programmes, and without seeing whether or not those allegations were correct. If they were correct the Board should have established what course of action Travenol, the main supplier of blood concentrates into Ireland at this time, was proposing to take about the infectious nature of the product.

Mr Trainor said it appeared that Baxter Travenol was capable of sending the chief executive of the BTSB to Las Vegas on a junket. If the company was able to fund such a trip, it would be equally capable of funding a tour of the company's blood collection facilities in the United States for BTSB personnel.

Mr Trainor said that, having regard to the content of the programme and the emerging urgency of achieving self sufficiency, the inactivity of the Board between 1975 and 1980 onwards was unforgivable.

Mr Trainor said that the capacity of the I.H.S. to cross-examine Dr Lawlor, and its capacity to make relevant submissions to the Tribunal, would be greatly hindered if the programmes, and the material contained in them, are not received in evidence.

Mr Trainor also said that the programmes are relevant to the Tribunal's work under the Terms of Reference, namely Terms of Reference 3, 4 and 5. Mr Trainor said that the exclusion of the material contained in the programmes will operate to the protection of the BTSB and others from being asked to confront the enormity of the omissions and neglect with which it is believed the Tribunal is charged to make findings.

Mr Butler, for Prof. Temperley, and Mr Clarke, for the BTSB, made observations on the application by the I.H.S. Neither party voiced any objection in principle to the screening of the video.

OBJECTION

Mr Finlay, for the Tribunal, addressed the Sole Member in the following terms: "Madam Chairperson, my advice to you in relation to this would be as follows…". Mr Finlay said the only relevance the videos had were that certain allegations were made at the time and would not be accepted as proof of the truth of the allegation made.

Mr Finlay said he noted that Mr Trainor accepted the contents of the video were not to be accepted as proof of the truth of the allegations made. However, Mr Finlay said that Mr Trainor appears to suggest that it would be appropriate for the Tribunal to receive evidence of opinions expressed by various experts or persons. He identified his experts in the programme through the medium of the programmes and, in the submission of the Tribunal Legal Team, such a course would be totally inappropriate. Mr Finlay said, that is not the way for the Tribunal to receive evidence of the opinions of experts. The appropriate way for that to happen is for somebody to come and give expert evidence.

Mr Finlay said the public display of such programmes was inappropriate, and as the programmes were a mixture of fact and allegation, that confusion would arise in distinguishing between the two, and consequently confusion would be borne among the public.

In reply, John Trainor, S.C. said, he noted that Mr Finlay agreed that the programmes were relevant. He said he could not see the logic in discussing the programmes without being able to see them.

RULING

The Tribunal then rose to consider the application. On her return, the Chairperson said she had viewed all three of the programmes and listened to the arguments made for and against the public display of them. She had formed the view that the programmes should not be shown in the public, and the reason for this is that they are of questionable evidential value. They did not constitute proper evidence. Proper evidence is when a person is brought to the Tribunal, is questioned and cross-examined. Persons appearing in the programme could not be cross-examined. The Chairperson said the programmes contained allegations. Allegations were not in themselves proof, and constituted no more than a record of the allegations.

The Chairperson said that the appropriate way to proceed was to make a transcript of the first two programmes and, should any person wish to question any witness on a relevant part of the programmes, they can do so in the ordinary way, in public, before the Tribunal.

CROSS EXAMINATION

Mr Trainor continued with his cross-examination of Dr Lawlor. Mr Trainor asked Dr Lawlor to consider the issue of self sufficiency by the BTSB from 1980 onwards.

In January of 1980, at a meeting of the NHSCC, it was decided that as a matter of urgency the Blood Transfusion Service Board be requested by the Department of Health to begin, as soon as possible, the production of a concentrated form of factor VIII.

The production of freeze-dried cryoprecipitate could be regarded as the starting point of the BTSB's factor VIII project, and Dr Lawlor agreed with this assessment. Dr O'Riordan wrote to the Department of Health outlining the policy of the NHSCC. This policy required the BTSB to embark upon production of a concentrated form of factor VIII. Dr Lawlor noted that the response from the Department was unenthusiastic, and was principally interested in how much the project would cost. Mr Trainor asked, was this not a reasonable request for information from the Department?

Dr Lawlor said the Department's response was not simply a request for information – it was a way of delaying the proposal. Dr Lawlor said that at this time the Board was strapped for cash and did not have the money to embark on such a programme.

Dr Lawlor said the response from the Department was a typical bureaucrat's letter. Mr Trainor asked, was it fair comment to say that, in the period from 1981 and 1982 and going into 1983, that the reality was the Board was in fact broke? Dr Lawlor replied: yes. Dr Lawlor also agreed that the bank was seeking to bounce a BTSB cheque to the Revenue Commissioners for£750,000.

Dr Lawlor gave evidence of transaction in the period 1980 to 1981, between the BTSB, the Department of Health and the Health Board, on the production of concentrates by the BTSB. A report by Mr Hanratty and Prof. Temperley on factor VIII production by the BTSB utilising the Gail Rock method was noted. Dr Lawlor said that Dr O'Riordan at this time was supportive of the project. However, Mr Trainor noted that Dr O'Riordan appeared to regard the production of a factor VIII by the BTSB as unnecessary, given the Board's capacity to supply freeze-dried cryoprecipitate. In these circumstances, he appeared to put the project on the long finger. Dr Lawlor disagreed.

Dr Lawlor said things appeared to keep moving, however the response by the Department of Health undermined the project, said added. The Department of Health would not support the project. Dr Lawlor said hospital administrators would get diplomas in delaying costly projects. The object seemed to be that, if enough paper work could be generated, the person looking for the money would go away, said Dr Lawlor. Dr Lawlor noted that if the project was delayed, it was delayed because of the Department of Health, and not the BTSB.

On 19th November 1981, the Scientific Committee meeting heard that the Gail Rock method worked and provided a satisfactory intermediate factor VIII yield.

On 22nd January 1982, the NHSCC heard that fund raising for the project was underway. Trials would take three months and the project would be in production in six months time. Dr Lawlor said she did not know whether the equipment for the project was in fact ordered.

At a meeting of the BTSB Board in October 1982, Dr Egan queried the progress in relation to factor VIII production. The National Director, Dr O'Riordan, indicated the BTSB was currently working on a more purified concentrate, more convenient and suitable for home use, the successful outcome of which would result in very substantive savings for the country, by virtue of the non-importation of costly products from abroad.

Dr Lawlor agreed that it would appear that Mr Hanratty's forecasts of January 1982 were somewhat optimistic. Mr Trainor asked Dr Lawlor, was the fact that the Board progressed slowly in the factor VIII project, anything to do with the fact that the Board's had more pressing financial needs during this period? Dr Lawlor said she was not sure about that, as she understood there was someone working on the project. Dr Lawlor said that if you have somebody on a research grant, they are still going to be in the building, unless they have been re-deployed for something else.

Mr Trainor asked, would this person be in a position to give evidence to the Tribunal, as to precisely what was happening on the programme during this time. Dr Lawlor agreed that this was the case. Dr Lawlor said that laboratory records existed outlining some of the work carried out on the factor VIII project. She said the research worker had a hands-on operation regarding the factor VIII project, reporting to Mr Hanratty.

The factor VIII project started sometime in August 1981, and ran until the end of 1983. At this stage, up to 15 patients were being treated with BTSB factor VIII. Mr Trainor said the reason he was inquiring into this evidence, was because, in her evidence to Mr Finlay, Dr Lawlor had described the project was alchemy - turning lead into gold; was it all wishful thinking? Dr Lawlor said that this was still her evidence.

Mr Trainor said he was suggesting to Dr Lawlor that this was a perfectly viable project, and the only reason it didn't proceed was because the Board realised that it could get more money by selling plasma, and getting concentrate back rather than making concentrate itself. Dr Lawlor said she disagreed with this assessment.

Mr Trainor asked Dr Lawlor, had she talked to the person who was working on the factor VIII project. Dr Lawlor said she had had a two minute conversation with her. She could confirm that the person had actually done some work on the project. The person was still alive and still working, however no statement was taken from this person to find out his/her involvement in the work. Mr Trainor put it to Dr Lawlor, was it the case, therefore, that her evidence regarding the factor VIII project, was based on a two minute conversation with the project worker?

At this point, Mr Clarke, Counsel for the BTSB, objected. The objections were endorsed by the Chairperson, who said the witness was a professional witness and should be treated with the respect due to a professional witness. Mr Trainor said, if he had over-stepped the mark, he apologised to all concerned, but that this was a subject to which he would return.

Mr Trainor turned to consider a draft letter by Prof. Temperley and Mr Hanratty, addressed to *The Lancet*. This letter indicated that the BTSB had successfully produced factor VIII using the Rock Palmer method, and treated up to 15 patients successfully with the end product. Mr Trainor said that the letter would seem to indicate to him that, as far as Mr Hanratty was concerned, that the project was going to be a runner. Dr Lawlor maintained that the problems with the project meant that it was non-viable. Why, then, would Mr Hanratty put his name to

a letter addressed to *The Lancet*, inquired Mr Trainor. He would be delighted to have a letter published in *The Lancet*, said Dr Lawlor; we all would.