

IRISH HAEMOPHILIA SOCIETY

TRIBUNAL NEWSLETTER

ISSUE 16

CONTENTS:

Page 2	Day 64 - Tuesday 7th November
Page 7	Day 65 - Wednesday 8th November
Page 10	Day 66 - Thursday 9th November
Page 14	Day 67 - Friday 10th November

16th November, 2000

TRIBUNAL OF INQUIRY

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

PROCEEDINGS: TUESDAY 7th NOVEMBER, 2000 – DAY 64

Mr Martin Hayden made an application on behalf of the Irish Haemophilia Society that the evidence of Mr E A Ryan, former accounting personnel officer of the B.T.S.B., be heard not before Tuesday 14th November 2000. Mr Hayden pointed out that on 31st October the I.H.S. had received a statement from Mr Ryan. This was despite the fact that on July 5th Dr Emer Lawlor of the B.T.S.B. had stated to Mr John Trainor S.C., in response to a question put by him, that Mr Ryan was deceased.

Mr Hayden pointed out that in a previous application by the I.H.S. in respect of Mr John McStay, who reviewed the B.T.S.B.'s financial situation, the Society had stated that it feared that the taking of a professional witness such as Mr McStay, before the factual witnesses who were available, would colour the evidence of the factual witnesses.

Mr Hayden said that this situation now appeared to have come to pass in that the witness now proposed, who had previously been reported as being deceased, had in fact read Mr McStay's report and said he agreed with it. Mr Hayden said that, in trying to put the I.H.S.'s case, a global correction of Mr McStay's views would now have to be undertaken. Mr Hayden said that this had been identified as a risk previously and had been the subject of an application by the I.H.S. Further, the Tribunal had been told that Mr Ryan was no longer with us. Given that the situation had now arisen, Mr Hayden said that the evidence of Mr Ryan should not be taken before 14th November. Mr Hayden said the substance of the application was all the more pressing given that Mr Ryan had apparently come back from the dead.

Mr Gerry Durcan for the Tribunal said it would appear that the B.T.S.B. had been under a misapprehension when it told the Tribunal that Mr Ryan was in fact dead. Mr Durcan said that Mr Ryan had contacted the office of Mr McStay during the course of Mr McStay's evidence. Mr Durcan said that the documents at play here were the same documents as those used for Mr McStay. Mr Durcan said that Mr Ryan could be asked questions on the documents which had been compiled for the examination and cross-examination of Mr McStay. Mr Durcan said it was therefore the case that parties were familiar with the documents and if there was any difficulty with respect to the documents, that could be dealt with as it arose. Mr Durcan said the witness was available and was prepared to give his evidence tomorrow and it would be inappropriate not to start as scheduled. The Chairperson refused the application and stated that Mr Ryan would give his evidence the following day.

Mr John Finlay S.C. then examined Dr Paule Cotter of the Cork Regional Hospital. Dr Cotter told the Tribunal that she qualified as a doctor in 1966 and Mr Finlay took her through her extensive C.V., and he noted that from 1979 Dr Cotter was the principal haemophilia treater in Cork. She selected home treatment for suitable patients and established a haemophilia referral centre at the Cork Regional Hospital. Dr Cotter agreed that, with her appointment to Cork Regional Hospital, the hospital also became the Regional Haemophilia Centre.

In 1980 Dr Cotter joined the National Haemophilia Services Co-ordinating Committee as an ex-officio member, due to her position as the regional treater in Cork. Dr Cotter agreed that she was familiar with the policy document on the bulk purchase of concentrate which had been considered by the NHSCC in 1980. With respect to any divergence of opinion which may have surrounded this document and different drafts of it available to the Tribunal, Dr Cotter said she did not recall any discussion regarding such a divergence.

When the BTSB first proposed that it would produce its own concentrate Dr Cotter said the treaters were in favour of such a move. With respect to plans to introduce the national production of concentrate products and various trials conducted on such products and decisions to defer any action until such trials had taken place, Dr Cotter said she only had a general knowledge of fractionation. She knew about concentrates with respect to purity and volume and administration, but did not recall any discussion considering the actual method of producing factor concentrates, such as the Gail Rock method as employed by Mr Hanratty.

With respect to her involvement in the selection of products in December 1981, Dr Cotter said that with Drs Egan, Basheer and Prof. Temperley, her input was to consider the concentration of the product, the diluent effects and the ease of administration. Dr Cotter said she could not remember any BTSB representative or representative of the NDAB being involved in the selection meetings. Dr Cotter said she could not remember meeting with Dr O'Riordan or Mr Hanratty with respect to meetings to select product. Dr Cotter said the meetings would discuss product availability, type of product and cost. She again said she had no expertise in fractionation.

Dr Cotter agreed with Mr Finlay that, in addition to commercial products selected by the treaters, the BTSB also supplied its own concentrate and some cryoprecipitate. Dr Cotter said she was aware that, with respect to plasma collection for factor VIII concentrate, the plasma was drawn from remunerated donors and was fractionated from large plasma pools. Dr Cotter said she was aware at this time of infection dangers arising from such products, especially with respect to hepatitis. However, this had to be balanced with the treatment regime and the various benefits to be derived from the products. Dr Cotter said these matters were discussed with the BTSB.

Mr Finlay referred Dr Cotter to a document of the 22nd January 1982, where Mr Hanratty expressed confidence that his new product would be available for trial in three months and concentrate would be available within six months. In May 1982 the NHSCC discussed the slow progress towards home production. Mr Hanratty, said Dr Cotter, reported technical difficulties. However she agreed that there was no note of technical difficulties recorded in the minutes of the NHSCC. Dr Cotter said that was her recollection of the events at that time.

Mr Finlay pointed out to Dr Cotter that the remaining references to Mr Hanratty's project all expressed optimism that the project would be successful. On 14th October 1983 clinical trials had been conducted and further optimism was expressed with regards to the home production.

Mr Finlay directed Dr Cotter to a minute of the 3rd February 1984, where the concept of home production via Mr Hanratty's project, gave way to the idea that the BTSB should engage in contract fractionation. Mr Finlay asked Dr Cotter, in May 1984 did she discuss custom fractionation with her colleagues and Prof. Temperley, or other members of the committee? Dr Cotter said she could not remember such discussions.

In May 1983 Mr Finlay pointed out to Dr Cotter that a discussion at the NHSCC seemed to take place with respect to AIDS. Mr Finlay asked Dr Cotter was any alternative to the use of

concentrates discussed at this meeting? Dr Cotter said the meeting occurred in the context of home production. Mr Finlay asked Dr Cotter did the discussion take place with respect to an alternative to commercial concentrates? Dr Cotter said that this was the context of the discussion on home produced product. Dr Cotter said she did not recollect any discussion concerning an alternative to home produced product.

With regard to whether or not the commercial product in use by the BTSB at this time, which included Kryobulin from Immuno, was drawn from U.S. or European plasma, Dr Cotter said this may have been discussed at the NHSCC.

Mr Finlay asked Dr Cotter did the Cork Regional Centre order its own product from Immuno? In 1983, Dr Cotter replied that it was always advisable to have more than one supplier, however she said that the products supplied to the Cork Regional Centre were all supplied by the BTSB. Dr Cotter agreed that stock built up in 1983 would have been used in succeeding years.

Mr Finlay then referred Dr Cotter to her statement and her attendance at the World Congress of Haemophilia in Rio de Janeiro in September of 1984. Dr Cotter said she attended a paper with respect to AIDS in haemophiliacs. Dr Cotter said as a result of attending this paper she was now convinced that a problem with respect to AIDS was present in Ireland. Up until this time Dr Cotter stated she was not aware of any infection dangers to Irish patients, and would have discussed such matters with colleagues in Cork or possibly with Prof. Temperley. Mr Finlay asked Dr Cotter did anyone from the BTSB tell her about the risk prior to the conference in Rio?

Mr Finlay then referred Dr Cotter to a meeting she attended on 13th December 1984 with the Department of Health. The meeting discussed the situation pertaining to the first Irish haemophilia person suffering from AIDS at St. James' Hospital.

Mr Finlay then referred Dr Cotter to a meeting of the National Haemophilia Services Co-ordinating Committee of November 1984. Mr Finlay pointed out that there was no mention of AIDS at this meeting, and no mention of the information that had been relayed to Dr Cotter at the Rio meeting. Dr Cotter said she found it amazing that there was no record of such a discussion, and agreed that all the relevant people to carry out such a discussion were there.

Dr Cotter and Mr Finlay then discussed a letter written by Professor Temperley to Dr O'Riordan on December 17th 1984. The letter concerned the Centre Directors' decision to use only heat treated product for 1984. In reply, Dr O'Riordan stated that urgent attention was being given to the problem. Dr Cotter said it was her understanding that this reply meant that the BTSB would heat treat both factor VIII and factor IX.

Dr Cotter said arrangements were made to supply heat treated commercial product from January 1985. Non-heat treated product held by the Cork Regional Centre was returned to the BTSB, said Dr Cotter.

Dr Cotter agreed that in 1985 factor IX was not heat treated. She said that the Cork Centre did purchase some heat treated factor IX through the BTSB. Dr Cotter said no commercial heat treated factor IX was available, and in this circumstance she continued to use non-heat treated factor IX. Dr Cotter said it was her belief that commercial heat treated factor IX was not generally available, however the BTSB did supply some heat treated commercial factor IX during 1985. However, Dr Cotter said they continued to use non-heat treated factor IX during 1985 as she believed that, given that this product was drawn from the plasma of Irish donors, it did not present a risk of HIV.

Mr Finlay then referred Dr Cotter to a meeting of the NHSCC in February 1985, where the custom fractionation plans of the BTSB were discussed. Dr Cotter said it was an acrimonious meeting and herself and Prof. Temperley voted against the BTSB in a vote of confidence.

Dr Cotter said she had reservations concerning custom fractionation because the initial work of the BTSB was very disappointing. The treaters had not been involved in the decision-making process and incomplete information had been offered on the products. Mr Finlay said was it not a two-way difficulty in that the BTSB was not included in the discussions between medical personnel and the Department of Health, such as at the meeting of December 13th 1984? Mr Finlay put it to Dr Cotter that it was important that the BTSB be put fully in the picture.

Mr Finlay asked Dr Cotter was the question of heat treatment raised at the February 1985 meeting? Dr Cotter said she could not recall. With respect to further communication on March 27th from Prof. Temperley to Dr O'Riordan, Dr Cotter agreed that Prof. Temperley had consulted with her before writing the letter. With respect to a record in the BTSB Dr Cotter said she did not attend any meeting with Dr McCann as recorded in the BTSB Board minute meeting of June 1985, and did not agree with the BTSB's choice of fractionator as recorded in the minute.

Dr Cotter agreed that she had seen the letter from Prof. Temperley regarding the heat treatment of all products and casting doubt on the choice of Travenol as a contract fractionator. Dr Cotter said that in August 1985 she was in contact with Dr Daly who was Prof. Temperley's locum at this time. She was aware of Dr Daly's concerns and was aware of Dr Daly's conversation with Prof. Temperley, where Dr Daly had informed Prof. Temperley of her meeting with the BTSB and their attitude towards heat treating factor IX. Dr Cotter said Prof. Temperley had informed her of what had happened. Dr Cotter agreed that the Cork Centre continued to receive non-heat treated factor IX from the BTSB during 1985.

With respect to a patient who was negative for HIV in Cork in January 1985, and who had seroconverted by July 1985, Mr Finlay asked Dr Cotter had she ever told the BTSB that this haemophilia B patient had seroconverted? Dr Cotter said she suspected she did tell the BTSB that this man had seroconverted on receipt of BTSB non-heat treated factor IX. Dr Cotter said from early 1985 the treaters were continually looking for HIV in both factor VIII and factor IX patients.

Mr Finlay asked Dr Cotter was it the case that there was no positive HIV tests in people with haemophilia B until 1985? Dr Cotter said it was difficult to decipher from the records the exact dates of some of the seroconversions. Mr Finlay asked Dr Cotter had she informed Prof. Temperley rather than the BTSB directly about the seroconversion of haemophilia B patients in 1985, as there did not appear to be any record of the BTSB being informed of these events? Dr Cotter said she had a lot of discussion with the BTSB at that time. Mr Finlay said was this a way of saying no, she had not informed the BTSB? Dr Cotter said she could not recall exactly whether or not the BTSB had been so informed.

In August 1986 it is recorded that the BTSB was informed by Prof. Temperley of haemophilia B HIV positive seroconversion in Cork. It would appear that Prof. Temperley, up to January 1986, was under the impression that there were six haemophilia B seroconversions. This would imply he was not aware of the Cork seroconversion and such was not reported until August 1986.

Dr Cotter was then cross-examined by Mr Jim McCullough for the Irish Haemophilia Society, with regard to voting against the BTSB in the vote of confidence in 1985. Dr Cotter said the

treaters were concerned at the prospect of having to use BTSB factor VIII. She did not remember having any meeting with the BSB in the company of Dr McCann in the absence of Prof. Temperley and did not agree the choice of fractionator with the BSB in its plans to award such a contract to Travenol. Dr Cotter said a breakdown of trust had occurred between the treaters and the BSB. The vote of no confidence was an expression of that opinion.

In response to cross-examination by Mr Michael McGrath for the BSB, Dr Cotter said something happened prior to the meeting in February 1985 which led to the breakdown in trust between the treaters and the BSB. Mr John Finlay asked Dr Cotter was she referring to something specific happening prior to the meeting in February 1985 which led to this breakdown in trust. Dr Cotter said she could not be specific as to what happened.

PROCEEDINGS: WEDNESDAY 8th NOVEMBER, 2000 – DAY 65

Mr Gerry Durcan S.C. examined Mr Edward A Ryan, former accountant and personnel officer of the B.T.S.B. It had previously been stated to the Tribunal by Dr Emer Lawlor that Mr Ryan was deceased. Mr Durcan asked Mr Ryan what caused him to make contact with the Tribunal. Mr Ryan said he was following the evidence of Mr McStay and Mr Keyes, and he contacted McStay Looby, the company employed by the B.T.S.B. to review the B.T.S.B.'s finances during the years under investigation.

Upon contacting the company Mr Ryan was put in touch with the B.T.S.B.'s legal advisers. Mr Ryan said he was also following the evidence given by Mr Keyes, particularly concerning AccuScience. Mr Ryan said he conducted the investigation into AccuScience in the first instance. With respect to whether or not he could be contacted by the B.T.S.B., Mr Ryan said he had been given an award by the B.T.S.B. some two years ago, and was in receipt of a pension from the B.T.S.B. However, Mr Ryan said it was obviously a case, as observed by Oscar Wilde, of a face once seen and never remembered.

Mr Ryan said with respect to his investigation into AccuScience he had noticed, when conducting an audit of the company, that one of the suppliers, AccuScience Ltd, listed among its directors a Mr James Hanratty. Mr Ryan said he believed that this Mr James Hanratty was one in the same person as Mr Sean Hanratty who sometimes signed himself as JJ Hanratty. Mr Ryan said he had an obligation under the Companies Acts 1963 to report the matter, which he did. Mr Ryan said he had since learnt that Mr Hanratty had resigned from the company in June of 1983. Mr Ryan said that he had been advised of this only recently by legal sources. Mr Ryan said the AccuScience matter was passed on to Dr O'Riordan. Mr Ryan said he was also in contact with a board member and that the issue of AccuScience was raised by Dr O'Riordan with the board of the B.T.S.B. Mr Ryan said Mr McCartney of the Department of Health, a board member, had contacted him and assured him that the AccuScience matter had been taken care of.

Mr Ryan said that up to 1978 the B.T.S.B. usually enjoyed a small profit and sometimes made small losses. Mr Ryan said up to this time the B.T.S.B. had been trading satisfactorily. However, the capital base was not catered for. Upon the move to Mespil Road, Mr Ryan said the deficiencies in funding the B.T.S.B. were exposed. Mr Ryan said that up until the 1970's the board had relied more or less on cash flow, and while there was the occasional difficulty it was nothing as to what would follow upon the move to the new premises.

Mr Ryan said the financial difficulties continued into the 1980's, and even in 1983, when financial matters improved, the B.T.S.B. was still in trouble but not in as poor a situation as had been the case in 1981 and 1982. Mr Ryan said he had no involvement in the choice of products and no involvement in custom fractionation. He was aware of sales of B.T.S.B. to Kabi and said this was a long-standing arrangement. Mr Ryan said between 1984 and 1986 financial circumstances improved, but not greatly. Mr Ryan said the problem went back to the statutory instrument under which the B.T.S.B. was established. The issue of capital funding was not addressed in the establishment order and remained uncertain.

Mr Ryan said the financial difficulties manifested themselves in the non-payment of accounts to suppliers. Mr Durcan asked Mr Ryan was it the case that companies such as Travenol were supplying the B.T.S.B. with product, the B.T.S.B. would sell it on but would then fail to discharge the debt due to the supplying company. Mr Ryan agreed this was the case. As the 1980's progressed

the situation regarding finances deteriorated to the point where the bank was refusing to meet BTSB cheques. Mr Ryan agreed with Mr Durcan that this was indeed a dire financial situation.

With regard to discussions concerning the home production of BTSB product and the economic prudence of continuing to import products, Mr Ryan said he could not recall the details of these discussions. However, Mr Ryan agreed that in July 1985 a stock run down had in fact taken place. Mr Ryan said too much stock remained in hand and gave cause for concern. In July 1985 it was decided that the stock should be reduced.

Mr Ryan said stock reduction was a method adopted by the BTSB at various times in order to prune its financial difficulties. Mr Ryan said the sale of derivatives represented a reasonably significant section of the BTSB's activities. He said this activity was relatively important and was seen as a source of profit.

Mr Ryan was then cross-examined by Mr Martin Hayden for the Irish Haemophilia Society. Mr Ryan agreed that he had read Mr McStay's report but did not give his own views on financial matters in his statement. With regard to whether or not Mr McStay's observation that a clear sense of financial stewardship prevailed at the BTSB, Mr Ryan said he regarded this as a laudatory comment by Mr McStay and hoped it referred to him.

Mr Ryan said he was constantly writing to the Department of Health and impressing upon the powers that be that the BTSB was in a very seriously detrimental financial situation. Mr Ryan said up to 1982 he was constantly seeking capital infusion. Financial pressures arose within the BTSB on the back of its move to Mespil Road and the demands from staff for settlements of outstanding monies.

With respect to whether or not it was financially prudent to embark upon the move to Mespil Road without the benefit of a grant in advance from the Department of Health, Mr Ryan said that in hindsight it would have been advisable to take such course. Mr Ryan reiterated the fact that the BTSB's financial difficulties could be traced back to the Establishment Order.

Mr Hayden directed Mr Ryan to a letter written by him to Mr O'Sullivan of the board of the BTSB. Mr O'Sullivan was an official at the Department of Health. While some money was forthcoming, Mr Ryan said sometimes the money would be made available and sometimes it would not.

Mr Hayden referred Mr Ryan to the concept of the BTSB's true overdraft position. In 1981 the BTSB had an authorised overdraft, however the true overdraft exceeded the authorised overdraft several times over. Mr Ryan said he left the Department of Health in no doubt as to the financial position of the BTSB in January 1981. However, it was hoped that the sale of the building at Leeson Street would assist the BTSB. However Mr Ryan agreed that the sale would only go approximately half way to reducing the BTSB's indebtedness at this point.

Mr Ryan agreed that in 1981 the BTSB experienced a difficulty in getting its accounts signed by its auditors. Mr Ryan said that at this time the BTSB was insolvent. As to whether or not it was technically insolvent, Mr Ryan agreed that if the BTSB had been a private company, this would have represented the end of the line. However, for the BTSB it was expected that the State would not allow the blood transfusion service to go out of business.

At the end of 1981 the BTSB's financial position was that it had an agreed overdraft of £200,000 and had a real overdraft of £1.1 million. A further £170,000 worth of cheques were under consideration at the bank.

Mr Ryan set out the strategies adopted in order to persuade the Department of Health to agree price increases for the BTSB. Mr Ryan said that, while the price increase would be requested, the board would allow a partial increase. Mr Ryan said that at this time he had the distinct impression that, not only was the BTSB in financial trouble, but that the Department of Health was also in financial trouble itself.

In March 1982 Mr Ryan's budget committee notes that a deficit of £479,000 is forecast for the year. Mr Ryan said that commencing in January 1982, most of his time had been and was being taken up with personnel matters. He said he had seven unions to deal with. Mr Ryan said the position was that he was dealing with the finances, but had no authority to make any changes. He said a committee was formed and each member of the committee would suggest a few cuts here and a few cuts there, but overall the strategy to reduce costs was ineffective. Mr Ryan agreed that the difficulty faced by the BTSB at this stage was a lack of liquidity. Mr Ryan said the business was growing and needed more liquidity, but money was never forthcoming from the Department of Health, and if it did come it would come late. Mr Ryan said that this constantly left the BTSB in trouble. Mr Ryan said he could not say whether the financial conditions had any impact on the board and its decision-making process.

Mr Hayden referred Mr Ryan to the transcript of Mr McStay's evidence on day 42, 27th September 2000, where Mr McStay agreed that financial matters permeated all decision-making at the BTSB at this time. Mr Ryan said his view was that not every person on the finance committee and in the BTSB saw finances as their responsibility. With respect to plans for computerisation, Mr Ryan said it didn't happen. Mr Ryan said his impression was that a man would appear and say, nothing is happening until the money is right, regarding any expenditure proposed by the BTSB.

In January of 1983, a year in which Mr McStay had made the case that the BTSB was enjoying a period of financial stability, Mr Ryan said, we felt the worst was behind us, and the BTSB was no longer going through the trauma of really bad years. However, the BTSB was still looking for a price increase of 10 per cent or else it could lose up to £45,000 per month. While it was envisaged in January 1983 that the year would have a positive outturn, Mr Ryan said that a deficit was still expected.

In February 1983, the year in which the BTSB was apparently enjoying financial stability, it is minuted at the board that cut-backs were expected on all fronts. Mr Ryan said he could not comment on budget committee memos of the time, even though he was present at the budget committee, particularly with respect to profits coming from home production and the blood fractions representing an economically prudent product. Mr Ryan said he could not remember discussions as to whether it would be economically prudent to continue importing blood fractions.

Mr Hayden asked Mr Ryan was the financial template set in 1983 ever revisited? Mr Ryan said he was vague in his memory of what happened then, but agreed that cost-cutting continued to some extent. As to whether or not the idea that it was economically prudent to continue importing blood fractions, Mr Ryan said he could not remember the context of this particular debate.

PROCEEDINGS: THURSDAY 9th NOVEMBER, 2000 – DAY 66

Mr Hayden continued his cross-examination of Mr E A Ryan, formerly accounting and personnel officer at the BTSB. Mr Hayden asked Mr Ryan, in late 1982 and into 1983 were there any discussions among the staff about AIDS. Mr Ryan said he could not remember.

Mr Hayden referred Mr Ryan to a memo by Mr Cann. Mr Cann had previously told the Tribunal that there was an awareness of AIDS at the BTSB from late 1982 and early 1983 derived mainly from U.S. literature. Mr Cann had said the top medical and scientific people at the board were all aware of the threat from AIDS from the end of 1982 and the beginning of 1983. Mr Ryan said this may well have been the case, but this information did not come down to him.

Mr Hayden asked Mr Cann would members of the scientific meeting and the top medical scientific people on board attend at the finance committee? Mr Ryan said this was the case with respect to purchasing of derivatives. Mr Hayden asked Mr Ryan did these products make a contribution to the Board's bottom line, and would he agree that the marginal cost of handling these products was small. Mr Ryan agreed that the mark-up on derivatives contributed to the Board's surplus. Mr Hayden referred Mr Ryan to documents prepared by him, ie. Mr Ryan, where he states that each 1p added to the price of an international unit of concentrate would result in a profit to the Board of £26,000. Mr Ryan agreed that the surplus achieved from derivatives would help defray the Board's costs.

Mr Ryan said that when the Department eventually paid grants over in 1982, they were paid without any strings attached. In his dealings with Dr O'Riordan, said Mr Ryan, finances were not part of Dr O'Riordan's agenda. Mr Ryan said that Dr O'Riordan was primarily concerned with safety. Mr Ryan said that he did not hold a decision-making role at the BTSB. He thought the scientific meeting may have discussed the prices of concentrates, but wherever it was agreed he was simply directed on the price and implemented the directions given to him.

Mr Hayden asked Dr Ryan, was it the case that in March 1983 he thought that no more grants would be forthcoming from the Department of Health? Mr Ryan agreed that at this time it appeared that capital grants were a thing of the past. In May 1983 the BTSB's Board recorded a relative improvement, however during this month the BTSB was in receipt of a summons from the Revenue Commissioners in respect of PRSI and PAYE accounts. Mr Ryan said the Revenue landed the BTSB with big bills. The Revenue had not received returns from the BTSB for a number of months and quite abruptly served proceedings, said Mr Ryan. The matter was resolved by the BTSB agreeing to make double payments after it received a grant. Mr Ryan said on 14th January 1983 his choice was between the Revenue and other creditors. Mr Ryan said it would appear that the other creditors prevailed on this occasion.

Mr Ryan said at this period he was rather optimistic that the Board could clear the position, and he so informed Dr O'Riordan. He said this was the case provided there were no further shocks, and that it would be critical to adhere to the budget committee decisions to cut costs.

With respect to the board's response to the scientific meeting of 9th June 1983, Mr Ryan said no costing was ever made of the proposals which appeared to emanate from this meeting, ie. that cryoprecipitate should be used pending intermediate concentrate. Mr Ryan said he imagined that the members of the scientific meeting would do the calculations themselves. Mr Ryan said they

may well get the information concerning the price of products from him, but this would be the extent of his involvement.

Mr Hayden put it to Mr Ryan that, despite an apparent improvement in finances in August 1983, the board's liabilities of £1 million plus were not met by a grant of £900,000 and no account was taken of making a provision for working capital. Mr Ryan agreed that it would appear the board made a commitment to expenditure which it was not able to fund. Mr Hayden put it to Mr Ryan that in reality the board's position had not improved at all in 1983. Mr Ryan said that he could see the logic of this approach. However, said Mr Ryan, the board knew at all times the state of finances, and had been specifically notified of some of the difficulties.

Mr Hayden referred Mr Ryan to a letter from the board's auditors, Coopers & Lybrand, 12th August 1983. Mr Ryan said this letter was not discussed by him with any other person at the BTSB. Mr Ryan said he had no concern about the auditors' comments. He had read the comments and had done nothing about it. Mr Hayden pointed Mr Ryan to a call for a price increase in blood products in December of 1983. The BTSB at this stage was looking for a 4% increase. The accountants' figures projected a profit for that year of £215,000, and in fact the board returned almost £700,000.

Mr Hayden suggested to Mr Ryan that the management accounting system did not appear to be able to provide accurate information upon which projections and price increase requests could be based. Mr Ryan said in the event the request was refused. He got a communication from Mr McCartney, saying that the board would not get a 4 per cent increase in 1984. By February of 1984 Mr Ryan indicated that, while the first half of the year was expected to be good in that a surplus would be returned, a poor second half was anticipated. By October 1984 the BTSB had returned to the position of operating a rail overdraft and was withholding cheques to its creditors.

In December 1985, in costing HTLV-III expenditures, it was noted that grave problems have returned. Suppliers who have not been paid or threatening non-delivery and the landlord was suing for rent arrears. Mr Ryan said he had to do what he had to do. He felt that he was robbing Peter to pay Paul at this time, and it was returned to the black years of the early 1980's. Mr Ryan said it was a difficult period and equally grave to that which had gone before. However, Mr Ryan said it was a different type of problem at this stage. Mr Ryan said in the early 1980's the problem had been caused by the expenses incurred in the move to Mespil Road. In the later 1980's the problem was caused by the growth of the BTSB and the lack of funding to underwrite such growth.

It was his opinion that all these problems went back to the financial footing upon which the BTSB was founded in its establishment order. The lack of a capital funding provision in the establishment order left the BTSB vulnerable to continuous financial crisis, said Mr Ryan.

Mr Ryan said the arrival of Mr Keyes in 1986 meant that someone with a degree of power and influence was available to sort out financial matters. He said Mr Keyes was far more powerful than he ever was. Mr Hayden referred Mr Ryan back to a memo written by Mr Ryan in 1981, wherein he indicates that a full-time financial person who would be able to construct and operate the budget, was needed to run the BTSB's finance. Mr Ryan agreed that the arrival of Mr Keyes, albeit five years later, fulfilled the requirement which he had identified back in 1981. Mr Ryan said he did not act in 1981 because, if he laid out a budget he would be left to deal with it, and instead of having two jobs, one as accountant, one as personnel officer, he would now have three jobs in controlling the budget.

Mr Ryan said that up to this period in 1986 the BTSB's finances were so poor, the BTSB resorted to door-to-door collection of monies outstanding to it from hospitals. Mr Ryan said if a hospital indicated that a cheque was ready and would be sent to the BTSB, someone from the BTSB would go to the hospital and pick up the cheque. Mr Ryan said in this way the board's debt collection procedures were improved.

With respect to extraordinary movements of stock mentioned in the budget in 1986 in a review by Coopers & Lybrand of the accounts commissioned by Mr Keyes, Mr Ryan said the review contained an assessment of the control and accounting systems in use. Mr Ryan said such systems were adequate in 1969 when he joined the board, but by the late 1980's no improvement or change had taken place and the system was no longer adequate for the financial needs of the BTSB. Mr Ryan said it was his opinion that the Department of Health put Mr Keyes in place in order to bring the financial affairs of the board under control. Mr Ryan said with the arrival of Mr Keyes, he moved largely into personnel. Mr Ryan said he retired from the BTSB in 1988 at a time when the public service was reduced by way of early retirement and career breaks.

Mr Hayden referred Mr Ryan to various documents concerning the board's factor IX production, where at the 18th December 1985 it was decided to continue with Pelican House production as it was not viable for Travenol to make factor IX for the BTSB.

By 6th January 1986 Mr Ryan said the financial down-turn experienced by the BTSB was accelerating. Mr Ryan said by 15th January 1986 the finances of the board were in a bleak condition. It was his opinion at this time that credit given to the board further decreased its position. With respect to a letter from Dr Barry to Mr Flanagan of the Department of Health, seeking compensation for an £80,000 loss incurred by the introduction of heat treated and screened product only, Dr Barry unsuccessfully sought compensation for the BTSB for losses amounting to about £80,000.

Mr Hayden directed Mr Ryan to documents contained in the Department of Health discovery. On 7th October 1981 the Department of Health noted that 80 per cent of the accounting personnel officer's time was spent on personnel matters. Mr Ryan said the Department of Health sought to effect a savings programme, and it was then that the need for a full time accountant was identified. This was not done until 1986. Mr Ryan said he had no power over other departments in the BTSB. No person with such powers was available until Mr Keyes was appointed in 1986. The Department noted in June of 1982 that the accounts had still not been brought under control, and that the ACP could not state if an audit had taken place.

On 26th October 1983 it was noted that weak external control in ineffective management characterised the BTSB. Mr Ryan said at this time a management reshuffle was due. He said the older guard, including himself, could not deal with the issues like computerisation. The introduction of controls previously unheard of, including increased internal control, meant that the old friendly ethos of the BTSB was removed.

Mr Hayden asked Mr Ryan, did the Department have a clear understanding of the difficulties facing the BTSB at this time with respect to finance. Mr Ryan said this was the case. He said the medical director, who was also the administrator, was well aware of what was going on.

On 25th May 1986 it was noted in a memo from Coopers & Lybrand that the board could not expect to rely on the Department of Health forever. In order to bring its finances under control a reduction in stock was organised. The stock reduction took place during the latter half of 1985. Mr Hayden asked Mr Ryan, had he prepared a spreadsheet put before the Tribunal, detailing the

reduction in stock. Mr Ryan said he could not remember the exact detail but he was aware that such an exercise took place. Mr Ryan said he may have prepared the figures but the details would have been supplied to him by those involved.

Mr Ryan was also cross examined by the Department of Health and by the BTSB.

PROCEEDINGS - FRIDAY 10th NOVEMBER 2000 - DAY 67

Mr Gerry Durcan S.C. for the Tribunal examined Dr James H Walsh, former deputy chief medical officer of the Department of Health from 1974 until 1988.

Dr Walsh told the Tribunal that AIDS was identified by the CDC, Atlanta in 1981. His job at the Department of Health meant that he had to deal with all aspects of AIDS. Dr Walsh said that dealing with AIDS in homosexuals and drug addicts was a difficult task in that in the early days, homosexuality was a criminal offence in Ireland. Condoms were only available on prescription and getting homosexuals and drug addicts to change their lifestyle was problematic.

On the other hand, said Dr Walsh, dealing with AIDS arising from haemophilia presented a more straight-forward difficulty. Given that AIDS in haemophilia was spread by blood products, concrete steps could be taken to reduce the risk. Dr Walsh said when HIV testing and heat treatment of concentrates were available, steps could be taken to prevent the virus spreading. Dr Walsh said AIDS and haemophilia was a medical/scientific issue and could be dealt with as such.

Mr Durcan referred Dr Walsh to a note of the BTSB's June 9th 1983 scientific meeting. Mr Cann's note of the meeting records "Meet Department re: policy. Use more cryo pending intermediate concentrate". Mr Durcan asked Dr Walsh did he have any recollection of such a meeting? Dr Walsh said he wasn't the contact point at the Department of Health for the BTSB, and would not attend such meetings. Dr Walsh said that the Department of Health contact was a doctor who was on the Blood Transfusion Service Board and who was a member of the Department of Health.

By the summer of 1983, Dr Walsh said it was obvious that AIDS was blood-borne. Dr Walsh said by this time Montagnier had isolated the LAV virus. He said prior to this a good deal of argument existed as to whether not AIDS was spread by a virus, but by 1983 it was confirmed that it was indeed a virus, and it became clear that the virus was spread by body fluids such as blood. Dr Walsh said it was equally clear that AIDS was not spread by droplet infection, as is the case with colds and influenza.

Dr Walsh said he would not be familiar at this time with the Council of Europe. Again, he said it was another doctor at the Department of Health who would have been concerned with Council of Europe matters. Mr Durcan referred Dr Walsh to a document of the 27th November 1984, from himself to Dr Buttimer, concerning the first case of AIDS in a person with haemophilia in St. James' Hospital. Dr Walsh said that he had been put on the alert that the case had occurred, and it was his first intention to contact Prof. Temperley. Dr Walsh said the arrival of this case was very significant and represented an ominous development.

On 13th December 1984 a meeting took place between the Department of Health, represented by Dr Walsh, and Prof. Temperley and Dr Cotter. The purpose of the meeting of 13th December was to decide the course of action designed to prevent the spread of AIDS through the use of factor VIII and factor IX. It was unanimously decided at this meeting that factor VIII and factor IX should be heat treated as soon as possible. Dr Walsh said there was total agreement about heat treating factor VIII and factor IX. It was realised that there was a great risk of infection from non-heat treated products, and the agreed course of action was that Prof. Temperley would write to the BTSB and refer them to the need to heat treat all (and Dr Walsh said he used the word "all" advisedly) blood products and derivatives.

Mr Durcan referred Dr Walsh to a letter from Prof. Temperley to Dr O’Riordan of 17th December 1984. Prof. Temperley, referring to his meeting with Dr Walsh, says that the haemophilia treaters will buy only heat treated factor VIII and factor IX from commercial sources in 1985, and urges the BTSB to consider heat treating all products. Mr Durcan asked Dr Walsh was he aware that the BTSB did not in fact heat treat factor IX upon receipt of this letter. Dr Walsh said he thought the BTSB was using only heat treated products from this time.

Mr Durcan referred Dr Walsh to a letter to Dr Aboud, Medical Administrator of St. James’ Hospital, also dated 17th December 1984. The letter indicated that the treaters have agreed to purchase only heat treated products, and that the BTSB would heat treat at the earliest possible time. Dr Walsh said this was also his understanding of the outcome of the 13th December meeting, and his understanding of what was happening at the time.

Mr Durcan referred Dr Walsh to a letter from Dr O’Riordan to Prof. Temperley. Dr O’Riordan told Prof. Temperley that the heat treatment of all products would be given urgent attention by the BTSB. Dr Walsh said his understanding of this letter, which was copied to him, was that the BTSB would implement the advice he had given and all products would be heated. It was noted on a copy of the letter, that he discussed the contents of the letter with Dr O’Riordan on 10th January 1985 re: the number of cases. Dr Walsh said he could not remember the exact discussion, but it could well have happened. Mr Durcan asked Dr Walsh, could the BTSB have been under any misapprehension as to the nature of his instruction to heat treat all products? Dr Walsh said, no, he was at the end of the phone if any clarification was needed.

In April of 1985 Dr Walsh attended the World Health Organisation conference in Atlanta where the heat treatment of factor VIII and factor IX was discussed. At this meeting Dr Walsh said he learned that it was considered essential that factor VIII and factor IX be heat treated. Dr Walsh said that on learning this information in Atlanta, he considered that the step he had taken was justified. Dr Walsh said he told his colleagues that the Irish authorities were indeed heat treating factors VIII and IX at this time. Dr Walsh said he continued in this belief throughout 1985.

With regard to his availability, Dr Walsh said there was no difficulty in getting in touch with him to discuss matters relating to AIDS as he took between 20 and 30 calls every morning, and was in constant touch with those who wanted information regarding AIDS. Dr Walsh agreed that this involved appearing in television and being interviewed on radio and in the newspapers.

On 27th August 1985 Dr Walsh agreed that he appeared on an RTE radio programme “Bodywise” with Dr Terry Walsh of the BTSB. The discussion was on AIDS. However, apart from these contacts Dr Walsh said he had no contact with anyone from the BTSB concerning heat treatment.

Mr Durcan asked Dr Walsh, if such contact had taken place how would he have reacted to the information that BTSB product was not heat treated? Dr Walsh said he would have reacted strongly. He would have went to the Secretary of the Department. He would have taken action, including going to the Minister himself.

Mr Durcan asked Dr Walsh did he consider that a risk was being taken in using non-heat treated factor IX? Dr Walsh said he agreed absolutely that this constituted a risk.

Mr Durcan then referred Dr Walsh to a meeting between the BTSB and the Department of Health on 21st January 1986, where the Department met consultants prior to a meeting within the BTSB. Dr Walsh said this meeting was called to discuss the recent introduction of HTLV-III screening by the BTSB, which had occurred in October of 1985. Dr Walsh agreed that he had instructed

that all non-tested products should be withdrawn. Dr Walsh said this was not so much a medical matter as an exercise of common sense to remove non-screened products, now that screened products were available.

Dr Walsh said he was very anxious to have screening introduced. The meeting on 21st January 1986 was not about non-heat treated factor IX, said Dr Walsh. He was under the impression that BtSB factor IX had been heat treated from the previous January. The meeting with the BtSB on 21st January 1986 was to discuss the issue raised by the BtSB about alternative sites for testing, as the BtSB was worried that at-risk groups would use its facilities to avail of a test for HTLV-III. Mr Durcan asked Dr Walsh was his concern at this time about untested donations continuing in use? Dr Walsh agreed that this was the case.

With respect to how he would have reacted had he been aware that unheat-treated product remained in circulation, Dr Walsh said he would have been horrified to learn this. Dr Walsh said he would have been horrified to know that unheat-treated and untested products also remained in circulation. Dr Walsh said that his instruction was that all blood products before testing should be withdrawn.

Mr Durcan referred Dr Walsh to a letter from Dr Barry to Mr Flanagan of the Department of Health dated 21st January 1986, with regard to unscreened products. Dr Barry wrote to the Department looking for compensation in respect of products made from unscreened donations which had now been withdrawn. Dr Walsh said he saw a copy of this letter and thought it reflected the fact that his advice had been acted upon. Dr Walsh said his instructions were to withdraw all blood products made from unscreened donations. That included factor IX. Dr Walsh said he used the word "all" advisedly.

In a letter from Mr Flanagan to Dr Barry in response to his communication of the 22nd January 1986, Mr Flanagan reiterated that products made from unscreened donations should be withdrawn. He said it was imperative that this take place. Mr Durcan asked Dr Barry how he would have reacted had he known that untested factor IX remained in the hospitals after this date. Dr Walsh said he would have been astonished. How would he have reacted had unheat-treated factor IX continued in use after January 1986? Dr Walsh said this was horrific.

Dr Walsh said he thought the doors on unheated and untested product had been closed. Dr Walsh said it was his understanding that non-heat treated product had not been used since the previous January, and that untested product had not been used following his instruction of January 1986. He now knew that this was not the case and said that he was learning more and more from the Tribunal, and from reading newspaper accounts of its investigation.

Mr Durcan referred Dr Walsh to a letter from Dr Terry Walsh of the BtSB to the medical officers in charge, of June 25th 1986. Dr Walsh said he did not see this letter, which purported to withdraw non-heat treated product from circulation. Dr Walsh said he thought he had dealt with this matter 12 months previously. Dr Walsh said in the spring and summer of 1986 he was not aware of a problem of seroconversion among people with Hepatitis B. Dr Walsh said the data on such seroconversion would be reported to him on a monthly basis, but it was not clear from this when such patients became positive.

Dr Walsh was then cross-examined by Mr Raymond Bradley for the Irish Haemophilia Society. Dr Walsh agreed that viral hepatitis was a notifiable disease. Dr Walsh said that the responsibility of notifying the Department lay in the first instance with the treating doctor, who would report the matter to his health board. The health board would then notify the Department

of Health. Mr Bradley asked Dr Walsh would he expect the B.T.S.B to make such notification if it came across cases of Hepatitis B? Dr Walsh agreed that this was the case.

Dr Walsh was then cross-examined by Mr Charles Meenan for Dr Terry Walsh.