IRISH HAEMOPHILIA SOCIETY

TRIBUNAL NEWS

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TRIBUNAL OF INQUIRY

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

PROCEEDINGS: TUESDAY 26th SEPTEMBER, 2000 – DAY 44

Mr. Martin Hayden continued his cross examination of Mr. John McStay,. Mr. McStay was giving evidence on behalf of the BTSB on financial matters.

Mr. Hayden referred Mr. McStay to the several internal control letters from Coopers & Lybrand, the BTSB's auditors. Mr. Hayden asked Mr. McStay had he seen the management letters from Coopers & Lybrants when preparing his report. Mr. McStay said he had asked for the letters but had not received them.

Mr. Hayden noted that the audit documents for the 1983 accounts were missing. He asked Mr. McStay did he consider it surprising that such documents could go missing from the BTSB. Mr. McStay said that he did not consider it surprising that the documents were absent.

Mr. Hayden referred Mr. McStay to an internal control letter from the auditors dated May 1986. The letter notes that in 1982 the Board could rely on the Department of Health for money but for the 1985 period the auditor stated that the Board could no longer rely on the Department of Health as a source of funding. Mr. McStay agreed that this was the case.

Mr. Hayden asked Mr .McStay was it the case that the Coopers & Lybrand document of May 1986 indicated that the BTSB appeared to be in financial trouble for every year except 1983? Mr. Hayden asked Mr. McStay was it his position that in 1983 the BTSB did not have financial difficulty? Mr. McStay said this was his view.

Mr. McStay said that from a cash point of view the position improved throughout 1983. He said that from the accounts, from the monthly management reports and from the true overdraft figure the BTSB's performance was improving.

Mr Hayden noted that it appeared to be Mr McStay's view that financial matters were improving. However, he put it to Mr McStay that the BTSB Budget Committee in February 1983 noted that while new products, such as Factor VIII concentrates were highly desirable as import substitutions they would not generate a profit in the early stages of production.

The views of the budget committee were reflected in a meeting of the BTSB Board held on the 16th February 1983, which noted that whilst it was appreciated that at present it

was economically prudent to purchase some blood derivatives abroad, more consideration is to be given to home production by the BTSB.

Mr. Hayden asked in view of the fact that it was Mr. McStay's estimation that matters improved in 1983 did the Board ever revisit the concept of home production and did it ever alter its view, expressed at the February Budget Committee meeting that it is economical prudent to continue with blood derivatives from abroad.? Mr. McStay said that he was aware from the documentation of tests and trials being conducted by the BTSB with regards to home production, but from his notes he observed no further reference to the question of whether or not it was economical prudent to continue the import of blood derivatives from abroad. Mr. Hayden asked was there any revisiting of this economic decision during 1983? Mr McStay he was not aware of it.

Mr. Hayden asked Mr. McStay was he aware of any matter of significance which occurred in the summer of 1983? Mr. Hayden asked Mr. McStay was the summer of 1983 not the summer of AIDS, when AIDS became a major issue in the context of the blood supply?

The chairperson intervened and asked Mr.Hayden how did the issue of AIDS relate to the financial matters scrutinised by Mr. McStay? Mr. Hayden said that Mr. McStay had indicated from his examination of the documents that there had been no revisiting of the economical prudence of continuing with imported products

Mr. Hayden put it to Mr. McStay that his position appeared to be that, based on the finance committee minutes everything seemed to be reasonably good shape for 1983. Mr. McStay said that from reading the Finance Committee meeting minutes that the Board was in a good financial position in 1983 and for most of 1984.

Mr. McStay said he thought he could put it a little bit further than that. The finance committee minutes of the 7th November 1983 indicated sales or services rendered were very healthy and the Board was anticipating a surplus of £600,000 to £700,000 for the year. Mr. McStay said that he thought the Board had a reasonably good handle on the financial position as it ran into late of 1983.

Mr. Hayden put it to Mr. McStay that it seemed to be the case therefore that from a financial point of view business was continuing, products were being sold and price increases were taking effect in 1983. Mr. McStay agreed that this was the case.

Mr. Hayden then referred Mr. McStay to a letter, dated December 2nd 1983. from Mr Ryan of the BTSB to the secretary of the Department of Health contained at volume 52, page 130 of the Tribunal core documents. The letter from Mr. Ryan enclosed the Boards budget of accounts for 1982 and estimated accounts for 1983 based on actual results to September 1983.

The Board's 1984 budget was projected from figures available as of December 2nd, 1983. The letter noted that the Board's overall deficit was £311,000 for the year 1982, this was

contrasted with an expected net surplus of £215,000 for the year 1983 and a projected net loss of £161,000 for 1984 assuming prices remained unchanged. The letter went on to ask the BTSB to approve a price increase a rate of 4 per cent on whole blood and blood products to cover the expected net deficit for the year 1984 and to provide for several adverse possibilities likely to arise during the coming period. The 4 per cent increase was projected to add £266,000 to the Board's revenue.

Mr. Hayden put it to Mr. McStay that the Board appeared to think that it was going to be in deficit for 1984. This was its position as of the 2nd December 1983. Mr. McStay agreed that this appeared to be the case.

Mr. Hayden put it to Mr. McStay that the Board had estimated that there was going to be a deficit of £161,000 for 1984. Mr. Hayden asked Mr. McStay that on the basis of the figures compiled by him if the Board stopped selling blood derivatives at this point would the £161,000 projected deficit be greater?

Mr. McStay said the letter indicated to him that it was the Board's decision that in order to continue the same profitable financial performance they experienced in 1983, Mr. Ryan was suggesting that it would be appropriate to increase the price of whole blood and other products.

Mr. Hayden said that the reason he put the letter to Mr. McStay was to determine the state of knowledge of the Board in late 1983. Previously Mr. McStay had indicated that the Board thought everything was going well up until middle 1984. Mr. McStay said that from the cash flow point view there was no suggestion of any cash flow difficulties until mid to late 1984 and that was the the issue he discussed last time. Mr. Hayden put it to Mr. McStay that the Board's position as of December 1983 was that everything remained unchanged the Board was going to be in deficit to the tune of £161,000 in 1984. Mr. McStay agreed that this was the case on the basis of assumptions set out in Mr. Ryan's letter.

Mr. McStay agreed that if the Board at this point discontinued derivatives the Board's financial position would disimprove accordingly. Mr. Hayden asked Mr. McStay why he had not mentioned the letter of December 1983 in his report given that the letter indicated that the BTSB was anticipating a deficit of £161,000 for 1984.

Mr. Hayden asked Mr. McStay was he saying that the Board did not perceive itself as having an overall financial difficulty in 1983 or early 1984? Mr. McStay said it depends on how one defines financial difficulty. Mr. McStay said from a cash point of view the Board did not have difficulties at this particular time. But the Board was saying to the Department, as it said on other occasions, our costs are increasing and we need an increase in the price of whole blood if we are to cover our costs in 1984. In the case of this particular letter Mr. McStay said he didn't attach any greater significance to this letter than to any comparable letter in any of the years under discussion.

Mr. McStay said that his understanding of the letter was that Mr. Ryan was saying that if we have to cover our costs in 1984 we need a price increase.

Mr. Hayden then referred Mr. McStay to a letter of the 10th February 1984 from Mr. Ryan to the chairman and members of the BTSB re: finances February 1984. Mr. Ryan's memo to the Board states … "further to the Boards application for a 4 per cent price increase the Department of Health has advised that on the basis of information furnished no increases on the existing prices of blood and blood products was indicated at this stage. Further consideration will be given to this matter when figures for the end of June 1984 are available."

The memo goes on to indicate that the Board's finances will do well in the first six months of 1984, the second half of the year may be another matter. Mr. Hayden put it to Mr. McStay the Board was therefore on notice that in February 1984 problems were arising in relation to the trading position of the BTSB?

Mr. McStay said that he would suggest that the Board was on notice of December 1983 upon Mr. Ryan's earlier letter to the Department.

Mr. Hayden further referred Mr. McStay to the minute of the Board of the 13th September 1984. Under the heading Financial Report, it is noted that while day to day operations continue to be satisfactory a liquidity problem is about to arise on the back of an adverse rent judgement leading to the back payment of £360,000 for which a provision of £300,000 had been made. The amount over and above the current contribution towards the expenses of transferring the Cork center to St. Finbarrs and an air conditioning system at Pelican House at a cost of £253,000 all payable within weeks.

Mr. Hayden put it to Mr. McStay that from December 1983 if would appear that the Board knew it would suffer a loss even without making capital expenditure and yet the Board went ahead and bought an air conditioning system. Mr. Hayden asked Mr. McStay would that strike him as being financially prudent? Mr. McStay said that the purchase of an air conditioning system in the circumstances was no less financially prudent in many similar capital expenditures undertaken during the period by the BTSB.

Mr. Hayden put it to Mr. McStay that as a matter of fact the Board knew it was not getting an price increase in February 1984 yet the Board proceeded to incur capital expenditure in circumstances no different from other decisions of a similar nature made by the Board. Mr. McStay said that the total capital expenditure in 1983-84 was £1.2 million.

Mr. Hayden asked if these were the circumstances which the financial officer had identified in December 1983 when he predicted that financial difficulties were in the offing? Mr. McStay said that he identified that if a price increase was not allowed the Board would not cover its operating costs in 1984. Mr. Hayden put it to Mr. McStay that in February the Board knew it was not getting an increase? Mr. McStay agreed that this

was the case. And yet the Board continued to make its capital expenditure? Again Mr. McStay agreed that this was the case.

Mr. Hayden put it to Mr. McStay that in those circumstances the Board had all the more reason to maintain all resources of existing cash flow including the sale of factor concentrates> Mr. McStay agreed that this was the case.

In addition to cross examining Mr McStay on his evidence concerning his report on the Board's financial position in 1983 and 1984 Mr. Hayden also covered the Board's plasma procurement program instituted in 1984 and 1985 and issues arising from the BTSB's stock management.

Mr. McStay agreed that the BTSB followed the Board's directive to reduce stock in the latter half of 1985. The stock production program accelerated the distribution of BTSB Factor IX in the months following Dr. Daly's request that non-heated products should not be used.

With regards to the sale of plasma to Kabi Mr. Hayden raised the issue of a discrepancy between the BTSB's record of its dispatch to Kabi and the companies receipt of plasma from the BTSB. The documents show that Kabi took receipt of considerably more plasma than the BTSB records as having been delivered in the years 1981 and 1982.

PROCEEDINGS: WEDNESDAY 27th SEPTEMBER, 2000 – DAY 45

Mr. John McStay was cross-examined by Mr. Ian Brennan for the Department of Health.

Mr. Brennan contended that the Department of Health allowed the BTSB to increase its prices and did not delay in granting permission to the BTSB when an application was made. Mr. McStay said it was his opinion that the Department of Health was reluctant to meet additional costs incurred by the BTSB and the price increases allowed by the Department were not enough to cover the BTSB's capital funding requirement. The uncertainty as to where money would come from was a major part of the BTSB's problems, said Mr.McStay.

Mr. McStay was examined by Mr. Michael McGrath for the BTSB. Mr. McGrath asked Mr. McStay was it the case that the demand for factor concentrates was effectively dictated by hospital requirements, Mr. McStay agreed this was the case. Mr. McGrath also raised the issue of a necessity for expenditure on the Mespil Road building especially in respect of the installation of an air conditioning system. Mr. MrGrath maintained that this was an essential expenditure on behalf of the Board.

Mr. McStay then withdrew.

The Tribunal then called Mr. Ted Keyes. Mr. Keyes is an accountant by profession, he qualified as an accountant in 1962 and made his career in various health service posts. Mr. Keyes was a program manager with the Western Health Board when he was appointed to the Board of the BTSB. His board appointment lasted him until June 1976. Mr Keyes said he was asked to join the Board to bring some financial expertise to its affairs with special emphasis on the Board's finance committee. In 1976 Mr. Keyes joined the Eastern Health Board and remained there until June 1986.

Mr. Keyes said he was asked by Mr. Gerry McCartney of the Department of Health to consider taking up a post with the BTSB. In January 1986 Mr. Keyes was appointed executive consultant with the BTSB. Mr. Keyes said he told Mr. McCartney he would take the job provided he did not have to deal with medical matters as he had no medical expertise. Mr. Keyes said that he was advised at the time that Dr. Barry had taken on the position of Chief Medical Consultant and that he would deal with all medical aspects of the Board's work.

Mr. Keyes was seconded to the BTSB for one year commencing in 1986 and subsequently became Chief Executive Officer in 1987. Mr. Keyes retired from the position as Chief Executive Officer in June 1995.

When Mr. Keyes replaced Dr. O'Riordan as Chief Executive Officer of the BTSB his job description was to deal with everything except medical matters. Dr. O'Riordan, when he had been national director of the BTSB, dealt with both administrative and medical matters on behalf of the Board. Mr. Keyes said that on his appointment to the Board the

immediate issues facing him were finance, contract fractionation, donor development and computerisation, he was also expected to look after the industrial relations of the Board. Mr Keyes said he was briefed by Mr. McCarthney of the Department of Health.

Mr. Keyes said he had a close working relationship with Mr. Fox, he said Mr. Fox was a very good chairman and very demanding. Mr. Keyes said he had also had a good relationship with Dr. Barry who was the chief medical consultant, however Dr. Barry did not want the job and he expressed his wish to return to Cork to attend to personal matters. Mr. Keyes said he advised Dr. Barry to talk to the Chairman, Mr Fox, as he [Keyes] had no authority to relieve Dr. Barry from his post as chief medical consultant.

Mr. Keyes said Dr. Walsh was then more or less designated as the consultant in charge of the Dublin area. Mr. Keyes said that he relied on Dr. Walsh to fulfill the role as chief medical consultant.

As chief executive Mr. Keyes said he reorganised the administration of the BTSB in that he designated the heads of each department to manage their respective departments and report to him on a monthly basis.

Mr. Finlay referred Mr. Keyes to a meeting between the officials of the Department of Health and BTSB officers on the 22nd January 1986. The main purpose of the meeting was deal with the withdrawal of stock which had come into existence prior to the introduction of HIV testing? Mr. Keyes agreed that this was a correct interpretation of the meeting, however Mr. Keyes was not in attendance at this meeting. Mr. Keyes said he understood that stock would be withdrawn but he did not know the reason for the withdrawal, he did not know whether or not the withdrawal was because the stock had not been tested for HIV or was non-heat-treated stock. Mr. Keyes said he was told simply because there would be financial implications.

Mr. Finlay referred Mr. Keyes to a letter written by Dr. Barry to the Department of Health wherein Dr. Barry asked the Department to approve the provision of replacement stock to hospitals in view of that which was to be withdrawn.

On behalf of the Department Mr. Flangan replied to Dr. Barry telling him that it was imperative that all stock issued to hospitals prior to introduction of HTLV-III antibody testing, and still held in stock, should be withdrawn. The Department instructed the BTSB to act immediately and stated that the financial implications of the action should be taken into account by the Board in determining its 1986 overall budget. No special provision would be made by the Department.

Mr. Finlay referred Mr. Keyes to a letter from Dr. Walsh of January 30th 1986. Mr. Keyes said he had seen a copy of the letter. Mr. Finlay put it to him that the letter did not deal with the point raised earlier, i.e. what was to happen with the BTSB non-heat-treated factor IX which might be in hospitals. The letter stated that non-heat-treated commercial stock should be returned but said nothing as to what would be done with non-heat-treated

BTSB stock. Mr. Keyes said that he thought Dr. Walsh's letter gave a clear indication as to what type of products should be used.

Mr. Finlay referred Mr. Keyes to the budget projections for 1986. Mr. Keyes said that a serious cash flow problem was being encountered at that time. He had written to the Minister requesting a refund following upon the Minister's directive to withdraw non-tested product from circulation. However in the letter the terms tested and non-heat-treated appeared to be used interchangeably. Mr. Keyes said he did not fully appreciate the difference between heat treated and tested product at this time.

With regards to the Travenol contract Mr. Keyes said it was estimated in January 1986 that 12,000 litres of plasma would be required, this projection was subsequently increased to 18,000 litres of plasma. No factor IX was returned to Travenol. Mr. Keyes said that this time he assumed that all plasma that had been collected had gone to Travenol, he knew nothing about the production of cryoprecipitate or factor IX from cryoprecipitate supernatant.

Mr. Finlay then referred Mr. Keyes to the question of sponsorship and Board members travelling to conferences aboard. A controversy had arisen on this topic following the decision to send three members of the BTSB to Sydney. Mr. Keyes said that he accepted the principal of travelling, in that Board members had to travel abroad in order to keep abreast of the latest developments but he instituted a series of guidelines which directed that the Board would pay for such travel and if commercial companies wanted to sponsor these activities they would do so through the Board by direct contributions. Mr. Keyes said that the Board did not receive any direct sponsorship in this way.

The guidelines were introduced to prevent the piece-meal sponsorship of Board members and officers travelling abroad, which Mr. Keyes said would have a detrimental public perception. Mr. Keyes said that from this point onward everything was above board. Mr. Keyes said he was well aware of the sponsorship issue. He said the idea of three board officers including the retired national director travelling to Australia paid for by commercial firms was bad for the Board's public image.

Mr. Finlay referred Mr. Keyes to a memorandum of a meeting held in Berne, Switzerland between the 28th to the 31st of May 1986 which was attended by Dr. Walsh. Dr. Walsh reported from this meeting the development of solvent detergent viral inactivation, which was effective against non A non B Hepatitis.

Mr. Finlay asked Mr. Keyes was he therefore aware of solvent detergent as a means of virally inactivating blood products for NANB in June 1986? Mr. Keyes said he became aware of the NANB issue later when he paid a visit to two blood transfusion services in the USA, one in New York at the New York Blood Bank and one in Charlotte, North Carolina.

Mr. Finlay asked Mr. Keyes was he aware, in 1986, that the heat treatment method being used by the BTSB did not effectively inactivate the virus for NANB Hepatitis? Mr.

Keyes said that it was generally accepted that this was the case. Mr. Keyes said that he thought it was clear that the product then being issued by the BTSB did not inactivate for NANB Hepatitis.

Mr. Finlay referred Mr. Keyes to a BTSB Board meeting of the 18th June 1986. The minutes of the meeting record that the executive consultant i.e. Mr. Keyes, informed the Board that the situation with factor IX was "unsatisfactory" and that he was examining this as a matter of urgency and that he requested that a BTSB consultant meet Professor Temperley to review standards.

Mr. Finlay asked Mr. Keyes was the reference to factor IX being unsatisfactory a reference to the possible infection with HIV of persons with Hemophilia from the BTSB product. Mr. Keyes agreed that this was the case. He said he asked Dr. Walsh to meet Professor Temperly.

Mr. Finlay asked Mr. Keyes was that all the information that the Board was given at that time about the problem. Mr. Keyes said he thought the Board was told about sero conversion but he just could not be sure as this would have been Dr. Barry's field.

Mr. Keyes said he could not elaborate on the medical aspects of it but clearly the Board was told that there was a problem with factor IX and that some people probably had seroconverted as a consequence of the BTSB product. Mr. Finlay said that this was not immediately obvious from the note. Mr. Finlay said that it appeared the problem was in a very, very coded form. Mr. Finlay put it to Mr. Keyes that this was a very significant understatement, if the reality was that a number of persons had become infected with HIV from using some of the Board's factor IX. Mr. Keyes said he would accept this.

Mr. Finlay then referred Mr. Keyes to a meeting that took place on the 1st of July 1986. While the meeting discussed various aspects of the factor IX situation there is no reference to the fact that a number of people had been infected or probably infected with BTSB factor IX. Mr. Keyes said that he suspected that most people there knew of the seroconversions. Mr. Keyes said the purpose of the meeting was to determine the level of heat treatment that should be applied to BTSB factor IX.

The meeting records that Mr. Keating joined the group and advised, following a Paris conference, that the minimum heat treated standard recommended was 60 degrees for a period of 72hours.

The BTSB changed its heat treating of factor IX from 60 degrees for 20 hours to this particular protocol. However this protocol was not known or used as a heat treatment method for factor IX it was in fact a factor VII heat treating protocol. This evidence emerged previously in the testimony of Mr. John Keating.

It was further recorded at the meeting that Mr. Keating advised that all patients from whom plasma was taken for factor VII purposes should be tested for HTLV-III. Mr. Keating said he accepted that this was incorrect and that he had taken the wrong meaning

from what Mr. Keating had said. Mr. Keyes said that the only decision taken at the meeting was to amend the heat treating protocol for the BTSB's factor IX.

Mr. Finlay referred Mr. Keyes to a board meeting of July 16th 1986. He asked Mr. Keyes had he informed the meeting of Dr. Walsh's advice following his meeting with Professor Temperly concerning factor IX seroconversions to HIV? Mr. Keyes said that this was a matter for Dr. Barry, he [Keyes] had chaired the meeting, but Dr. Barry had not supplied this information.

The Board meeting of July 16th notes that the manufacture of factor IX plasma from Travenol is being explored and evaluated. The decision had also been taken to heat treat existing stocks to 60 degrees of heat for 72 hours. It was estimated that 10 per cent of the stock would be lost as a result of heat treating the stock.

Mr. Finlay asked Mr. Keyes had the Board been informed of the seroconversions at this time? Mr. Keyes said it was possible that he had mentioned at the board meeting and it was just possible that he didn't record it.

Mr. Keyes said that the Board was certainly aware of the seroconversions. He said that it may be the case that they were told "Off Board" that this had happened.

Mr. Finlay asked Mr. Keyes was there any reason why there were only two very guarded references to this very serious matter. Mr. Keyes said that he did not know why this was the case.

Mr. Finlay then referred Mr. Keyes to a review of Factor VIII in the first year. This was a review of the Travenol contract. At the top of the agenda was the fact that the contract was experiencing yield problems i.e. Travenol was not meeting the expected yield. Furthermore, the Board was experiencing liquidity difficulties. The auditors had commented that matters have got worse and not better. Mr. Keyes said that if the Board was going to solve its cash problems then it had to create a surplus. 1986 and 1987 were bad years there were cutbacks, redundancies and bed closures leading to a reduced demand for BTSB products and a reduced income as a result.

Mr. Keyes agreed that as far as the contract was concerned yield was the critical matter. Mr. Finlay also addressed the issue of alt testing with respect to NANB Hepatitis with Mr. Keyes. Mr. Keyes said that he knew the dangers of NANB Hepatitis and approved Mr. Keating's private study.

Mr. Keyes told Mr. Finlay that he had visited the New York Blood Centre and that he was particularly interested in the operations of the U.S. Blood Banks. He also visited Charlotte, North Carolina. Mr. Keyes said that the visit was not directed at investigating viral inactivation but he was more interested in the administration of blood banking rather than clinical matters. Mr. Keyes said that he was aware of the implications of testing in that tests were costly and could lead to a loss in blood donations, but he had not visited the blood bank from a safety viewpoint, this was not on his agenda.

In October 1986 the BTSB addressed the future management structure of the organisation. With respect to Dr. Walsh's position Mr. Keyes said it would have been easier if Dr. Walsh had been the Chief Medical Consultant in 1986. He was in fact the Chief Medical Consultant on an *adhoc* basis. Mr. Keyes said that he accepted that this was a weakness. Mr. Keyes said if a medical matter was put to the board he could not deal with it and it would have been better if Dr. Walsh had been on hand to speak to the meeting on any particular medical matter which arose.

With respect to NANB Hepatitis Mr. Keyes said in relation to a memo of a meeting on 29th October 1986 with the Elstree UK Group that they were aware from this date that 80 degrees by 72 hours was an effective viral inactivation protocol for NANB Hepatitis.

Mr. Finlay asked Mr. Keyes was he aware of the fact that the product in England heated to 80 degrees appeared to be safe against NANB Hepatitis. Mr. Keyes said he was told that there were some worries about the type of yield you would get at that level of heat. The implications of a lower yield said Mr. Keyes was that more plasma would be required. Mr. Keyes said that he was aware that neither the dry heat treatment being used by Travenol for Factor VIII nor the heat treatment being used by the BTSB for its own Factor IX would in 1986 effectively virally inactivate either product for NANB Hepatitis.

PROCEEDINGS: THURSDAY 28th SEPTEMBER, 2000 – DAY 46

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

Mr. Finlay referred Mr. Keyes to a BTSB Board Meeting held in November 1986. At this meeting it is recorded that the Scottish Blood Transfusion Service would be interested in fractionating BTSB plasma. Mr. Keyes agreed that the Scottish product at this time was heat treated.

Mr. Finlay also referred Mr. Keyes to a visit by Mr. Seàn Hanratty to Belfast on the 13th of February 1987. At this time Northern Ireland plasma was fractionated in Scotland. However, Northern Ireland did not receive Factor concentrates made from its own plasma, instead the plasma was pooled with Scottish plasma and the products were returned. Super heat treatment was used on these products i.e. they were heated at 80^0 for 72 hours. Mr. Keyes said that preference at this time was for products from Irish plasma and that the arrangement as pertained in Belfast would not provide this.

Mr. Finlay asked Mr. Keyes what would have been the difference between Scottish voluntary donations, which had been screened for HIV, and Irish voluntary donations, which had been screened for HIV? Mr. Keyes said probably none, but there was a government policy on self-sufficiency and the Board felt that it had to honoUr the policy at that time.

Mr. Finlay referred the witness to a memorandum by Mr. Keyes dated the 9th of March 1987 to the Heads of the Department in the BTSB. The memo sets out the difficulties experienced by the BTSB when it tried to find replacement contract fractionators, and the reasons why the BTSB turned to Armour as the successor to the Travenol contract.

The memo noted that a trial batch of plasma had been dispatched to Armour, even though Armour was unlicensed at the time. Mr. Keyes said that he was optimistic that Armour would get the licence. Mr. Keyes said that HIV Welcome test in use by the BTSB at the time was the most sensitive test available. The BTSB could not get into the expense of running a second test. Mr. Keyes said that there was no mention of viral inactivation in the memo as this was a medical matter, principally for Professor Temperley. With respect to the purchase of blood agitators Mr. Keyes said that these steps were taken to improve the quality of blood products. Mr. Keyes acknowledged that the lack of ALT testing effectively excluded the BTSB from seeking a contract fractionator in the US.

Mr. Finlay referred Mr. Keyes to a meeting between the BTSB and Armour held on the 19th of June 1987. The meeting discussed the licensing, heat treatment at 68 by 72 hours for both Factor VIII and Factor IX. The meeting noted that Armour did not have a license for Factor IX. It was proposed that the named patient basis procedure would be used to overcome this difficulty.

In July 1987 the Board approved the introduction of ALT testing, if the Minister agreed to pay for the tests. Mr. Keyes said that everything appeared to be satisfactory with the Armour contract, except for the fact that it did not deal with the NANB Hepatitis, and that the BTSB would have to take back the entire product from the contract. The dry heat proposal attached to the Armour contract was not going to make the product safe for NANB.

Mr. Finlay put it to Mr. Keyes that the BTSB could have looked to the Elstree solution i.e. super heat-treated method of 80^0 x 72 hours. Mr. Keyes said that there was no evidence that this was effective for NANB Hepatitis. However, the Tribunal has previously heard that the Elstree delegation of Mr. Lane and Mr. Pettit, had pointed out to the BTSB that their superheat-treated product was effective for NANB Hepatitis, in that no evidence of infection for NANB had occurred in eighteen months of its use. Mr. Keyes said that viral inactivation was not his area.

Mr. Finlay referred Mr. Keyes to a document of July 1987, where Mr. Bishop of Armour, writes to Mr. Keyes, informing him that Armour cannot make Factor IX from BTSB plasma. Armour proposes to return Factor IX to the BTSB in the form of a paste. It was determined that Factor IX would be virally inactivated using Travenol's protocol. Mr. Keyes said that the Travenol agreed to a request from Mr. Hanratty, that its Factor IX heat-treating protocol could be used for the BTSB Armour product. Mr. Keyes said that it was reported at a Board meeting that Travenol had verbally agreed to allow its heat treatment protocol to be used.

Mr. Keyes said that in May 1987, a communication from the Swiss Red Cross concerning solvent detergent viral inactivation was received by the BTSB, the solvent detergent information arrived at the BTSB at the same time as discussions were taking place between the organisation and Armour. The question of solvent detergent was discussed with respect to NANB Hepatitis. However, the BTSB continued its project with Armour with regards to the financial arrangements on the Armour contract.

Mr. Finlay referred Mr. Keyes to the document of the 27th of November 1987. This is Mr. Ryan's costing on the Armour contract. The document projects a surplus to the BTSB of £372,000 per anum. Mr. Keyes said that this was what had been planned for.

Mr. Finlay then referred Mr. Keyes to a further document prepared by himself for submission to the Department of Health. Mr. Keyes' document indicates that the Armour contract would cost the Board £900,000. However, Mr. Finlay put it to Mr. Keyes that the Board in fact stood to make a surplus of £385,000 on the contract. The impression given to the Board of the BTSB as Chief Executive, that the project would cost the Board and not produce a surplus. Mr. Keyes said that he accepted the fact that his figures were inaccurate.

Mr. Keyes produce a document to the Tribunal which he said was based on the actual figures of plasma sold, income received and costs incurred. Mr. Keyes said that the

actual benefit to the Board of the first year of the Armour contract was £124,000 as opposed to the estimate of £385,000.

Mr. Finlay referred Mr. Keyes to a Board meeting of the 16th of December 1987. The meeting records that an agreement has been reached with Travenol which allows the BTSB to use Travenol's patent for Factor IX production.

Mr. Finlay said he had been unable to find an answer to the letter to Travenol from Mr. Hanratty. Mr. Keyes agreed that the letter had not come to hand but it must be some where in the Boards documentation. Mr. Keyes said that a modest charge had been mentioned in connection with the use of the Travenol patent by the BTSB. Mr. Finlay said that in relation to this particular aspect would it be correct to suggest that the BTSB had been doing other business with Travenol at that time. Mr. Keyes said that the BTSB had a major contract for the purchase of blood bags with Travenol. Mr. Finlay said that in this context Mr. Hanratty had asked for Travenols permission to use its heat treating protocol.

Mr. Finlay referred Mr. Keyes to an article in the magazine "Blood bank for the weak" of January 1988, which announced the withdrawal by Armour of its dry heat treated product in Canada as a result of some sero conversions that were reported in Canada. Mr. Keyes agreed that he had seen the document at the time. Professor Temperley had raised this issue at the Board meeting of January 1988 and was very concerned about it. Mr. Finlay put it to Mr. Keyes that the heat treatment protocol in question was 60^0 centigrade for thirty hours, and that this was the same heat treatment protocol which had proved a problem in England the year previously. Mr. Keyes agreed that the Armour product being prepared for the BTSB was being heat treated to a different protocol. Mr. Finlay put it to Mr. Keyes that the Cutter heat treatment protocol was being applied to the Armour product for the BTSB. Mr. Keyes said that he did not know that but agreed that this may be the case.

Mr. Finlay referred Mr. Keyes to the minutes of the Board meeting of the 20th of January 1988. Here it is recorded that the arrangement between the BTSB and Armour would not be incorporated into a formal contract.

Mr. Finlay referred Mr. Keyes to a letter from Armour of the 27th of January 1988. Armour informed the BTSB that it no longer wanted to conduct contract fractionation with the dry heat treatment protocol envisaged by the Armour BTSB contract. In addition to informing the BTSB that the company intended to phase out its operations in West Germany concerning dry heated product, Armour went on to ask the BTSB to furnish an indemnity in contemplation of continuing to dry heat BTSB product for the remainder of 1988. Mr. Keyes said that the letter had created a considerable problem for him and the Board as it put the self-sufficiency project of the BTSB at considerable risk, and that he had to refer the matter on to Professor Temperley. Mr. Keyes said that the BTSB had managed to water down the indemnity, but that it was under the terms of the indemnity that the arrangement with Armour continued until the end of 1989.

Mr. Finlay put it to Mr. Keyes that the fact that Armour was looking for an indemnity from the BTSB in respect of the product and the custom fractionation which it was carrying out, would that not have suggested to Mr. Keyes that Armour was distinctly worried about the product? Mr. Keyes agreed that that was the implication to be taken from it. Mr. Keyes said that the Board was worried about the indemnity and discussed the matter with Professor Temperley, but said Mr. Keyes, Professor Temperley ultimately said that he wanted this product for his patients and he would use this product, and he specifically asked that the arrangement would be continued to the end of 1989.

Mr. Finlay put it to Mr. Keyes that the worry was specifically in relation to NANB Hepatitis. Mr. Keyes agreed that appeared to be the problem. Mr. Keyes agreed with Mr. Finlay that he immediately sent the information regarding the indemnity request from Armour to the Department of Health.

Mr. Finlay referred Mr. Keyes to the Board meeting of the 17th of April 1988, wherein the Board notes that the indemnity dated the 14th of March 1988, had been signed on behalf of Armour Pharmaceutical and was approved by the Board. Mr. Keyes was then asked to address the issue of Armour's monoclonal product. He acknowledge that in April 1988 the product was probably effective for NANB Hepatitis, at this stage it was anticipated that the BTSB may have to opt for the monoclonal product from Armour. Mr. Keyes said that he had not at this point looked at the Factor IX situation. Mr. Keyes said that a further alternative to monoclait was to pasteurise, however this was out of the question for the BTSB as it required too much plasma. Mr. Keyes said that the pasteurise option would have required up to 25,000 litres of plasma, with a yield of less than 50 per cent.

Mr. Finlay suggested that the BTSB may at this point have examined the idea of fractionation by Elstree or Scotland. Mr. Keyes said that this idea had not been revisited at this time. The problem with Scotland was self-sufficiency he said, and the BTSB did not examine the possibility of fractionating in Scotland during the Armour contract phase.

PROCEEDINGS: FRIDAY 29th SEPTEMBER, 2000 – DAY 47

Mr John Finlay, SC continued his examination of Mr Ted Keyes, formerly chief executive officer of the BTSB.

Mr. Keyes referred to his evidence of the previous day concerning the projected earnings from the Armour contract. Mr. Keating said that he intended to convey to the Board that a surplus of £385,000 would accrue on foot of the contract. However, he accepted that the document as presented to the Board was misleading, in that the Board was informed that the cost to the BTSB of the Armour contract would be £900,000. Mr. Finlay for the Tribunal pointed out that not withstanding the fact that the Board had been told that it would cost £900,000 to fund the Armour contract the Board went ahead and agreed to follow through with the arrangement.

Mr. Finlay then referred Mr. Keyes to a letter from Professor Temperley to the Board of the 14th of June 1988. The letter was presented to the Board in circumstances where Professor Temperley was unable to attend the Board meeting. This letter had been opened to the Tribunal previously. Mr. Finlay drew attention to some of the contents of it. The letter points out that Professor Temperley was well aware of the NANB risk from first generation dry-heated products. He is also aware that this group of products has been rapidly removed from the world market, partially because of previous HIV disasters and also because dry-heat treatment seems inadequate to destroy NANB Hepatitis.

Mr. Finlay pointed out that a crucial part of the letter read as follows:

> "The Board should understand that in the present period of financial stringency the hospitals could not be expected to meet the doubling of the cost of concentrates in 1989, some balance would have to be struck between costs and the infection dangers associated with blood products. Using Cutter, Koate HT and Irish plasma/Armour products, no new HIV seroconversions have occurred for at least twelve months. Virtually all our treated haemophiliacs have had NANB there is no definite evidence that crude products such as the Irish plasma Armour Factor VIII product produces immune deficiency despite their large content of protein. In my view therefore, the logical conclusion for the Board is to make every effort to obtain Armour's agreement to take on production of Factor VIII concentrates using Irish plasma for 1989 in the same manner as for 1988. This would have my support as Director of the National Haemophilia Centre. For virgin patients, usually infants, Haemate P will be used for protecting them from NANB."

Mr. Finlay put it to Mr. Keyes that the cost in question was a cost identified by Professor Temperley as a cost to the hospitals and not directly a matter for the BTSB? Mr. Keyes said that the BTSB would have its mark up. It was therefore immaterial as to the price charged by the BTSB to the hospitals. Mr. Keyes agreed that the letter meant that the hospitals couldn't afford to pay twice the amount for the product. He also agreed that the

financial consideration addressed by Professor Temperley had nothing to with the finances of the BTSB. Furthermore the letter only addressed the Factor VIII situation, Mr. Keyes agreed that this was the case. He also agreed that no consideration was given to Factor IX at this time. Mr. Keyes said that he did not remember it being specifically raised.

BTSB Board meeting of the 15th of June 1988, considered and adopted Professor Temperley's letter. On foot of Professor Temperley's letter and the Board's decision Mr. Keyes proceded to make arrangements with the Armour Company to contract fractionate BTSB plasma for Factor VIII for the year ending December 1989.

Further complication arose with the Armour product, in that it was not included in the UK's Centre Directors' document which assessed blood products. Armour's response to this omission was to say that the product was not registered in the UK and was only registered in Ireland and did not therefore come under the consideration of the UK Centre Directors.

Further problems arose in that Armour could not supply Factor IX to the BTSB. Mr. Keyes agreed that during the negotiation of the Armour contract and the difficulties arising thereon, alternative products were available from BPL of Elstree or the Scottish Blood Transfusion Service at Edinburgh. These super-heat treated product however were not considered by the BTSB.

Mr. Finlay referred Mr. Keyes to a letter from Seàn Hanratty to Mr. Keyes, which was written during a trip to Octapharma by Professor Temperley and Mr. Hanratty and others. Mr. Hanratty indicates in his letter that Professor Temperley would be agreeable to using the Octapharma, solvent detergent product on the basis that he would be funded to conduct trials on the product and to carry out long term research and development. When the Octapharma contract was eventually agreed the company dealt directly with Professor Temperley in his trial of the product. The BTSB said that it was not party to this arrangement. Furthermore Mr. Keyes agreed with Mr. Finlay that he did not see anything wrong with this research funding.

During 1988 Octapharma started to come on stream. BTSB plasma was manufactured into Factor VIII at Lille, France. However, the Octapharma trials were disappointing with a yield of only 15 per cent. During this time the Armour arrangement continued in parallel to the Octapharma fractionation. Professor Temperley continued to express reservations about NANB arising from the Armour product.

At a meeting in Gatwick Airport, Mr. Bishop of Armour, denigrated the Octapharma product and solvent detergent in general. Mr. Keyes explained that this was part of the cut and trust of commercial enterprise. He also agreed that he continued to press Mr. Bishop to supply the BTSB as he had no choice, given supply side problems for Factor VIII.

Mr. Finlay referred Mr. Keyes to the I.H.S. campaign for compensation for people infected with HIV, arising from the use of blood products. Mr. Keyes said that he was worried that the campaign would have an adverse effect on blood collection. He said at a board meeting that it was unfair of the I.H.S. to run this campaign as the HIV infections had been caused by imported blood products. Mr. Finlay put it to him that this comment might have been fair enough for haemophilia A infections, but was not accurate with regard to infections of persons with haemophilia B? Mr. Keyes agreed that this was not clear from the minutes. Mr. Keyes said that he was aware that at this time BTSB product had infected people with HIV, and agreed that this was not averted to at the Board meeting. Mr. Keyes said that his concern at the time was about the effects of the campaign on blood collection. Mr. Keyes further agreed that the HIV infection of people with haemophilia B was well known to Professor Temperley and Dr. Walsh at this time, Mr. Keyes said that they would have known this better than he would.

Mr. Finlay directed Mr. Keyes to the Board meeting of the 15th of February 1989. It was recorded that the Chief Executive Officer was concerned about the present campaign by the Irish Haemophilia Society to obtain certain concessions from the Minister for Health, such campaigns do not help blood donations and indeed can damage it to an extent. The particular concern is that certain statements had been made which would indicate that some of our products were infected whereas it is quite clear that the source of infection was imported products, even though these were ordered and supplied by us to different hospitals. The Minister has been fully advised by us, in regard to these events and a detailed memorandum was submitted to his officials. The Chief Executive Officer had refrained from issuing any public statement since it was felt that this might exacerbate the situation. However, one of the Board's officer is talking to people involved outlining the Boards particular position. If the above is the case the question arises did the BTSB tell the Minister of the FIX HIV infections?

Mr. Finlay put it to Mr. Keyes that at this time the Board was concerned with NANB Hepatitis. Mr. Keyes disagreed he said that the focus at this time was on HIV.

Mr. Finlay referred Mr. Keyes to the documents that had been examined in his evidence all of which point to the fact that the Board was concerned with the infection of people receiving Factor VIII with NANB. Furthermore once testing had commenced the problem with HIV was alleviated with regards to Factor VIII.