IRISH HAEMOPHILIA SOCIETY

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TRIBUNAL OF INQUIRY

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

PROCEEDINGS: WEDNESDAY 13th SEPTEMBER, 2000 – DAY 38

The Tribunal of Inquiry, which had adjourned on The 27th of July, resumed on the above date. The Tribunal Chairperson offered her sympathy to the family of the late Mr. John Berry. The Tribunal Chairperson with members of her legal team attended the funeral of Mr. Berry in Athy, County Kildare on the previous day.

The Tribunal then called Mr. John Keating, a former technical officer with the BTSB. Mr. Keating commenced work with the BTSB in 1966 as a laboratory technician. He went on to become a Technical Officer, a Senior Technical Officer and the acting Chief Technical Officer. His present position is that of Project Officer for the BTSB's development of its new premises at St. James Hospital.

Mr. Keating was, during his time at the BTSB, stationed in the microbiology laboratory and was concerned with the BTSB Hepatitis B surface antigen testing program. Mr. Keating said that he generally kept himself abreast of the literature concerning non-A, non-B Hepatitis. He said that he availed of the comprehensive library in Pelican House and this way he kept up to date.

Mr. Keating told the Tribunal that he did not attend any Scientific Committee meetings until in or around 1980 when he had been promoted several times from his starting position as a laboratory technician. Mr. Keating agreed however that he had attended a scientific committee meeting on the 2nd of November 1978. This meeting discussed the test for Hepatitis B surface antigen, and Mr. Keating is listed as present.

In response to Mr. Finlay's questions to his recollection of the BTSB's project to develop its own Factor VIII using the Rock Palmer Method, Mr. Keating said that he had no distinct recollection of this particular project. He had had, however, a good working relationship with Mr. Hanratty, yet he could remember no discussions about this project.

Mr. Keating told Mr. Finlay that by 1983 there was a real awareness of the risk of Aids from HIV. However, the BTSB was awaiting a test to become available and the virus had not been identified and self-sufficiency was brought into sharp focus by the threat of Aids from HIV. Mr. Keating said that he had no direct memory of a link between the issues of self-sufficiency and HIV.

The thrust of Mr. Keating's evidence was that while he attended numerous meetings concerning Hepatitis B testing and the documents produced by the Tribunal could support

the view that he did attend such meetings, his memory of these meetings had faded to the extent that he had no recollection of any detail. Mr. Keating was also involved in the evaluation of kits for HIV testing.

In mid 1985 Mr. Keating attended the International Aids conference in Paris. Mr. Keating said that as far as he was concerned the emphasis of this conference was on testing. Mr. Finlay asked did the meeting also deal with Viral Inactivation by heat treatment and had Mr. Keating taken a note of this? Mr. Keating said that he had understood the question and he did take a note, but the issue of Viral Inactivation was conveyed at a satellite meeting.

Mr. Keating drew up a list of points of interest in which he noted among other things, the HIV sero-convertion of a Dutch person with haemophilia.

Mr. Finlay asked: that arising from this meeting, was Mr. Keating aware of the value of surrogate testing for Hepatitis B. Mr. Keating said that he had been aware since the early 1980s that a debate was being conducted in the literature concerning the value of using Hepatitis B testing as a surrogate marker for NANB.

Mr. Keating agreed with Mr. Finlay that he was indeed aware of the 1983 document by Ach and others in Transfusion. This article attracted debate concerning the value of ALT testing and anti-Hepatitis B Core testing. Mr. Keating noted that AABB eventually directed that both forms of testing become mandatory, furthermore there is no question of introducing ALT testing at this stage as a surrogate test.

Mr. Keating said that the ALT testing was insensitive and gave a high rejection rate among donors. It was not a good test and it was not within the decision making power of Mr. Keating to introduce such a test. Mr. Keating agreed that he did not bring the debate concerning this test to the attention of the BTSB with respect to NANB Hepatitis.

Mr. Keating conducted a limited study on how the introduction of Hepatitis core testing would affect donor rejection rates. Mr. Keating's Hepatitis core testing study received support from Mr. Cann and the decision to conduct a limited study was taken.

Mr. Finlay noted that Mr. Keating was involved in HIV testing which was introduced in October 1985. Mr. Finlay said this matter would be dealt with in another section of the Tribunal and that Mr. Keating would be asked to come back and give evidence on this issue.

Mr. Keating was then cross-examined by John Trainor SC for the Irish Hemophilia Society. Mr. Trainor referred Mr. Keating to a memo of the BTSB Scientific Committee of 1983. The meeting which held on the 13th October 1983 noted that T4/T8 cell ratios were being examined. The fact that T4T8 ratios were being examined at this time indicated that Hemophilia patients were being tested for AIDS, Mr. Keating said he could not recollect any discussion on T4/T8 cell ratios at this time.

Mr. Trainor then referred Mr. Keating to an article published in the Irish Journal of Medical Science in 1989 which recorded a three fold increase in Hepatitis B cases in people with Hemophilia, in the early 1980's. Mr. Keating said he did not recall this article in any way. He said he was not aware of any increase in Hepatitis B among people with Hemophilia during the years in question. Mr. Trainor asked Mr. Keating given that Hepatitis B was on the increase among people with Hemophilia and factor concentrates were screened for Hepatitis B, did the occurrence of infections indicate the screening process was not working and, further, did the presence of Hepatitis B indicate that other infections could also be transmitted to people being treated with factor concentrates. Mr. Keating said he did not know the answer to this question.

Mr. Trainor asked Mr. Keating could an increase in Hepatitis B among people with Hemophilia indicate that NANB Hepatitis was also contained in the factor concentrates? Mr. Keating agreed that this could be the case.

Mr. Trainor asked Mr. Keating, that given there was an increase in Hepatitis B should the Board continue to distribute the products. Mr. Keating said he was not involved with the distribution of products and this was not his decision, he was not consulted about the products. Mr. Keating said he had formed no view as to whether or not the Board should continue or should not have continued to distribute the products at this time.

It would therefore appear that despite being aware that Hepatitis B was a surrogate marker for NANB Hepatitis, senior persons at the BTSB were not aware that Hepatitis B infection had increased in people with Hepatitis they were therefore not aware of the dangers presented by blood products, this was despite being aware of the discussion surrounding the efficacy of Hepatitis B as a surrogate marker for HIV.

With regard to testing donors for HIV Mr. Keating said that all donations taken from 1985 were tested, this included plasmapheresis donors in addition to blood donors. Mr. Keating said all donations were tested. With respect to Factor IX which had been issued prior to the introduction of donor testing, Mr. Keating said batch testing of this product took place. Mr. Keating said he could not recall whether or not the Department of Health had been told that batch testing of Factor IX was taking place. Mr. Keating agreed that testing a vial of Factor IX from a batch was not an ideal way of ensuring safety but it was the only means at the disposal of the BTSB at the time.

In response to a question as to who directed the batch testing Mr. Keating agreed that it may have been on the authority of Dr. Walsh. Mr. Meenan, counsel for Dr. Walsh, said that none of this had been put to Dr. Walsh. Mr. Keating said he could not recall whether any written protocol existed concerning the batch testing. Mr. Trainor then referred Mr. Keating to the meeting he attended in Paris in the summer of 1985. Mr. Keating returned from the Paris meeting with the news that a minimum viral inactivation protocol being used was 60 degrees centigrade for 72 hours. Mr. Keating reported that no fractionators were using 60 degrees centigrade for 20 hours for Factor IX which was then the viral inactivation protocol being utilised by the BTSB.

Mr. Clarke counsel for the BTSB and Mr. Keating pointed out that Mr. Keating was not an expert in viral inactivation.

The Tribunal adjourned at 4.00pm.

PROCEEDINGS: THURSDAY 14TH SEPTEMBER, 2000 – DAY 39

John Trainor S.C., for the Irish Haemophilia Society continued his cross-examination of Mr. John Keating of the BTSB. Mr. Trainor referred Mr. Keating to the BTSB board meeting of July 1st 1985. Mr. Keating said that he was called into the meeting on the basis of having been in Paris. Mr. Keating said he did not usually attend meetings discussing Factor IX. The meeting was in possession of the memo that he had prepared on points of interest arising from the Paris conference. Mr. Keating said that he brought the information back from the meeting, however there are no abstracts in writing recording the Paris conference in the BTSB documents. Mr. Trainor asked: that when Mr. Keating advised the meeting was any distinction drawn between heat treating protocols for Factor VIII and Factor IX, Mr. Keating said that this was not his area and that he did not recall any such distinction being drawn. However, Mr. Keating agreed that he did advise the meeting.

Mr. Trainor referred Mr. Keating to a hand written note which recorded that Travenol heat treated Factor VIII to 60 degrees centigrade for 72 hours, it was then agreed that the BTSB's product would be heat treated for 72 hours. However the BTSB's product was in fact Factor IX, so it therefore appeared that the BTSB amended its heat treating protocol on the advice of Mr. Keating, however the distinction was not made between Factor VIII and Factor IX, with the result that the BTSB used a Factor VIII heat treating protocol as a Viral Inactivation method for Factor IX. Mr. Keating said that his only input was to relate what had happened at the Paris meeting.

Mr. Trainor noted that in Mr. Keating's points of interest, recorded from the Paris meeting, he does not take a note of 60^0 centigrade for 72 hours as a heat treating protocol and would this indicate that this particular issue was not of interest to him when he did not take a note of it? Mr. Keating said that someone must have told him about the heat treating protocol.

Mr. Trainor then referred Mr. Keating to an article by Carol Kasper. The article sets out all the known heat treating protocols for different products in use at the time. 60^0 x 72 hours is not a recognised heat treating protocol for Factor IX. Mr. Keating agreed that this would appear to be the case but he had no recollection of how the decision came to be made.

Mr. Trainor asked Mr. Keating how did Ms. Cunningham get her instruction to change the heat treating protocol, Mr. Keating said that this was the responsibility of Dr. Barry and it would have been conveyed on the instruction of the Chief Technical Officer, Mr. Cann. Mr. Keating said that he could not recall if his news that the 60^0 x 20 hours was inadequate, came as a surprise to the meeting. Mr. Trainor said that it would appear surprising if this was not the case, in fact, it would appear startling.
The Tribunal advised Mr. Trainor to put this matter to the other witnesses as Mr. Keating would appear to have no recollection of it. Mr. Trainor said that his difficulty was that

Mr. Keating was there for the discussion and could therefore be expected to comment on it.

Mr. Trainor asked Mr. Keating could he recall if there was any discussion at the meeting on the issue of loss of yield. Mr. Keating said that he had no recollection of this particular discussion, but if it had occurred then he would have noted it. Mr. Keating agreed that Viral Inactivation was more than just the use of time and heat. Other Factors came into the equation such as the use of stabilisers. Various patents would have to be discussed with companies, however he had no knowledge and no recollection of the various protocols, but agreed that if they had been used they would have to have been validated.

It would therefore appear that the BTSB used the wrong heat treating protocol for its Factor IX. From July 1986 the Board was using a Factor VIII protocol for Factor IX product. In his note of the meeting Mr. Keyes wrote that plasma patients should be tested for HTLV III. Mr. Keating said that what should have been written was that plasma samples would be tested for HTLV III.

With regard to Mr. Keatings pilot study on the possible effects on donor recruitment policy of the introduction of Hepatitis B Core and ALT testing as a surrogate test for NANB Hepatitis, Mr. Keating agreed that the study was conducted to assess the effect on donor numbers of the introduction of such tests with regard to the BTSB Factor IX. Mr. Keating said that he was not aware of any pre-1985 plasma being used for the production of Factor IX. Pre 1985 plasma would be untested plasma.

Mr. Keating agreed that NANB Hepatitis would have serious consequences, however he did not agree that surrogate testing would remove a significant risk factor. With respect to an anticipated deferment rate of 3.45 per cent and whether or not such a rate would be an acceptable deferment rate, Mr. Keating said that he had no view on this particular issue. Mr. Keating said that from a blood transfusion viewpoint any deferment rate is unacceptable. Mr. Keating said that while surrogate testing may have removed up to 40 per cent of NANB Hepatitis other factors would have to considered.

Mr. Trainor put it to Mr. Keating that he did not advocate the safety of products over the other Factors? The Chairperson intervened and said that this was not Mr. Keatings function. Mr. Keating said that he was not a clinician. Mr. Keating agreed that the pilot study conducted by him was on the issue of donor deferment and not safety.

With respect to the EC directive on product liability upon which Mr. Keating had written a paper, Mr. Keating said that this was a layman's guide to product liability.

In the Spring of 1988 ALT testing had still not been introduced. Mr. Keating agreed that it would have been desirable to have had some form of surrogate testing at this time. Mr. Trainor asked Mr. Keating should he not have been examining safety instead of writing on product liability at this point? Mr. Keating said that he did not know why the paper was written. Mr. Trainor asked Mr. Keating should he not have been addressing the

safety issue, Mr. Keating said that it was up to his superiors to make the decision, he had done the work and it was not fair comment to suggest that he should have done more.

Mr. Trainor referred Mr. Keating to the Hepatitis B outbreak in 1975 when the Factor concentrates concerned in the outbreak were withdrawn. He then referred Mr. Keating to the 1983 occurrence of Hepatitis B, and asked should the products have been withdrawn at this stage? Mr. Keating said that he had no view in this matter. This concluded Mr. Trainor's cross-examination.

Mr. Padraig Dwyer for Dr. Walsh put it to Mr. Keating that the instruction to commence batch testing had not emanated from Dr. Walsh. Mr. Keating now accepted that this instruction had come from another source.

Mr. Keating was examined by Mr. Clarke for the BTSB in the issues of surrogate testing, and on the issue of the pilot scheme concerning donor deferral. Mr. Clarke noted that surrogate testing could lead to a deferral rate of between 1 and 7 per cent. Prior to Mr. Keating's pilot study there was no knowledge of where Ireland would fit in the range of 1 to 7 per cent.

In the respect of Scientific Meetings Mr. Keating said that these meetings were ad hoc meetings, which took place occasionally, long periods of time could elapse between meetings and no records were kept of these meetings. Mr. Keating said that he had no memory of any scientific committee meetings.

Another of Mr. Keatings duties was to keep stock records. Mr. Keating said that the purpose of keeping such records was to ensure an adequate supply of concentrates for treators. Mr. Keating was also in charge of ensuring that tests were preformed and that they were done properly. That new tests would be evaluated and that all blood donations would be tested for HIV and Hepatitis B. Mr. Keating attended conferences and was likely to attend conferences where new tests would be discussed.

With regard to the July 1st meeting in 1985, Mr. Keating noted that the hand written note of the meeting was that of Mr. Cann, and that the typed version of the meeting was signed by Mr. Keyes, and that he understood the technical issues involved. This concluded Mr. Clarke's cross-examination of the witness.

The Tribunal then called Dr. Helena Daly.

Mr. Finlay for the Tribunal examined Dr. Daly who set out her career details for the Tribunal.

The Tribunal drew Dr. Daly's attention to a letter published in the Lancet in 1983, which recounted the death of an Aids patient at the Bristol Royal Infirmary. The patient was attended by Dr. Daly.
This man was one of the first men with haemophilia to die from Aids in the United Kingdom.

Mr. Finlay noted that the care afforded to people with haemophilia by St. James Hospital was not under examination in this particular part of the Tribunal, while Dr. Daly would give evidence it would be in relation to the BTSB only.

Dr. Daly said that when she arrived at St. James Hospital in 1985 the products in use were freeze dried cryo which was unheat treated, Factor VIII which had been heat treated since December 1984, BTSB Factor IX unheat treated, and commercial Factor IX which was heat treated.

Dr. Daly said that at that time due to her state of knowledge her medical practice and her belief as to what practices should be adopted differed. Dr. Daly said that products in use in Bristol, where she had been working before she had arrived in St. James Hospital, were BPL Factor VIII and U.S. Factor VIII concentrate some unheated treated Factor VIII was also in use in the U.K, as was DDAVP. In May 1985 BPL unheat treated Factor IX was also in use in Britain, however it was Dr. Daly's view that all products used for the treatment of haemophilia in the Summer of 1985 should have been heat treated.

Dr. Daly recounted how she attended a meeting at Pelican House on August 13th 1985. Dr. Daly said that from the document supplied it would appear that she had attended a meeting with the I.H.S. While she had very little memory of this I.H.S meeting she did however remember talking to Mrs. Aldrich.

While she could not remember the meeting with the I.H.S. Dr. Daly did have distinct memories of her meeting on the same day with Dr. O'Riordan and Mr. Hanratty at Pelican House. At the meeting with Dr. O'Riordan and Mr. Hanratty, Dr. Daly suggested that all blood products should be heat-treated including Factor VIII and Factor IX coming from the BTSB.

Factor VIII in question was cryoprecipitate and it was explained to her that it was not possible to heat treat cryo. It was accepted that cryo could not be heat treated as the fibrinogen content in the cryo would gel.

With regard to Factor IX no technical reason was advanced as to why it should not be heat-treated. Mr. Finlay asked was there any risk attached to heat treating Factor IX. Dr. Daly asked Mr. Finlay what sort of risk was he talking about? Dr. Daly said that there was no mention of thrombosis by Dr. O'Riordan. She said Dr. O'Riordan and Mr. Hanratty were very surprised at her request that the products from the BTSB should be heat-treated. It would appear that they were not expecting such a request and did not think it necessary for either product.

Dr. Daly said that Factor IX complex always contains some risk of thrombogenecity but it was not a major issue for haemophilia treators and it was not regarded as a big problem in the United Kingdom to her knowledge.

Dr. Daly said that as no reason was advanced as to why heat-treated Factor IX should not be made available she wanted it to be made available in the month of August 1985.

Dr. Daly said that the issue of contract fractionation was also discussed. Dr. Daly said that she now realised that if the BTSB was to cease using cryoprecipitate would have serious implications for its contract fractionation plans. No cryoprecipitate would mean that the BTSB would be unable to produce Factor IX and this would have an implication for self-sufficiency.

Dr. Daly was asked by Dr. O'Riordan to provide a letter from Professor Temperley, which would be used by the BTSB to obtain funds from the Department of Health to make up the shortfall represented by stopping the use of cryoprecipitate. Dr. Daly said that she left the meeting disturbed and upset, she said that the meeting had been hard going.

PROCEEDINGS: FRIDAY 15TH SEPTEMBER, 2000 – DAY 40

Mr. Martin Hayden made an application on behalf of the Irish Haemophilia Society in relation to the intended sequence of witnesses. Mr. Hayden's Application was that the Tribunal should not take the evidence of an expert before hearing the factual evidence. Mr Hayden referred to the fact that the I.H.S had been under the impression that the witness as to financial matters would be Mr. Keyes, this had been alluded to on the 5th July 2000, Day 21 of the Tribunal of Inquiry, when the Chairperson had indicated that she presumed Mr. Keyes would be the appropriate witness to deal with financial matters on behalf of the BTSB. Mr. Hayden referred to the fact that the I.H.S. had been put on notice on the 12th of September that Mr. McStay would be the expert witness with respect to finance.

Mr. Hayden said that Mr. Keyes would indeed be an appropriate witness to deal with financial matters as he was an Accountant by his training. Furthermore Mr. McStay who was now to deal with financial matters on behalf of BTSB had said in his report that he had no access to the management and would have no knowledge of what had occurred in the decision making process of the BTSB. While he had access to the minutes, these may not contain a fully accurate reflection of what had actually happened, therefore Mr. McStay would be an interpreter of events.

Mr. Hayden said that while in some circumstances whether by death, ill health or otherwise witnesses may come out of sequence, in the instant case to put Mr. McStay in before the factual matrix has been established would unfairly prejudice the other parties to the hearing. Mr. Hayden said that upon hearing such explanations, the witness as to fact, recalling events from a considerable period of time, could be influenced by the explanations given by the expert witness and in this respect it would be fairer if the witnesses as to fact preceded the expert evidence offered by Mr. McStay.

Mr. Hayden said the evidence of persons involved with the Board finances should be heard before Mr. McStay in order to avoid prejudice. Mr. Hayden said that a situation could well develop whereby Mr. McStay, not being in a position to answer some of the issues because all the information isn't at hand, will have to be recalled if he goes first. Which situation, would be contrary to that, indicated to the Dàil in the second interim report of the Tribunal, whereby it was said that expert witnesses would come at the end of a particular section so as to be able to give their view from start to finish on a particular point in any circumstances.

Mr. Frank Clarke for the BTSB replied to the application. Mr. Clarke said that Mr. McStay had had access to any of the financial executives of the BTSB who are still available, however for much of the time investigated by Mr. McStay the financial executives were no longer alive and in this sense Mr. McStay conducted the same exercise for the BTSB as had Dr. Lawlor when she investigated the medical side of the

BTSB's activities. Mr. Clarke said Mr. McStay was attempting to piece together what had happened from the records on such information as was available.

Mr. Clarke said it was most likely that Mr. McStay would indeed have to return to give evidence as there were bound to be other questions on the issues raised, Mr. Clarke said he accepted the authorities opened by Mr. Hayden. However, the Tribunal was not a civil process and in an inquisitorial role much weight would have to be attached to the view of the Tribunal itself as to how it would conduct its inquiries.

Mr. Clarke said it would be the BTSB's preference that Mr. McStay would give evidence first. The reasons for this, said Mr. Clarke, was that the significant people involved in financial affairs up to 1986 were no longer with us. He said many of the issues raised by the I.H.S relate to that period and it would be logical therefore to take the issue in sequence.

On behalf of the Tribunal Mr. Durcan said the Chairperson was charged with investigating certain matters under the Terms of Reference, in this respect the order of witnesses should be determined by what would be of most assistance to the Chairperson in carrying out the task before her.

Mr. Durcan said it was clear from the evidence that Dr. Lawlor dealing with the documents of the BTSB was not in a position to deal with finance. Mr. Durcan said that he expected Mr. McStay to give his evidence based on the information and documents which were available, in this respect he was akin to Dr. Lawlor. Mr. Durcan said that with regard to Mr. Keyes it was clear that any party who has questions for Mr. Keyes can put those questions to him. This was the case with regard to financial matters in addition to any other evidence Mr. Keyes may have to offer. Mr. McStay's evidence would therefore not be allowed to pre-empt or prevent any party asking Mr. Keyes relevant questions.

Any frailty contained in Mr. McStay's evidence, said Mr. Durcan, could be dealt with by way of submission. Mr. Durcan said he thought it would be better to proceed on the basis that people would do their best and give their evidence as best they can uninfluenced by other matters and in this respect he did not expect other witnesses to be influenced by what Mr. McStay would have to offer.

The Chairperson gave her ruling on Mr. Hayden's application at 2.00pm. In rejecting the application the Chairperson noted that it was up to the Tribunal to determine the order of witnesses. The Chairperson said it would be beneficial to the Tribunal to hear Mr. McStay in the order proposed. She said that the overview of Dr. Lawlor as offered had been very helpful to the Tribunal and Mr. McStay came into the same category with respect to finance, especially with regard to the early years under investigation. She did not consider that Mr. McStay would prejudice the succeeding witnesses. In these circumstances Mr. McStay would be heard on Wednesday 20th September followed by Mr. Keyes.

Mr. Finlay for the Tribunal then recommenced his examination of Dr. Daly.

Mr. Finlay referred Dr. Daly to a letter written by Professor Temperley to Dr. O'Riordan on the 21st of August 1985. In which Professor Temperley tells Dr. O'Riordan of his conversation and subsequent visit by Dr. Daly, concerning her meeting with Dr. O'Riordan and Mr. Hanratty in Pelican House on the 13th of August. The essence of the letter was that the BTSB had now until November 1st to stop using non heat-treated BTSB Factor IX. It was pointed out by Professor Temperley that by this time the BTSB would have had eleven months in which to stop using BTSB Factor IX. With respect to this letter Dr. Daly said that she did not recollect any discussion about Thrombogenecity in her discussions with Professor Temperley.

Mr. Finlay then referred Dr. Daly to a study entitled "A review of liver disease in Hemophiliac's in Ireland, 1979" Dr. Daly said she conducted this study in 1979 when she was the laboratory senior house officer based at the Meath Hospital. Dr. Daly said that this document was the uncorrected draft of a document, which she produced as a senior house officer 21 years ago. Dr. Daly said that as such there would be a number of things in it that need to be corrected. Dr. Daly said that this study had never been published other than to be used as the basis for a lecture to medical laboratory technicians at Kevin Street Technical College in and around 1980.

Dr. Daly was then cross examined by Mr. Jim McCullough on behalf of the Irish Haemophilia Society.

Mr. McCullough referred Dr. Daly to the meeting she had had with Dr. O'Riordan and Mr Hanratty of the BTSB on August 13th 1985. Dr. Daly said that at the meeting she discussed the issues of cryoprecipitate and the contract fractionation which was about to commence in January. The issue of heat treating Factor IX concentrate was also raised. Dr. Daly said she was surprised to learn that the contract fractionation was to be carried out by the Travenol Company. Dr. Daly said there had been problems with Travenol Company at this time.

Dr. Daly said she was also very surprised to learn that the Board intended to continue their production of Cryoprecipitate which could not be heat-treated. Dr. Daly said she was surprised to learn that the BTSB planned to supply 20 percent of the needs of patients with Hemophilia in 1986 with a non heat-treated product. Dr. Daly said she regarded this as unacceptable. Dr. Daly said that when she pointed out to Dr. O'Riordan and Mr. Hanratty that it was unacceptable to use non heat-treated products in the treatment of haemophilia including cryoprecipitate that this was not news to them.

Dr. Daly agreed that if the BTSB ceased using cryoprecipitate it would have to gather more plasma for its contract fractionation production of Factor VII. With respect to Factor IX Dr. Daly said that there was no discussion concerning thrombogenecity and there was no technical reason advanced as to why Factor IX could not be heat treated.

Dr. Daly said that it was her understanding that if money was forthcoming from the Department of Health then Dr. O'Riordan and Mr. Hanratty would agree to discontinue the use of cryoprecipitate for the treatment of Haemophilia. Dr. Daly said that she knew of the direction that was issued from Professor Temperley concerning the use of un-heat treated products to the BTSB in the early part of 1985, or late 1984. She said that by the middle of 1985 the BTSB could not have been unaware that heat treatment was required.

With regard to the proposal to use Travenol as the contract fractionator for BTSB plasma, Dr. Daly said she thought there were problems with Hepatitis B in the Travenol product. Dr. Daly said her observations on Travenol did not go down well with Dr. O'Riordan or Mr. Hanratty. Dr. Daly said she thought that Mr. Hanratty and Dr. O'Riordan thought she was interfering in their plans. Dr. Daly said in her discussions with Dr. O'Riordan and Mr. Hanratty she pointed out that from a patient safety point of view the reason heat treatment was required was because patients with both Haemophilia A and B had become infected from non heat treated products. It was known that the blood supply was infected and that it was also known that HIV could be inactivated by heat. However, Dr. Daly left the meeting without achieving her objective. She said she felt deflated upon leaving the meeting.

Mr. McCullough referred Dr. Daly to her letter to Professor Temperley dated August 20th 1985 in which she informed Professor Temperley that she had told Dr. O'Riordan and Mr. Hanratty that it was unethical to use non heat treated products for the treatment of Haemophilia. Dr. Daly said she had subsequently come to the view that the use of the word unethical was an overstatement on her part as it was also considered to be unethical to not treat at all. Dr. Daly said that rather than use unethical that she would subscribe to the view of Professor Bloom in his statement on behalf of the Haemophilia centre of Directors in June of 1985, when he said that the use of non heat products was no longer justified and in this sense maybe her statement that to use those products for the treatment of Haemophilia was unethical was an overstatement. Dr. Daly agreed that with regards to whether or not it was ethical to use non heat treated products in 1985, her efforts at that time were directed at not having to use non heated products.

Dr. Daly was questioned by her own counsel Mr. McGovern. Mr. McGovern asked Dr. Daly did the question ever arise of telling the BTSB to stop using non heat-treated Factor IX or would that be within her competence to tell them. Dr. Daly said she suggested that the BTSB should stop using non heat-treated Factor IX. Dr. Daly said that she recommended to the BTSB that they withhold non heat-treated Factor IX and use heat treated only. Dr. Daly said that it was her view that enough heat-treated Factor IX could be made available for the treatment of Haemophilia B at the time. The BTSB could therefore have agreed to withhold their product and use heat treated product only. However, this was not acceptable at all to Dr. O'Riordan and he became very angry at this suggestion.

In response to re-examination by Mr. Finlay, Dr. Daly said that with respect to the meeting of August 13th that if the BTSB was unable to heat treat Factor IX in August

1985 the other possibility was that the BTSB would withhold the product and that she would use heat treated product only, provided she could get enough of it and she thought she could have got enough.