TRIBUNAL OF INQUIRY

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

PROCEEDINGS: MONDAY 17th JULY, 2000 – DAY 29

Mr Charles Meenan, SC appearing for Dr Terence Walsh, Prof. Ernest Egan and Dr Joan Power cross-examined Dr Lawlor of the BTSB. Mr Meenan said most of his questions would be directed at dealing with the position of Dr Walsh.

Mr Meenan put it to Dr Lawlor that Dr Walsh had worked in the BTSB from 1969 as Senior Medical Officer, and continued in this position until 1976. From 1976 until 1981 he was Assistant Director of the BTSB, and from 1981 onwards he was Consultant Haematologist, with functions and duties consonant with those of the Assistant Director.

Mr. Meenan put it to Dr Lawlor that Dr Walsh had not enjoyed the same clinical independence as a consultant in the Dublin hospitals at the time. Dr Lawlor agreed with this proposition. Mr Meenan said an example of this lack of independence was illustrated in the case of Hepatitis C. Consultants in the BTSB could not order the introduction of testing in the same fashion as what had been available to a consultant working in a hospital. Again, Dr Lawlor agreed with this proposition.

Mr Meenan put it to Dr Lawlor that the area under investigation could be broken into two periods, the O'Riordan period when Dr Jack O'Riordan was in control of the BTSB, and the period thereafter. During Dr O'Riordan's period in control, he enjoyed the position of National Director, where he was effectively Chief Executive Officer and Chief Medical Consultant. Following his retirement in 1985 his post was divided into the role of Chief Executive Officer and Chief Medical Consultant. Mr Meenan put it to Dr Lawlor that, during this period, a new management ethos came into being at the BTSB. Dr Lawlor agreed with this idea. In conjunction with the new management ethos, Mr Meenan put it to Dr Lawlor that the medical influence within the BTSB was on the wane at this stage. Dr Lawlor again agreed with Mr Meenan.

Following Mr O'Riordan's retirement, Dr Vincent Barry became the Chief Medical Consultant. However, in October 1986 Dr Barry departed Pelican House for Cork, and Dr Walsh took up the day-to-day management of the medical side of the BTSB. Under these circumstances Dr Walsh became the de-facto Chief Medical Consultant, but he had no access to the Board except through Dr Barry, said Mr Meenan.

It was also pointed out, by Mr. Meenen, that after 1985, when Dr O'Riordan had retired and Dr Wilkinson had retired, they were not replaced for a number of years later. Consultant cover at the BTSB from 1986 until 1989 was seriously low. Dr Joan O'Riordan was appointed in 1989, and Dr Lawlor was appointed to a full time post in 1996.

Mr Meenan pointed out that between 1986 and 1989, the BTSB in Dublin lost approximately 20 per cent of its work force. In Cork, during the same period, a 10 per cent reduction occurred.

Mr Meenan put it to Dr Lawlor that the needs of persons with haemophilia received a high priority from the BTSB. Dr Lawlor agreed with this idea. Mr Meenan said that the BTSB had other tasks to carry out. Dr Lawlor briefly outlined these tasks as the provision of red cells, platelets, plasma and the therapeutic needs of the patients. Dr Lawlor said that during the period, the BTSB should have had at least five consultants. In fact it had one in Dublin and one in Cork. In summary, Mr Meenan said that the new management arrangements appeared to have been put in place with no notification to those who were working for the BTSB of what was involved. The ad-hoc management arrangements led to an increased workload during a time when the number of those available to do the work was decreasing.

Mr Meenan then examined the issue of the leaflet to donors, and Mr Finlay's observations that the symptoms of AIDS were not included in the leaflet. Mr. Meenen pointed to the fact that the donor leaflet required a doctor's signature to witness that the donor had read and understood the leaflet, and said that this attribute of the BTSB leaflet was not included in the United States Red Cross leaflet. Nor was it the practice in the United States to have a doctor in attendance at a blood donation station. Dr Lawlor said this could well be the case.

Mr Meenan directed Dr Lawlor to correspondence concerning the withdrawal of non-screened BTSB factor IX. He referred to correspondence from Dr Barry to Dr Flanagan of the Department of Health, dated 21st January 1986, when it was agreed that non-screened products would be withdrawn.

Mr Meenan said no reference was made in this letter to the withdrawal of non-heat treated BTSB factor IX. The January 1986 notice recalled untested products. It appeared to be Dr Walsh's position that BTSB factor IX was not withdrawn in January in 1986. Mr Meenan also referred to a letter from Prof. Temperley to Dr Walsh, dated 22nd April 1986. He further referred to a letter from Dr Walsh to Dr Barry of 25th June 1986, in which he says an investigation by Prof. Temperley shows that non-heat treated product was causing seroconversion in six, possibly seven, haemophilia A patients.

Mr Meenan put it to Dr Lawlor that the letter constituted a recall notice, and as such, could not have been clearer. Dr Lawlor said, yes, it could have said it was a recall notice. The words “recall notice” were not used on the letter. Mr Meenan said that the letter was between professionals and was thus sufficient to constitute a recall notice, and any professional reading the letter would have realised this. Dr Lawlor agreed that the letter, as read by professionals, would be clear, and would clearly constitute a recall notice. However, there was no mention of tested products in this notice. A subsequent memo did mention tested products only.

With respect to Hepatitis C testing, Mr Meenan said it was clear that Dr Walsh and other medical professionals within the BTSB, were anxious that the Department introduced Hepatitis C testing at an early point. On 17th January 1990 a discussion took place at the BTSB under the heading of “insurance”. From the discussions held at the Board meeting, it appeared the Board had taken the position that, if the Department would not introduce testing, the Board would introduce testing itself. However, it then appeared to withdraw from this position.

On 7th February 1990 the consultants called for Hepatitis C testing to be started. Hepatitis C testing was subsequently introduced in October 1991, with the introduction of second generation testing. Testing had been available from 1990 on a first generation test.

With regard to the Octapharma contract entered into in October 1989, Dr Lawlor agreed with Mr Meenan that Dr Walsh had done all he reasonably could to ensure that the contract was entered into as soon as possible.

There was no cross-examination of Dr Lawlor forthcoming from Counsel for the NDAB or from Ms Cecily Cunningham.

Dr Lawlor was then cross-examined by Mr Brennan for the Department of Health. Mr Brennan put it to Dr Lawlor that the BTSB was established under the BTSB Establishment Order, which set up the BTSB as an executive body designated to carry out specialised work gathering the expertise to perform that work under one roof. Dr Lawlor agreed with this assessment of the statutory instrument and the establishment order. Dr Lawlor agreed that the statutory instrument allowed the Minister to appoint the Board. Dr Lawlor also agreed that, during his tenure, Dr O'Riordan had "run the show" and, while Dr O'Riordan had no vote at the Board, he could direct the meeting of the Board.

Mr Brennan asked Dr Lawlor, where did the Scientific Committee fit into the scheme of things? Dr Lawlor said it had an advisory function within the Board. Other members of the Scientific Committee were in-house, apart from Dr Kirrane, who could be consulted from time to time. Information from the Scientific Committee was filtered through Dr O'Riordan to the Board, but if Dr O'Riordan ignored the scientific Committee, that would be the end of it. Dr Lawlor agreed with this proposition.

Mr Brennan referred Dr Lawlor the discussions she had previously had with Mr Trainor concerning the recommendations of the Committee of Experts for the Council of Europe, and that in 1983, more was known about dangers posed by blood products than previously. Mr Brennan also said that the BTSB had a role in stocking concentrates. Dr Lawlor agreed with this proposition.

Mr Brennan referred Dr Lawlor to paragraph 4C of the Board's Establishment Order. The order requires the Board to make available blood and blood products. Mr Brennan said, arguably, that is what you are doing distributing the concentrates? Dr Lawlor agreed that in doing so, the Board would be fulfilling its statutory obligation. Again Dr Lawlor agreed with his proposition.

Mr. Brennan then referred Dr Lawlor to paragraph 4F, of the Establishment Order which requires the board to: "… furnish advice, information and assistance in relation to any aspect of the service to the Minister, Health Authority or any Hospital Authority". In this regard, the Minister would issue a licence under the advice of the NDAB. The licences might last for 2, 3 or 5 years. Dr Lawlor agreed with this proposition.

Mr Brennan put it to Dr Lawlor that, during the intervening period after the granting of licence, the state of knowledge concerning the licensed product could change. Dr Lawlor agreed with this.

Mr Brennan then put it to Dr Lawlor that, as an executive arm of the Health Service principally concerned was with the manufacture and supply of blood products. And, if the Board of the BTSB had cause for concern because of information that had come to light from an international forum and from domestic sources, that product which had been licensed may not now be all it appears to be; and if there are serious doubts about it, wasn't there a statutory obligation of the Board, irrespective of whether it could merely stop stocking or stop

distributing, to furnish advice, information and assistance in relation to any aspect of the service to the Minister? Dr Lawlor asked Mr Brennan, when talking about the Minister did he mean the Department of Health. Mr Brennan said: "I mean the Minister, that's what it says here, and okay, the Department of Health if you wish."

Dr Lawlor said the Board furnished the information and sent on the recommendations. Dr Lawlor said it would have been nice if the Board had said we are not going to handle this. However, there is no evidence it did say anything like that. Mr Brennan put it to Dr Lawlor that her evidence was that the BTSB just stocked concentrates, and if it stopped stocking them, because they were a licensed product, they would get into the country anyway. Dr Lawlor agreed.

Mr Brennan put it to Dr Lawlor that, while the treaters may have had a professional obligation to voice any concerns they had in June of 1984, concerning blood products, to relevant departmental authorities; the BTSB, on the other hand, had a statutory obligation to advise.

If the BTSB had serious reservations about a product which had been distributed from under its roof, then would Dr Lawlor not think that, in addition to giving consideration to not stocking it, those concerned should have been advised formally through the Department of Health? It was up to the BTSB to decide on the safety of the products it distributed. Dr Lawlor said she thought that may have been a good idea. Mr Brennan said that he was not talking about a good idea, he was talking about a statutory obligation.

Dr Lawlor said that the reason the BTSB had not issued such advice was that, in 1980 the NHSCC took on the responsibility of determining which products would be suitable for its distribution.

It therefore appears that the Department of Health considers the BTSB to have been in breach of its statutory duty in failing to warn the Minister of any concerns it may have had in respect of blood products it was importing and distributing during the early 1980s. The BTSB's position seems to be that the NHSCC had taken responsibility on for this function. However, it would not appear that there was any statutory obligation on the NHSCC. Statutory obligation does rest on the BTSB.

Mr Brennan referred Dr Lawlor to her position with respect to any evidence concerning financial matters. Given that Dr Lawlor declined to give evidence on financial matters, any evidence that she did give in this respect had amounted to comment only, said Mr Brennan. Dr Lawlor said that any person at the time could see that there were financial problems within the BTSB. Mr Brennan asked Dr Lawlor that, was she leaving the matter of finance to a financial witness, or was she going to get into it? Dr Lawlor said she was not getting into it with anybody, but anybody with general education could see that the Board was strapped for finance. Mr Brennan said that Dr Lawlor spoke of funding with reference to the Department. The inferences in her evidence were a matter of comment to be thrashed out by a financial witness. Dr Lawlor agreed that this would be the case.

Dr Lawlor was then examined by counsel for the BTSB, Mr Frank Clarke S.C. Mr. Clarke touched on various aspects of Dr Lawlor's evidence. With regard to 100 vials of Armour A28306 which were unaccounted for by the BTSB, Dr Lawlor said that over the weekend she had located documents that indicated that 60 of these vials had been sent to Cork and 40 remained unaccounted for.

Mr Clarke referred Dr Lawlor to an article by Zuck and Eyster published in Transfusion, in which the authors challenge an Institute of Medicine report, which examined the reaction of the blood industry to the treats posed by AIDS. The article was a rebuttal to a major report published on the subject.

Dr Lawlor was then examined by Mr Trainor concerning her assertion that 95 per cent of those infected with HIV were so infected by the start of 1983. Dr Lawlor appears to have drawn her figures from a study by Kroner of US and Western European statistics.

Dr Lawlor was briefly examined by Mr Finlay, with reference to an article she quoted in support of her position on thrombogenicity. Dr Lawlor had mentioned a fatal case of thrombogenicity in a haemophilia B patient, but this was incorrect. The case in question was that of a haemophilia A patient who was treated with factor IX after he had developed inhibitors to factor VIII. Dr Lawlor said that she would now accept that very large doses of factor IX had been administered in this case. The person receiving treatment had been exposed to doses of factor IX greatly in excess of what would have been used for an ordinary patient with haemophilia B.

The Chairperson had no questions for Dr Lawlor, who withdrew after 18 days of evidence.

Mr John Finlay S.C. for the Tribunal, examined Dr. Vincent Barry. Dr Barry is former Chief Medical Consultant of the BTSB. Dr Barry qualified as a doctor in 1948 and went to work in Britain. He specialised in immuno-haematology and red cell serology. He did not specialise in the treatment of haemophilia, but was familiar with the use of concentrates and had experience in the administration of fresh frozen plasma, and the treatment of mild haemophilia in the 1950s and 1960s.

In 1976 he was asked by the BTSB to work in Cork. During the 1970s he was generally aware of controversy surrounding the use of concentrates and the attendant risk of Hepatitis.

On returning to Ireland in 1976, Dr. Barry was appointed Regional Director of the BTSB in Cork. He was joined by a Mr. Seamus O'Brien, who was seconded from the technical staff of the BTSB in Dublin to assist in the establishment of a blood service for Cork. During this time Dr. Barry said he had a lot of duties, among which was the treatment of haemophilia patients. Dr. Barry said that in 1976, the principle treatment available for the treatment of haemophilia A was the cryoprecipitate. Haemophilia B patients were treated with fresh frozen plasma at this time. Subsequently, the BTSB developed its own Factor IX for the treatment of haemophilia B. This product was never made in Cork, said Dr. Barry, but was supplied to Cork from Pelican House in Dublin.

During the mid to late 1970s commercial concentrates became available, chiefly US products. Some European products and Immuno products were also imported by the BTSB. These products arrived in Cork and were held in a refrigerated unit at the Regional Hospital, now Cork University Hospital, and were despatched from there to the patients.

At the end of 1985 Dr. Barry was appointed to the post of Chief Medical Consultant. Mr. Finlay asked Dr. Barry how he came to be appointed to this post. Dr. Barry said he wasn't appointed and that it was more in the nature of an invitation. Dr. Barry said he was asked if he could act in a capacity of medical consultant, pending the appointment of a permanent medical consultant. Dr. Barry said he was reluctant to take up the post, as he was purely a serologist. But he had read a lot and knew what was going on, and had been to Dublin to see what they were doing. Dr. Barry said he had a "hellish commitment in Cork" and didn't think he would have enough time to spend in Dublin to cope with the requirements of the job. But he was asked to assume the name and impart the knowledge he had acquired in the four different units in the UK. As far as blood products were concerned, he said he wasn't a suitable person to administer and discuss these matters.

Dr Barry said that between 1980 and 1985 he was based in Cork. As Regional Director, he would furnish a report each month to the BTSB. He attended Scientific Committee meetings on an irregular basis of just once a month. If there was a meeting organised and it was considered that he had something to offer the meeting, then he would attend the meeting.

Dr. Barry said that in the 1980's he was aware of a self-sufficiency project undertaken by the BTSB to produce a Factor VIII. The project appeared to involve Dr. O'Riordan, Mr Cann, Mr. Hanratty and other medical colleagues. He was aware that the particular method, set out by Rock and Palmer, was being used to realise the project aims of producing a form of factor VIII concentrate.

Dr. Barry said that the BTSB in Cork did not purchase any concentrates itself. Its concentrates were supplied through BTSB, and were in turn used by the Cork University Hospital for the treatment of Haemophilia. The BTSB in Cork was not involved in the purchasing of the concentrates.

Mr Finlay drew Br Barry's attention to a memo addressed to the Future Developments Committee, BTSB, concerning links between commercial companies in training on such concentrates. The memo complained to the Future Developments Committee that the decision to centralised the purchase of blood products would preclude staff in Cork from availing of sponsorship for training offered by drug companies. Mr. Barry said that such practice never occurred during his time in Cork. He said other items other than blood products may have been purchased from companies, but there was no sponsorship provided for training that he knew of.

Mr. Finlay referred Dr. Barry to the findings of the Future Developments Committee report which was published in December 1984. Here, the Future Developments Committee recommended the continued use of cryoprecipitate and the fractionation of excess plasma, and to produce its own fibrinogen from selected Hepatitis-free donations. However, it wasn't determined how Hepatitis-free donations could be delivered, as there was no test at this time for Non-A, Non-B Hepatitis.

With regard to screening, the report recommends that it might be extended to CMV and, when suitable tests were available, to Non-A Non-B Hepatitis and to AIDS. This reference to AIDS is the only reference within this 1984 report to the condition. Dr Barry agreed that it was curious that this was the only reference to AIDS contained in the entire report. Dr. Barry agreed that the subject of AIDS would have been discussed between himself and his colleagues at this time, but he said there was no test available for AIDS and it was untreatable at this point. He said he did not know why there was no further mention of the condition.

Mr Finlay asked Dr Barry if, at the start of 1985, heat-treated products replaced non-heat treated products in respect of Factor VIII? Dr. Barry agreed that this was the case. Dr. Barry also agreed that the BTSB continued to produce its own unheat-treated FIX during 1985, and that this product continued to be supplied to Cork University Hospital. Dr. Barry was asked had he received a report from Dr. Cotter concerning a problem with a patient or patients with Haemophilia B in 1985 or 1986, and specifically a problem that a patient with Haemophilia B had seroconverted and become positive for HIV? Dr. Barry said he did not recall it, but he knew that it had happened. Dr. Barry was asked, did Dr. Cotter mention this fact to him? Dr. Barry said "I'm afraid she didn't, I can't recall her saying it". Dr. Barry said he realised that the news that a patient had seroconverted was a serious matter. If it had been said to him he was sure that he would have remembered.

Dr Barry said that around this time, he contacted his colleagues in the UK to discuss heat treatment protocols. He said he discussed heat treatment with his colleagues at Elstree. The heating protocol should have been 80 degrees for 72 hours. Dr. Barry said he had this conversation in early 1985. However, Mr. Finlay pointed out that in early 1985, this heat treatment protocol had not been introduced in the UK. Dr. Barry agreed that this conversation may have taken place in July of 1985. He said that while he could not recall hearing about the patient seroconverting, however he may have contacted in UK on hearing this type of news. Dr Barry agreed that Dr. Cotter may help with the exact dates.

Dr. Barry took up the position Chief Medical Consultant in January of 1986. Dr O'Riordan offered him the position. Dr. Barry said he was reluctant to take up the post. Dr. Barry said that, upon being persuaded to accept the job of Chief Medical Consultant in January 1986, he travelled up and down from Dublin to Cork and he spent more time on the road than anything else. Dr Barry said he would spend a few days in Dublin and then return to Cork.

By the end of 1986 Dr Barry said that, while he was back in Cork full time, he still tried to attend Board meetings and Finance Committee meetings.

Mr Finlay directed Dr. Barry to a memo from Mr. Keyes in the early part of 1986, when fractionation was in being and yield problems were manifesting themselves in the Travenol contract. Mr. Finlay further directed Dr. Barry to a handwritten note of the 21st of January 1986 concerning the withdrawal of products. The note stated that products which had not been tested, were to be withdrawn. Dr. Barry said that in 1986 when he arrived at the BTSB as Chief Medical Consultant, unheated Factor IX product was still being used. He did not recall any discussion about this particular subject, nor did he recall any particular problem being discussed about BTSB Factor IX.

Dr Barry said that, at the time when he arrived, this section had been provided for by Dr. O'Riordan and was staffed by very competent people. It was up and going so he wasn't told a lot. Dr. Barry said that there were a number of matters he didn't find out about at this stage. He found out subsequently, so in other words, there was no red carpet laid out for him and he was not welcomed by his medical colleagues. He said it appeared to be the case that they had been working there for years and they didn't know what he was doing there.

Dr. Barry said that during 1985, he was not aware that BTSB Factor IX was not heat treated. A letter of the 22nd of January 1986 from Dr. Barry to Mr. Flanagan of the Department of Health, set out the costs of withdrawing non-donor screened products. The letter contained no reference to heat-treated product. In essence, the letter was a request for compensation in respect of the products withdrawn by the BTSB exchanged for donor screened products. In reply, the Department indicated that no compensation would be forthcoming. However, Dr. Barry said that the BTSB was subsequently compensated for the loss.

On the 22nd of April 1986 Professor Temperley wrote to Dr. Walsh, and informed him that Factor IX infections had occurred. The letter was marked confidential. However, Dr. Barry's initials were not on the letter. Dr. Barry said he did not recall seeing the letter. Dr. Barry acknowledged that this letter contained very serious information that had not been discussed with him.

In further communication in June 1986, Dr. Keyes wrote to Dr. Barry telling him he had met with Professor Temperley to discuss the problems that had arisen in respect of the use of BTSB Factor IX for the treatment of haemophilia B patients. Six haemophilia B patients had antibodies to HTLV III at this point. Professor Temperley and Dr Walsh agreed that it was likely that these seroconversions had been caused by BTSB factor IX. Dr. Walsh informed Dr. Barry that he was issuing a circular to hospitals to advise them to return any non-heat treated material that may still be in circulation and that any future materials should be heat treated and drawn from screened donors only.

Dr. Barry said that, as he appeared to have written the letter of June 30th, 1986 recalling BTSB Factor IX, he must of known something about it, but he did not explicitly recall this event. Mr. Finlay said he found this surprising as it was apparent that Dr. Barry had been

informed of the events leading up to the recall. He could not be said to be out of the loop in this matter. Dr. Barry said he took action when he received the information, so he must have known something about it. Dr. Barry said he had returned to Cork at the time these events came to pass, and he had permission from the Chairman of the BTSB to do so.

Mr. Finlay put it to Dr. Barry that his recall letter of the 30th of June 1986 could have been more explicit about the problems caused by the BTSB Factor IX. Dr. Barry said the problems were already known. When asked how the problems were known, he said that the problems had been discussed in telephone conversations. Mr. Finlay asked Dr. Barry was the problem with the BTSB Factor IX reported to the NDAB? Dr. Barry said he did not report it, as this matter was been dealt with from Dublin. Mr. Finlay said that Dr. Barry was the Chief Medical Consultant at the time, to which Dr. Barry responded that he was Chief Medical Consultant in name only, and that he had asked to be released from the post at this point.

Mr. Finlay pointed to a special meeting on Factor IX held on July 1st, 1986, chaired by Dr. Barry. Dr. Barry said he had no recollection of this meeting, but he could remember Mr. Keating coming back from Paris with information on heat-treatment protocols. With respect to the Travenol contract, Dr. Barry said Mr. Hanratty was in charge of plasma procurement for this project.

Mr. Finlay then referred Dr. Barry to the correspondence between Professor Temperley and Professor Egan in Galway concerning the seroconversion of Haemophilia B patients using BTSB Factor IX. Professor Egan subsequently wrote to Dr. Walsh and complained that he had discovered from a third party about problems arising from the use of BTSB factor IX.

Mr. Finlay put it to Dr. Barry that, when problems concerning BTSB Factor IX had become apparent in May and June of 1986, all the hospitals should have been informed. Dr. Barry agreed that they should, and he said he presumed they probably were. Mr. Finlay replied: "well, it's clear they weren't, it was particularly clear that at least Professor Egan hadn't been informed". Dr. Barry said that the hospitals should have been informed and that this information was emanating from Dublin. However, Mr. Finlay suggested to Dr. Barry that the ultimate responsibility of ensuring that the hospitals had been informed of the problems arising from BTSB Factor IX, lay with the Chief Medical Consultant, namely Dr. Barry. It may not have been his responsibility to actually inform the hospitals himself, but it was his responsibility to see that it was done. Dr. Barry said that this was true but he was not acting as Chief Medical Consultant at that stage, he had been relieved of the post.

Mr. Finlay put it to Dr. Barry that, when Dr. Walsh had communicated with him on the 25th of June 1986 and put the information concerning the seroconversion of haemophilia B patients being treated with BTSB Factor IX before him, Dr. Barry then had a responsibility as Chief Medical Consultant to take the appropriate action. Dr. Barry said that this would have been the case if he had still been acting as Chief Medical Consultant, but that as he was no longer in this position. Dr. Barry said that there was no correspondence between himself and the haemophilia treaters. All the correspondence was to either Professors Egan or Temperley, or Dr. Cotter. Dr. Barry said that, while there was communication between himself and the treaters, there was never any direct correspondence concerning these matters.

At a Board Meeting on the 3rd of October 1986 it was stated that Dr. Barry and the Executive Consultant, Mr. Keyes, had agreed that it should now be deemed that Dr. Walsh was to be the consultant in charge of Pelican House, and that Heads of Department in Dublin in particular would now deal with Dr. Walsh. It was also agreed that Dr. Walsh would consult Dr. Barry

as appropriate. This had come to pass as it was now apparent that Dr. Barry was now spending most of his time in Cork.

On the 29th of October 1986 a delegation from Elstree visited Pelican House, accompanied by Dr. Barry. Dr. Barry said these were former colleagues.

PROCEEDINGS: WEDNESDAY 19th JULY, 2000 – DAY 31

Mr John Finlay S.C. continued to examine Dr Vincent Barry, formerly Chief Medical Consultant of the BTSB. Mr Finlay asked Dr Barry about a visit to Dublin by a delegation from Elstree on 9th October 1986. Dr Barry was present. Dr Barry said he knew at this time that heat treatment at 80 degrees for 72 hours was effective for Non-A, Non-B Hepatitis and HIV. Dr Barry said he knew before the meeting that different factor concentrates required different heat treatment. He also knew that the Elstree heat protocol was good for Hepatitis and HIV.

Mr Finlay traced Dr Barry's involvement with the Travenol fractionation contract. In mid-1987 the Travenol contract was experiencing difficulties in achieving promised yields. In an attempt to overcome the problem, plasma was despatched to Belgium and to the U.S. Dr Barry said he could not answer questions on attempts at finding alternative fractionators, as this was a yield matter. However, on 2nd April 1987. It was noted that Dr Barry attended a meeting with Travenol executives. Dr Barry said he had no recollection of this meeting. The meeting discussed monoclonal extraction. Mr Finlay asked Dr Barry, would he have been aware of this as a new form of fractionation? Dr Barry said he understood it, but he did not remember the meeting.

Mr Finlay referred Dr Barry to a *New England Journal of Medicine* edition of April 1987, which contained an article by Schipp and Manucci on the pasteurisation of factor VIII. This method was described as effective in producing a product free from Hepatitis. Dr Barry said he was aware of the benefits of pasteurisation, and he was also aware of the low yield problem it gave rise to. Dr Barry said he was familiar with different methods of viral inactivation, but he was not party to any efforts to seek new fractionators for the BTSB.

Mr Finlay drew Dr Barry's attention to the appointment of Prof. Temperley to the Board on 20th May 1987. Prof. Temperley was appointed for three years from this date. Dr Barry said thereafter, he had no recollection of any negotiations on the Armour contract. He could not remember anything to do with any forms of viral inactivation specified in the contract. He acknowledged that this was a medical concern. He would have taken note of what was happening and the heat treatment required. Dr Barry said it would have been known at the time that dry heat treatment was effective for HIV, but not good for Hepatitis C. Dr Barry said he knew that 80 degrees at 72 hours was good for both HIV and Hepatitis, and did not have a seriously adverse consequence for the thrombogenicity with respect to factor IX. Dr Barry said he may have expressed his view initially to Dr O'Riordan, but as far as he was concerned he was not involved with the fractionation at all. He was not involved in discussions or meetings with Armour. “I was a Serologist. I served no useful function in fractionation,” said Dr Barry.

Mr Finlay asked Dr Barry, would he not have made inquiries as to the state of the contract fractionation negotiations. Dr Barry replied that he had no experience in blood products, therefore he would not have made any inquiries. He didn't make any form of inquiry as to viral inactivation to be used in the Armour contract. Dr Barry said that the BTSB, Pelican House were the experts in this area. Dr Barry retired from the BTSB on 31st December 1987.

Mr John Trainor, for the I.H.S., then cross-examined Dr Barry.

Dr Barry recalled his early days with the BTSB in Cork, he had a good working relationship with Dr O'Riordan in Dublin. He found Dr O'Riordan extremely helpful. He said Dr

O'Riordan allowed him to get on with it, and they had a good working relationship. He submitted a monthly report. He talked to Dr O'Riordan on a regular basis. He would meet with him in Dublin and also communicate with him on the telephone. He said Dr O'Riordan would sometimes travel to Cork, but more often he would go to Dublin.

Mr Trainor asked Dr Barry, had he any views on the Hemofil issue at this time? Dr Barry said the BTSB in Cork would store the product. They had refrigerated storage facilities and the product was issued as required

Dr Barry said he was not aware of any Council of Europe recommendations or World Health Organization recommendations concerning the sources of blood products. He said he did not realise that Dr O'Riordan had a strong view on the undesirability of factor concentrates during the 1970's. While he did not know that Dr O'Riordan held these views, he was not surprised to learn that he did so. Dr O'Riordan did not share these views with him.

Dr Barry said he had no knowledge of the pricing or costs of factor concentrate products. He could not recall whether these matters were discussed at Finance Committee Meetings he attended.

Dr Barry said the Board's policy of not standing over the safety of products was not passed on to him, and he could not recall any discussion on this matter. Dr Barry said that, as far as he was concerned, the BTSB product was on all fours with the fresh frozen plasma which he had administered to people with haemophilia in Liverpool. With regards to imported products, he understood that it was imported from reputable firms. Dr Barry said that's all he could judge by. Dr Barry said, as far as he was concerned, the product was available for the treatment of haemophilia and supplied for this purpose.

Mr Trainor asked Dr Barry, if a safety question mark arose on a product, would he expect the Board to do something about it? Dr Barry replied that he would expect the Board to react. Mr Trainor asked Dr Barry, if a problem arose, would he expect the Board to discontinue using the product? Dr Barry said, if the tests were done and the blood was safe, he would expect it to be used.

Dr Barry said that Scientific Committee Meetings were conducted on a regular basis during his time with the BTSB. Dr Barry said a full set of Scientific Committee Meetings were available up to the time of his retirement in Cork, subject to the periodic disposal of documents by his secretary on a five or six year basis. Mr Trainor asked Dr Barry, was the issue of AIDS ever discussed at the Scientific Committee Meetings during the years of 1983/1984? Dr Barry said he could not recall any such discussions taking place. Dr Barry said it was generally appreciated that blood products were capable of transmitting HIV. He can't be sure how this came to his attention, but he expected that it was in the course of general discussion.

To the question of whether AIDS was discussed at BTSB meetings, Dr Barry said the answer is yes, it was discussed among medics over the period. Mr Trainor asked Dr Barry, had he had such discussions with Dr O'Riordan, with Dr Walsh, or with Mr Hanratty? Mr Barry said he could not recall having specific discussions with any of these men. Mr Trainor asked Dr Barry, had any discussions about safety of concentrate or about discontinuing concentrate ever take place with respect to the unfolding AIDS situation? Mr Barry said that the product had to be made available for the treatment of haemophilia.

Dr Barry was asked, was there any discussion as to whether or not cryo was safer than imported blood concentrates? Dr Barry said that he could recall such discussions. It was generally held that cryo was safer, and that cryo had been about for a long time.

Dr Barry said that, due to the small plasma pool, it was generally appreciated that cryo was a relatively safe product. Mr Trainor asked Dr Barry, was cryo considered by the Board to be an alternative to factor VIII with respect to safety? Dr Barry said these type of discussions took place with medical and technical staff. But there wasn't enough cryo. All these discussions took place against a background of a threat of AIDS.

Mr Trainor asked Dr Barry, was he an advocate of a return to cryo in view of the threat of AIDS? Dr Barry said he held these views, and others were also of this view at the time. Mr Trainor asked Dr Barry, were there any persons within the BTSB who held contrary views, and could he name them? Dr Barry said he was not able to do this. Dr Barry was asked, did Dr Walsh hold this view? Dr Barry said he could not be sure who was for or who was against use of cryo as an alternative to factor VIII concentrates. Dr Barry said that, as far as he was concerned, the concentrates were a hospital problem. His problem as far as the hospitals were concerned was the supply of whole blood. It was the product of choice for the hospitals at this time.

Mr Trainor asked Dr Barry, did he recall November 1984 and reports of a person with haemophilia being diagnosed with AIDS and being treated in St. James' Hospital? Dr Barry said he had no recall of this particular event.

Mr Trainor referred Dr Barry to the circumstances of his appointment as Chief Medical Consultant in 1985/6. Dr Barry said he had a conversation with Dr O'Riordan. The conversation took place in a motor car. Dr Barry's understanding of the appointment was that it was an interim appointment, and was made pending a permanent appointment. Dr Barry said that he had been invited to be the Chief Medical Consultant due to his extensive experience in serology and immunohaematology. Dr Barry agreed that the position was that of acting Chief Medical Consultant, and that no additional payment was made for taking up the post.

Mr Trainor asked, what was Mr Barry's understanding of what the Chief Medical Consultant post would entail? Dr Barry said it was just based on his experience. He was reluctant to accept it, but did so out of a sense of duty. Dr Barry said Dr O'Riordan told him that a very efficient team was looking after blood products. The efficient team, as far as Dr Barry was concerned, was Drs Walsh and Wilkinson, and Mr Hanratty, Mr Cann and Mr Keating - they were looking after the blood products.

Dr Barry said that the two principle employees, with respect to blood products, were Dr Walsh and Mr Hanratty. Dr Barry said it was his understanding that he would have no role with respect to blood products. The team looking after these particular products was entirely reliable, and it would be safe to leave the blood products to the Pelican House team. Dr Barry said that he indicated at the time he would take up the post as a caretaker. Dr Barry said he understood that Dr O'Riordan had discussed the matter with the Board. Mr Barry said he was not expected to report to the Board or to advise the Board, or to advise anyone else on his activities as Chief Medical Consultant. The reporting structure of the Board was therefore unaltered by his appointment.

With respect to issues arising from the blood products division the BTSB's business, Dr Barry said he knew that testing had been introduced in October of 1985. He did not know until 1986 that a donor had proved positive for HIV. Dr Barry said he did not know anything about the heat treatment or non-heat treatment of factor IX at the end of 1985. Nor was he aware of any matters arising on the testing and distribution of non-heat treated factor IX. He was not briefed in any issues. He continued to do the work he had already been doing within the BTSB. No formal discussion took place in respect of the role of Chief Medical Consultant or of the role of blood products experts at Pelican House.

Discussing the circumstances of his appointment as Chief Medical Consultant. Dr Barry said that, upon taking up the post, he was not welcomed by his medical colleagues in Pelican House. He was criticised for accepting the position. The two senior consultants at Pelican House at this time were aggrieved that he had accepted. He explained the situation and told them he was not going to interfere in their work, and that he was merely a stand-in until a decision was made as to who would be appointed as the successor to Dr O'Riordan.

Dr Barry said that a practical manifestation of this bad feeling was that senior staff would not enter into conversations with him when they met in the corridors at Pelican House. At this point Mr Meenan, for Dr Walsh, objected to the use of the term "acting Chief Medical Consultant", which was contained in the cross-examination of Mr Trainor. Also, Mr Brennan, for the Department of Health, wanted to know Mr Trainor's authority for stating that ministerial approval was required for the appointment of the Chief Medical Consultant.

Mr Trainor referred Dr Barry to an early 1986 letter written in under his name to Mr Flanagan of the Department of Health, concerning compensation for recalled factor IX. Mr Trainor asked, why was the Chief Medical Consultant writing to the Department of Health? Mr Barry said he was obviously instructed to do this, as it would not come into his mind to do so. Mr Barry said that it did not appear to be the sort of letter that he would write. Dr Barry said that, in April 1986 he was still the only consultant in Cork, and that the medical community in Cork was anxious that his links with Cork should be maintained.

In February 1986 Mr Barry compiled his monthly report for the Cork Region. It was read to the Board as the Report of the Chief Medical Consultant, Regional Centre, Cork. In fact it was the normal monthly report that Dr Barry would have filed as the Regional Director.

Mr Barry said it was his understanding that the Board was aware that his role was that of transfusion and not blood products, and that he had accepted the post of Chief Medical Consultant under certain qualifications, among which were that he would not contribute to discussions on blood products.

With regards to communications between Prof. Temperley and Dr Walsh, in April 1986, concerning the seroconversion of factor IX patients, Dr Barry said he did not know about any letters relating to this matter. Mr Barry said he thought the Blood Products Division of the BTSB was an excellently run section, and did not dispute what was going on there.

With regards to Mr Hanratty's proposal that Dr Barry be nominated as Chairman of the NHSCC in May 1986, Dr Barry said he could not recall details of this event. He agreed with Mr Trainor that, to propose him without his knowledge as chairman of this committee, in competition with Prof. Temperley, would amount to an extraordinary slight and a disrespectful act by his subordinate.

PROCEEDINGS: THURSDAY 20th JULY, 2000 – DAY 32

John Trainor S.C. for the I.H.S. continued to cross-examine Dr Vincent Barry, formerly of the BTSB.

Mr Trainor drew Dr Barry's attention to the issue of sponsorship. A BTSB Board meeting of 26th March 1986 directed the Executive Consultant to report on the forthcoming International Society of Blood Transfusion Congress, to be held in Sydney in May 1986, and the attendance of BTSB staff at this conference. He noted that personal sponsorship for such events was not acceptable.

Dr Barry's understanding of personal sponsorship was sponsorship which applied to the individual rather than to the Board; when the individual was nominated by an outside agency this was regarded as personal sponsorship. As far as Dr Barry understood, at a subsequent meeting of the Board on 16th April 1986, the Executive Consultant delivered a report of attendances at courses, meetings, sponsorship, etc. He noted that three staff members were at the Congress in Sydney, and was seriously concerned about the implications of such sponsorship and, in the circumstances, the Board should meet the cost of such attendance.

One of the three was Dr O'Riordan, who had retired from the Board in December 1985. In addition to guidelines concerning sponsorship, the Executive Consultant was directed to ensure that the normal processes in regard to the purchase of items in the public service, were observed. The Executive Consultant was directed to satisfy himself that the best possible price was obtained, and in future all purchases of this nature, including contracts, must be approved by him.

Dr Barry said he had no knowledge of the BTSB's finances. Dr Barry agreed that part of his role as Chief Medical Consultant was to give clinical advice to the Board of its Chief Officer from time to time as required. Referring to Board minutes of October 1985, Mr Trainor noted that it was recorded that there had been some difficulties in staff having access to clinical advice from the chief medical consultant from time to time, that Dr Barry was now spending much more of his time in Cork and accordingly, both Dr Barry and the executive consultant had deemed Dr Walsh to be the consultant in Pelican House, and heads of department in Dublin would now deal with Dr Walsh. Dr Barry said he did not recollect any difficulty in anyone having access to him, nor was there any difficulty in obtaining clinical advice from either himself or from Dr Walsh. He received no calls which would indicate that such a difficulty existed.

Mr Trainor asked Dr Barry, was he correct in saying that Dr Barry's evidence was that he had obtained the consent of Chairman Mr Noel Fox. allowing him to return to Cork? Was it the case that this permission had been obtained some months prior to the October 1985 Board meeting which officially recorded the decision? Dr Barry concurred with this observation. Mr Trainor asked Dr Barry, was it also correct that the Executive Consultant, Mr Keyes, had agreed Dr Barry's return to Cork? Dr Barry said his arrangement was initially with Mr Fox and this conversation took place in June of 1985.

Dr Barry was due to retire in July 1987. It would appear from the minutes of the meeting of May 20th 1987, Br Barry was asked to remain at his post in Cork until the end of that year. Mr Trainor noted that Dr Barry's pension entitlement was augmented by the addition of two

years to his service. Mr Barry said this was done in respect of his early years in Cork, when he was alone and did not take any leave for about three or four years.

Mr Trainor drew Dr Barry's attention to two factor IX recall letters, one of the 25th June 1986 written by Dr Walsh, and one of the 30th June 1986 signed by Dr Barry. Apart from the different signatures and different locations to which the factor IX should be returned, the letters appeared to be identical. A letter sent by Dr Barry at a later date was effectively a copy of the letter sent by Mr Walsh on the earlier date. Dr Barry said he accepted that the letter was sent down and repeated. As to whether or not Dr Barry had advised the National Drugs Advisory Board of the recall of factor IX, Dr Barry said the whole matter was being handled from Dublin, and that the consultant in charge in Dublin was Dr Walsh.

Mr Trainor asked Dr Barry, who would report to the Board on the progress of the factor concentrate issues? Dr Barry said he understood that reports would go to the Board from Pelican House. Before his retirement Dr O'Riordan would report, then Dr Walsh or Dr Wilkinson. After Dr O'Riordan's time, reports went through Mr Keyes, and from Dr Walsh and Dr Wilkinson.

Mr Charles Meenan S.C. cross-examined Dr Barry. Mr Meenan represents Dr Terry Walsh, Dr Joan Power and Prof. Ernest Egan.

Mr Meenan commenced his cross-examination by asking Dr Barry what he understood by the meaning of the word “chief”, as contained in the title Chief Medical Consultant. Dr Barry said he understood this to be an interim title - until a full-time appointment was made. Mr Meenan put it to Dr Barry that “chief” meant that he was the head of the medical team at Pelican House, and that he was the only doctor at Pelican House with access to the Board and influence over blood product policy. Mr Barry agreed with this proposition.

Dr Barry said he was not an expert on factor VIII or factor IX blood products. Mr Meenan asked Dr Barry, did he know that in October and November 1985, blood product concentrates were a source of infection for persons with haemophilia? Dr Barry said he was aware of that.

Mr Meenan put it to Dr Barry that, as the doctor on the Board with responsibility for medical matters, was it the case that he was there to inform the Board? Dr Barry said he was not there to inform the Board of blood products. He said, “I would advise them on general medical matters.” He said the whole issue of blood products meant little to him. Mr Meenan asked Dr Barry, what do you think it meant to Dr Walsh, who had to report to you? Dr Barry said that he was concerned with serology and immunohaematology. They were his fields, not blood products.

Mr Meenan directed Dr Barry to the Board minutes of February 1986. It was noted that the post of consultant pathologist would be advertised. This was the post that Dr Barry had vacated in Cork. Was he not aware that the post was to be advertised? Dr Barry said he was not aware of this particular fact. Mr Meenan pointed out that Dr Barry had been at the board meeting and this had been discussed.

In the Board minutes of April 1986 the Executive Consultant advised the Board that he had sought approval from the Department of Health to advertise the post of consultant pathologist as quickly as possible. It would therefore appear that three months after a meeting, at which Dr Barry's job was discussed the Executive Consultant was still in the process of obtaining approval from the Department to advertise the job.

In the BTSB Board minutes of 20th May 1987, Dr Barry was asked to remain on as consultant in Cork until the end of that year. Mr Meenan had put it to Dr Barry that, when his retirement date arrived in July 1987, this was a perfect opportunity for him to take up his retirement and leave the BTSB. Mr Meenan again put it to Dr Barry that he was the only doctor with access to the Board with respect to policy matters. Dr Barry said he had access to the Board on these matters in name only.

Mr Meenan put it to Dr Barry that he was head of the team in Pelican House. Dr Barry agreed with this. Dr Barry said Dr Walsh occasionally attended board meetings. Mr Meenan said he was instructed that Dr Walsh had never attended a Board meeting in respect of blood products and product safety.

Mr Meenan put it to Dr Barry that he should have retired from the position as Chief Medical Consultant in mid 1986? Dr Barry said he returned to Cork and he did not retire at that point. Dr Barry said he had taken up the job of Chief Medical Consultant simply to please the Board and Dr O'Riordan.

Mr Meenan asked Dr Barry, was he fulfilling his duties as Chief Medical Consultant in July 1986? "No, I'd returned to Cork at that stage", said Dr Barry. Mr Meenan put it to Dr Barry that his return to Cork did not change the role of the Chief Medical Consultant. Dr Barry agreed. Nor had it changed the role of Dr Walsh? Dr Barry agreed that neither role changed.

Mr Meenan put it to Dr Barry that the role as Chief Medical Consultant was more far-reaching than that being portrayed by Dr Barry. An illustration of this, said Mr Meenan, was the fact that Dr Barry's name was on the letterhead of the Blood Transfusion Services Board where he was described as Chief Medical Consultant. Reports from Dr Barry in the Minutes were described as the report of the chief medical consultant. Dr Barry said these reports were the reports that he always filed from Cork, ie. the regional report. If there was a report on matters other than those emanating from Cork Region, then they were being made by Mr Keyes, said Dr Barry.

Mr Meenan pointed to Dr Barry's attendance at a Travenol fractionation meeting to discuss poor yield. Mr Meenan asked Dr Barry, what was he doing at the meeting if he wasn't there in his role as Chief Medical Consultant. Dr Barry said he didn't recall the meeting.

Mr Meenan asked Dr Barry, was it the case that yield from plasma was a medical matter? Dr Barry agreed that it was. Mr Meenan pointed to various places in the BTSB minutes where Dr Barry acted in the capacity as Chief Medical Consultant. Dr Barry said he is mentioned in the minutes in his role as a blood transfusion expert, and not as a blood products expert.

In April 1987, the Chief Executive Officer reported to the Board that two donors tested positive for HIV. Mr Meenan said, was this not a medical matter? Dr Barry agreed that it was a medical matter, but he was not in Dublin at the time. Evidence would appear to indicate that the Chief Executive Officer was dealing with fractionation. Dr Barry agreed that these were medical matters.

Mr Meenan drew Dr Barry attention to the Chief Executive Officer's report on the efficacy of testing. Mr Meenan asked Dr Barry, was it appropriate that the chief executive officer, an Accountant by training, should give an opinion on a clinical matter. Mr Barry agreed that this was unusual. Mr Meenan pointed out to Dr Barry that he was at the meeting when this

opinion had been delivered. Mr Meenan asked Dr Barry if he had any views on the matter at the time. Mr Barry said it struck him as odd that the Chief Executive Officer should report on the efficacy of testing, but that he assumed Mr Keyes, the Chief Executive Officer, had the information for the meeting from another source.

Mr Meenan noted that Dr Barry was not completely absent from clinical discussions on the board. Mr Meenan asked Dr Barry, was he playing an active role in the board of BTSB. Dr Barry said he was playing an active role, but that the Chief Executive Officer had taken over the issue of blood products and blood product safety.

Mr Meenan directed Dr Barry's attention to a meeting with the Department of Health which Dr Barry attended in his role as Chief Medical Consultant on the 22nd January 1986. The meeting discussed the use of products supplied from untested donors. Dr Barry said he did not recall this meeting. Dr Barry was directed to a letter from Dr Walsh of 25th June 1986, which informed him that seroconversions had taken place among haemophilia B patients. Dr Barry agreed that this was a devastating letter. Mr Meenan asked Dr Barry, where was he in June 1986. Dr Barry said the issue mentioned in the letter was being handled from Dublin. Mr Meenan said, was it not the case that urgent action should be taken, and Dr Barry agreed that it should be. Mr Meenan said should urgent action have been taken by him as Chief Medical Consultant? Dr Barry said, no. When asked by whom action should have been taken? Dr Barry said Dr Walsh was looking after fractionation matters from Dublin.

Mr Meenan said Dr Walsh had to act as there was no-one else on the medical side in Pelican House who could act. Dr Barry agreed that this was the case. Mr Meenan wanted to know, had Dr Walsh acted immediately? Dr Barry agreed this was the case. Mr Meenan put it to Dr Barry that Dr Walsh was himself in a position of having to issue a letter of recall, but had no authority to do so. Dr Barry said this appeared to be so.

Mr Meenan asked Dr Barry why was there was no mention of this devastating news at the following Board meeting? Mr Meenan asked Dr Barry, what was going on in the BTSB in 1986, as the matter did not appear to have been raised by the Board at any time. Dr Barry said he presumed that the matter was being dealt with by Dr Walsh.

Mr Meenan asked Dr Barry if, during his term of office as Chief Medical Consultant, the job was being done? Dr Barry said that the job was done to the best of his ability. He always understood, even when he returned to Cork, that some action would be taken and an appointment would be made. Dr Barry said he attended the Board meetings month after month on the understanding that an appointment would be made.

Mr Meenan put to Dr Walsh that the only access to the BTSB board the medical side of the organisation had was through the Chief Medical Consultant in the person of Dr Barry? Dr Barry disagreed with this assertion, saying that representation came through Mr Keyes. Mr Meenan put it to Dr Barry that the medical side of the BTSB was effectively denied access to the Board? Dr Barry agreed with this proposition. Mr Meenan asked: "In a sense weren't they just cut adrift? "They were cut adrift, yes. This was the policy, this was the way it went."

Dr Barry was briefly examined by counsel for the BTSB.

Mr Gerry Durcan S.C., for the Tribunal, examined Dr Terry Walsh, formerly of the BTSB. Mr Walsh outlined his medical qualifications and told the Tribunal he joined the BTSB in 1969 and retired from his post in April 1995. Dr Walsh told Mr Durcan he did not attend Board meetings in his early days with the BTSB, and had no contact with the National Haemophilia Services Co-ordinating Committee until 1987. Dr Walsh said his basic duty at the BTSB was selecting and immunising Anti-D programme donors. He looked after donor clinics and had overseen the use of cell separator machinery for plasmapheresis of patients.

Dr Walsh described his working relationship with Dr O'Riordan. Dr Walsh said Dr O'Riordan was the boss. He was the captain of the ship and all officers reported to Dr O'Riordan. He made the decisions, subject to approval by the Board. After his retirement, Dr O'Riordan's post was divided into two. Within three months of Dr O'Riordan's retirement, Dr Wilkinson, the former Assistant National Director, also retired. And Dr Barry was appointed Chief Medical Consultant. The retirement of Doctors O'Riordan and Wilkinson within a short period of each other increased Dr Walsh's workload, he said.

Dr Walsh told the Tribunal he reported to Dr Barry during Dr Barry's tenure as Chief Medical Consultant. The reporting took place on an informal basis. The day-to-day business for Pelican House was directed by Dr Walsh. Dr Walsh said that up until the retirement of Dr O'Riordan in 1985, he had no involvement in product selection with respect to blood products or concentrates. After the retirement of Dr O'Riordan he had some involvement in this activity.

Dr Walsh said that, as the particular person in charge of the plasmapheresis unit, he obtained plasma for the BTSB but did not decide what was done with it thereafter. Dr Walsh said that from 1988 onwards, he was the only consultant haematologist at Pelican House. He was also Chief Medical Consultant in this period. Dr Walsh said that, for a period prior to the appointment of Dr Joan Power, he was the only consultant haematologist in the country. The BTSB was under-staffed with respect to transfusion personnel, and demands were growing all the time, said Dr Walsh. An annual five per cent increase in blood issues was noted during this time.

Dr Walsh said he was also a member of a number of international committees. He was a member of the ISBT Committee on Automation. He was on the Committee of Experts on Blood Transfusion of the Council of Europe. He was on the select committee of the Council of Europe Automation and Quality Control, and he was engaged in a series of lectures for national blood services of Eastern European countries, following the break-up of the Eastern Block.

Dr Walsh said he had nothing whatever to do with the cryo programme; this was a technical matter that was dealt with by Mr Hanratty. He had no involvement in factor VIII imports. With respect to BTSB factor IX, Dr Walsh said this was a biochemical-technical matter. Dr Walsh said he was involved in implementing policy - he did not make the policy. He was not involved in virology testing. Dr Walsh said he did not test for various other conditions, such as Non-A, Non-B as no test was available for Non-A, Non-B. As to the risk arising from HIV, Dr Walsh said this matter was addressed by the National Director.

The ultimate responsibility for product safety it was with the Board itself, said Dr Walsh.

With respect to testing kits for Hepatitis C, Dr Walsh said he was a concerned person and was anxious that tests be introduced. With respect to self sufficiency, Dr Walsh said he became involved in self sufficiency when he was asked to produce plasma via plasmapheresis. Mr Durcan asked Dr Walsh, did he also write to positive donors following the introduction of HIV testing? Dr Walsh said that this was his responsibility from 1988 onwards. He noted in the documents that he had wrote to a positive donor in 1987. However this was not his area of responsibility as it was the responsibility of the chief medical consultant or the national director. Dr Walsh said he was not involved in any look-back programmes conducted by the BTSB.

Mr Durcan directed Dr Walsh to a document which seemed to indicate he had attended a course in 1977 on factor VIII and factor IX production. Dr Walsh said Prof. Temperley attended this meeting; he did not attend the meeting.

Mr Durcan directed Dr Walsh to a document within the book of documents concerning the use of factor VIII concentrate. The document of January 1981 is the deliberations of the Future Developments Committee of BTSB, Dr Walsh said that in discussing the HIV threat, all were conscious of the position regarding HIV.

The document indicated that the BTSB may be in a position to produce up to 80 per cent of the factor VIII required for the treatment of haemophilia A. Mr Durcan asked Dr Walsh would it be fair to suggest there was no medical or technical reason as to why 80 per cent of the needs of haemophilia A patients could not be met by locally produced factor VIII in June of 1981? Dr Walsh said, that is what the document states. In the final report of the Future Developments Committee, it is suggested that it is within the competence of the Board to produce up to 80 per cent of the requirement of haemophilia treatment by way of factor concentrate. Dr Walsh said that it may have been within the ability of the Board to make an intermediate product. While the document said it could be done, Dr Walsh did not agree that it was a practical proposition to produce that amount of intermediate factor VIII. However, he agreed that this was what was within the Future Developments Committee Report.

Mr Durcan put it to Dr Walsh that if it was generally desirable in 1981 to have a locally sourced supply of factor VIII, surely it was of absolute importance in 1984 that this be so? Dr Walsh said it would have taken a number of years to get any factor VIII product into production. He did not feel he could comment upon this aspect of the Tribunal's investigations, as he was not a treater or a fractionator.

Mr Durcan asked Dr Walsh was it not obvious by 1983 that such products were highly desirable, and it was highly desirable that such a product be made from local sources? Dr Walsh said that he was not aware of any national blood transfusion service which succeeded in making intermediate concentrate. Mr Durcan asked Dr Walsh, would such a product have led to a decrease in infection? Dr Walsh agreed that this was the case.

Mr Durcan asked Dr Walsh, who was responsible for the decision regarding the manufacture or non-manufacture of concentrates? Dr Walsh said the National Director on the Board. Dr Walsh said he did not know why the BTSB did not produce factor VIII. He did not know why the BTSB had engaged in a three-year experiment directed at producing its own factor VIII only to abandon it in 1984. He said that other laboratory people may be able to answer these questions. He also agreed that the Future Developments Committee, in a Report of 1984 which was signed by all members of the committee, stated that it was within the technical competence of the BTSB to produce 80 per cent of the state's factor VIII needs.

But, said Dr Walsh, such a project would have run into licensing difficulties and taken 3-4 years to realise. The fact that everyone signed up to it didn't mean that they agreed to the proposition. Dr Walsh said that everything was possible if enough resources, personnel and ability were present to make it possible.

Dr Walsh noted that the final suggestion of the Future Developments Committee was to engage in custom fractionation. Mr Durcan asked Dr Walsh why was there such a change of viewpoint. Dr Walsh said he didn't know who thought up the idea of custom fractionation. Dr Walsh said custom fractionation had become technically feasible, and seemed to be a sound concept, at the time. Dr Walsh said that, as regards custom fractionation, his task was to obtain plasma. Dr Walsh said the technology to custom fractionate in a practical way was not available until 1984. Plasma needs were only met when the cell separator machines became available and plasmapheresis became a practical proposition.

Mr Durcan asked Dr Walsh, was he familiar with the heparin project? Dr Walsh said this was Mr Hanratty's project, and had been discussed over a long period of time. Mr Durcan asked Dr Walsh, had it been discussed over the years? Dr Walsh said it had been discussed over a period. Mr Durcan asked Dr Walsh would he not regard a number of years to be a period. Dr Walsh said the results from the heparin project were satisfactory, however they were not proceeded with. A problem came to light regarding the gathering of blood in heparin. Dr Walsh said that the presence of heparin interfered with the red cells, making the product useless for blood transfusion. Dr Walsh said this may not be the only reason why the project was dropped, but he was not directly involved in the project itself. Dr Walsh said that the BTSB did not have any research and development facilities. Mr Hanratty was doing his ordinary and important every-day work in addition to doing the heparin project. Mr Durcan said this matter would have to be assessed in light of future expert evidence.

Mr Durcan directed Dr Walsh to the subject of fractionation by Travenol of BTSB cryo as a precursor to full-scale custom fractionation. Dr Walsh said he had no input into this arrangement with Travenol. He said, however, that the cryo was stockpiling and it was not being used, and there was no way of using it up. For this reason, perhaps, the idea of fractionating the cryo came into being.

Mr Durcan directed Dr Walsh to Prof. Temperley's letter of 17th December 1984, where Prof. Temperley informed the BTSB that in future, only heat treated factor VIII and factor IX should be used.

Mr Durcan asked Dr Walsh, did this letter not undermine the Future Development Committee Report? Dr Walsh said it was not known at this time that cryo could not be heat treated. He also said he did not know what BTSB policy was at this time. The cryo continued to be used. Mr Durcan asked Dr Walsh, did the BTSB have a view on what form of factor VIII should be used at this time? Dr Walsh said the policy makers were of the view that cryo was safe at the time. The Board's preference was for cryo.

Mr Durcan directed Dr Walsh to the Board's meeting with Cutter, at which Dr Walsh was present. Dr Walsh said his contribution at this time was to advise on plasma. In 1985 that it emerged that cryo could not be heat treated. Had this caused a problem for the Board? Dr Walsh said this did cause a problem - it increased the amount of plasma required for the custom fractionation.

In August, 1985 Dr Helena Daly informed Dr O'Riordan and Mr Hanratty that it was unethical to continue issuing unheat treated factor IX. Dr Walsh said he was not expert enough to offer an opinion on the advisability of heat treating factor IX. He was aware of the controversy with respect to heat treating factor IX and the risks of thrombogenecity.

Mr Durcan directed Dr Walsh to a letter from Prof. Temperley to BTSB. Mr Durcan asked Dr Walsh, was there any evaluation of the risk of making unheat treated products available? Dr Walsh said such matters were the clinical decision of the user; the user being the treating doctor. Dr Walsh said he did not know why the decision to continue using unheated factor IX it was made by the BTSB.

Mr Durcan asked Dr Walsh, was a decision taken by the BTSB to continue using unheat-treated products, or was it simply arrived at by default. Dr Walsh said he did not know - that it was the treating doctor's call as to what product he used

Mr Durcan drew Dr Walsh's attention to the transcript of a radio interview given by Dr Walsh on 28th August 1989. Dr Walsh stated in the interview that the BTSB was heat treating factor IX at this time. All factor IX was the heat treated said Dr Walsh in the interview. Mr Durcan put it that it was at best inaccurate to state that all factor concentrates from the BTSB were now being heat treated. Dr Walsh said that he had made a mistake in not making it clear that not all product from the BTSB was in fact heat treated, and asked a person with haemophilia B listening to the interview gave an impression that they may be getting heat treated product from the BTSB. Dr Walsh said people with haemophilia had their own sources of information, and were not dependent on the radio. Mr Durcan asked Dr Walsh if it was possible that a person listening to the radio, could construe that there was no risk attached to using BTSB product at this time, because they could assume that it was heat treated? Dr Walsh said he did not think people would believe what they heard on the radio.

Mr Durcan drew Dr Walsh's attention to Anti-D donor H, who tested positive for HIV, and the subsequent product recall which occurred in October 1985. Dr Walsh agreed that this was a very serious matter. Advice had been obtained from Dr Hoppe in Hamburg. Dr Hoppe gave advice on whether that the Anti-D process screened out the HIV virus. It would appear from Dr Hoppe's advices that the HIV virus is inactivated by the Anti-D process. Nevertheless it was decided that a full scale recall of potentially infected Anti-D would take place.

Mr Durcan asked Dr Walsh did the donor scare raise any questions with respect to BTSB factor IX and if it did was there cause for concern? Dr Walsh said he was concerned at all times. But, said Dr Walsh, he was so upset about the Anti-D situation that this was his main focus. With respect to factor IX products Dr Walsh said that this particular aspect of the HIV donor event was Dr O'Riordan's responsibility.

In November 1985 Dr Hoppe visited the BTSB. Mrs Cunningham took a note of the meeting, and recorded a suggestion that Dr Daly's direction that only heat treated product be used might be rescinded to allow the Board use cryo for a while as a temporary measure. Mr Durcan put it to Dr Walsh that the board had considered pushing cryo as it had a lot of cryo on hand at the time. He said he would not be surprised if that was the situation

Mr Durcan drew Dr Walsh's attention to a letter to Dr Egan of 23rd December 1985 written by Dr Walsh: "With regard to the Anti-D immunoglobulin, the recall of certain batches was a

precautionary measure due to a quality control problem. The Board's officers are satisfied, however, that there is no risk for recipients of the batches in question".

Mr Durcan asked Dr Walsh, was the quality control problem in question a reference to the fact that a donor had been found positive for HIV? Dr Walsh agreed that this was the case.

Mr Durcan put it to Dr Walsh that was it not something of an understatement to describe a HIV donor as a "quality control problem". Dr Walsh said that a subsequent letter from Dr Egan clearly illustrated that he knew the nature of the problem. Dr Walsh said that the issue of the HIV donor was discussed at a meeting of Dr O'Riordan and Dr Walsh of the Department of Health, it was decided that panic might ensue if knowledge of the potential infection became public. Mr Durcan put it to Dr Walsh that, if Prof. Egan had known of the problem, the nature of the problem being a positive HIV donor, there would have been no difficulty in describing the problem as such in the letter. Mr Durcan said, presumably the reason, to use the euphemism "quality control problem" was because Dr Egan did not know the nature of the problem.? Dr Walsh disagreed with this proposition. Dr Walsh said there was no reason for him not to tell Dr Egan the nature of the problem. Dr Walsh said the National Director instructed him to be very confidential in dealing with anything about HIV positive donors and that is why the issues was described as a quality control problem.