TRIBUNAL OF INQUIRY

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

PROCEEDINGS: MONDAY, 24th JULY 2000 - DAY 34

Mr Durcan, Counsel for the Tribunal, continued his cross-examination of Dr Terry Walsh, and referred Dr Walsh to the year 1986. When did Dr Walsh first became aware of the seroconversion of haemophilia B patients being treated with BTSB factor IX? Dr Walsh said he received a letter from Prof. Temperley in April of 1986 saying that a haemophilia B patient had seroconverted. Dr Walsh said he thought Prof. Temperley indicated in his letter that the problem could be related to newly heated products being used at that time.

Mr Durcan asked Dr Walsh, was this the first time he became aware of a seroconversion in haemophilia B patients? Dr Walsh said he couldn't say for definite, but that he had filled in the survey for the Council of Europe and indicated that a high percentage of haemophilia A and a small percentage of haemophilia B patients had seroconverted.

Mr Durcan asked Dr Walsh, was there any arrangement in place whereby the BTSB would be made aware of the seroconversions in people with haemophilia? Dr Walsh said no formal procedure existed. On this occasion Prof. Temperley wrote to the BTSB. Dr Walsh agreed that the news of seroconversions among haemophilia B patients was viewed with some alarm at the BTSB.

Mr Durcan asked Dr Walsh about product recall attempts in 1986. Dr Walsh said a meeting took place between representatives of the BTSB and the Department of Health. The meeting looked at the situation that had arisen since the introduction of HIV testing. It was decided that products prepared before HIV testing and subsequently issued should be withdrawn from the hospitals. Dr Walsh said he believed Dr Barry had called the meeting. Dr Barry was the chief medical consultant at this time.

Mr Durcan directed Dr Walsh to a letter from Dr Egan on 15th January 1986. Dr Egan asked the BTSB to replace untested and unheat-treated product and told Dr Walsh he would use only HTLV-III-screened cryo. He also asked that the BTSB issue guidelines for the continued use of factor concentrates. Mr Durcan asked Dr Walsh, did he recall a conversation with Dr Egan at the time? He said he did not recall any such conversation, but it may well have taken place.

Mr Durcan referred Dr Walsh to a report sheet dated January 1986. The report sheet was a record of product issued by the BTSB. The sheet recorded units of factor IX used in the Regional Hospital, Galway, and was in respect of a patient who had undergone treatment to his left knee; 1700 units of factor IX were infused on January 12th, 1986. The batch number was 90753. Dr Egan was the treating doctor. Dr Egan contacted Dr Walsh the following day.

Mr Durcan asked Dr Walsh would it be a reasonable inference to draw that Dr Egan became concerned because he found himself using untested and unheat-treated factor IX on a patient in Galway? Dr Walsh said he would have to ask Dr Egan about that. Mr Durcan said, the reason I am asking you, Dr Walsh, is because you had the conversation with him at the time. Therefore you were involved in this, and it is not a matter about which you don't know anything. Dr Walsh said he was not suggesting he knew nothing about the matter and he did not know what Mr Durcan was getting at. Mr Durcan said he would put it absolutely clearly. Dr Egan used the factor IX on the 12th. He contacted Dr Walsh on the 13th and wrote to Dr Walsh on the 15th, and all this together suggested he was concerned. These transactions would, suggested Mr Durcan, indicate some concern on the part of Dr Egan.

Mr Durcan referred Dr Walsh to a memo from Mrs Cunningham. The memo lists a number of BTSB factor IX batches that were neither heat treated, nor drawn from HTLV-III tested donors. One of the batches was 90753 which later proved infective for HIV.

Mr Durcan asked Dr Walsh, could it be taken from the above that considerable concern was being expressed by treating doctors about the use of untested and unheat-treated product? Dr Walsh agreed that this was so. He also agreed that the concern of the treating doctors was such that the BTSB and the Department of Health met to consider the events.

Senior personnel from the BTSB and the Department of Health met to consider a product recall list put together by Dr Walsh. Mr Durcan put it to Dr Walsh that Department of Health official Dr James Walsh suggested the withdrawal of products prepared before testing had been introduced. Dr Walsh said his draft letter contained proposals for withdrawal of various products, with which Dr James Walsh agreed. Dr Walsh said he had drafted the withdrawal letter before the meeting.

Mr Durcan directed Dr Walsh to a handwritten memo of the meeting between the BTSB and the Department of Health. The memo suggests that a decision was made at the meeting to stop issuing non-heat-treated BTSB factor IX and that commercial products should be used if necessary. With regard to stock already in hospitals the memo says “TW’s note covers this.”

Mr Durcan then referred Dr Walsh to the recall notice that he issued to hospitals in from Pelican House. The recall notice described products by testing status. The recall letter said all cryo prior to 1986 was untested and should now be returned. Factor VIII in issue was now heat treated and any non-heat treated factor VIII should be returned to the manufacturer. Heat-treated commercial Factor IX concentrate is now available. It is hoped that heat-treated Factor IX prepared by the BTSB will shortly be available.

Dr Walsh confirmed that the letter was drafted by him. Dr Walsh said he was acting under the instruction of Dr Barry. Mr Durcan asked Dr Walsh, did Dr Barry tell him what to put in the letter? Dr Walsh said that Dr Barry had discussed the content with him.

Dr Walsh said the purpose of the letter was to give advice and information on the status of blood products in relation to HTLV-III testing, and to bring about the withdrawal of products insofar as that was practical. Mr Durcan asked Dr Walsh, was it the intention of the notice to withdraw untested products? Dr Walsh said the intention was to withdraw untested products where feasible.

Mr Durcan asked Dr Walsh, was it the case that the notice was not designed, or did not have the intention of bringing about a withdrawal of non-heat treated products? Dr Walsh said the notice was intended and clearly advised in a strong sense, that heat-treated factor IX is available. Dr Walsh said he felt people would understand that. Mr Durcan wanted to know was the notice intended to bring about withdrawal of non-heat treated products? Dr Walsh said that the notice was not intended to bring about a recall of unheat-treated products. Mr Durcan asked if the focus of the letter was the withdrawal of untested product, why was unheated product, with respect to factor VIII, included in the letter?

Mr Durcan put it to Dr Walsh that heat-treated factor IX from the BTSB had been available and had been issued to St. James' Hospital for some three months prior to this. Dr Walsh said he was aware of that, and that factor IX issued to St. James was being evaluated for safety at the time. Dr Walsh said that the letter amounted to advice only, that it was up to clinicians to make the decision whether or not to use treated or unheat-treated factor IX. Dr Walsh said he was acting under the directions of two very experienced people who were above him in Pelican House, and they were there to make the decisions.

Mr Durcan put it to Dr Walsh that the entire meeting saw the draft letter, and they all agreed that the letter was adequate. Dr Walsh agreed with this proposition. Mr Durcan wanted to know, was it therefore decided not to withdraw non-heat treated factor IX? Dr Walsh said that it was not up to the meeting to dictate what the clinicians would use. Referring back to the handwritten note, Mr Durcan asked Dr Walsh, was it not the consensus of the meeting that heat treated commercial factor IX should be used pending the availability of BTSB heat-treated factor IX. Dr Walsh said it was up to the doctors to decide which product to use once the relevant information and advice had been put to them. Mr Durcan put it to Dr Walsh that the notice should have said, use commercial heat treated product pending the availability of heat-treated BTSB factor IX. Dr Walsh maintained that the notice did say that, in that it noted that heat-treated commercial factor IX was now available. Mr Durcan put it to Dr Walsh that those words were not used, and if the notice was to reflect the decision of the meeting it should have said use commercial heat-treated factor IX pending the availability of BTSB heat-treated factor IX. Dr Walsh said there was only a limited amount of things he could put in the notice. To him it was quite clear that the intention was that heat-treated product was available and, if there were any doubts, the BTSB was proposing the use of commercial product.

Mr Durcan put it to Dr Walsh that the logical thing the BTSB to have done would have been to say, use the safer product, ie. commercial heat treated factor IX, and send back the less safe product, ie. unheat treated, untested BTSB factor IX. Dr Walsh said the debate was not clear-cut at the time, that he was being put in a difficult position. He was being asked to adopt one side or the other. Mr Durcan put it to Dr Walsh that the reason he was asking him the questions was that he was part of the decision-making process, and he was the person who issued the notice under

his own name. Dr Walsh said he issued the notice to oblige Dr Barry and help him in his work-load at the time. Dr Walsh said he wasn't the chief medical consultant, he was only doing some work for Dr Barry.

Mr Durcan asked Dr Walsh, was he satisfied that the notice was adequate for what it intended to do? Dr Walsh said it was adequate at the time. Mr Durcan asked Dr Walsh, could the notice have been more happily worded? Dr Walsh said he would concede that the notice re: heat treatment might have been more positively worded. Dr Walsh said the notice was not intended to bring about a recall of the heat treated products.

Mr Durcan directed Dr Walsh to a letter from Dr Walsh to Dr Egan of 15th January 1986. The letter informs Dr Egan that heat treated factor IX from Travenol had been in issue since January, and that BTSB heat treated factor IX would shortly be available. The letter does not say or instruct Dr Egan to stop using BTSB factor IX.. Dr Walsh said it was not his responsibility to tell Dr Egan what to use.

Mr Durcan asked Dr Walsh, did anybody at the meeting of the 22nd January 1986 take responsibility to say to stop using BTSB factor IX? Dr Walsh said it was not his responsibility at the time it was up to the chief medical consultant or the deputy national director. Dr Walsh said his reply to Dr Egan reflected what he believed to be the policy of the Board at the time. He also said that they had just emerged from a period of dictation and that there was a change in leadership at the Board that took a bit of time getting used to. This was the first major decision that the BTSB had had to make since the retirement of Dr O'Riordan. Dr Walsh said that the person who had the power to make the decision at that time was the chief medical consultant. Dr Walsh said that the Chief Medical Consultant was clearly involved in these events as he had written to the Department of Health, and the Department of Health had written to him.

Dr Walsh was referred to a letter from the Department of Health of 31st January 1986, where Mr Flanagan instructed the BTSB to withdraw untested stocks. Dr Walsh said it was impossible to comply with the Department's instruction. Nobody wrote back to the Department to tell them that this was impossible. Dr Walsh said the Department officials were part of the decision-making process, and they should have told the Minister the state of affairs that existed at the time.

As a consequence of not recalling BTSB factor IX batch 90753 it remained in use. On 20th February 1986, it was administered to a man who subsequently seroconverted. He and tested positive for HIV in May 1986.

Mr Durcan referred Dr Walsh to a Council of Europe report completed by him in April 1986. It was noted, among other things, that there were 61 haemophilia B patients, 17 had been tested and four were positive for HIV. Mr Durcan asked Dr Walsh, did the presence of four HIV patients among haemophilia B set off any alarm bells with him? Dr Walsh said in April 1986 he received a letter from Prof Temperley informing him of seroconversions among haemophilia B patients. A further product recall notice was issued in June of 1986.

Mr Durcan put it to Dr Walsh that it would appear, even prior to the notice issued in January of 1986, that certain product had been returned to the BTSB and had been heat treated and reissued. Dr Walsh said he did not know why this had happened. Mr Durcan said, would this not indicate that it would have been possible in the month of January, to get all the product back from the hospitals into the BTSB, and at least heat treat it, making it somewhat safer.

Mr Durcan said that a synopsis of the events upon which Dr Walsh had just answered questions would be that Drogheda sent back product and got it heat treated. Dr Egan wrote to, or telephoned, BTSB asking for direction. There was no overall plan or policy as to what was to be done. Mr Durcan said, if a particular hospital was proactive and did something it brought about this type of result, as happened with Drogheda, product was sent back and heat treated. If a hospital wasn't proactive, nothing happened. Dr Walsh agreed that this was a correct summary.

Mr Durcan put it to Dr Walsh that since that the product in question issued from the BTSB, did he not think the organisation should have a policy, or at least guidelines, in respect of its use? Dr Walsh agreed that this should have been the case. Dr Walsh said that the guidelines gradually came into being. Mr Durcan said this was the problem, that while the gradual process was taking place, the product was out there being used by people. Dr Walsh said this was the case but this was not his responsibility at the time. Asked whose responsibility it was, Dr Walsh said it was the Board's responsibility ultimately, and it was the National Director's responsibility.

Mr Durcan put it to Dr Walsh that the situation that prevailed at the time, was that at best treatment, or the return of product, was haphazard, particularly with respect to factor IX. It depended on whether or not a hospital took an active or non-active approach to the situation. Dr Walsh agreed that this was the case.

Mr Durcan put it to Dr Walsh that this was an extraordinarily unsatisfactory situation. Dr Walsh agreed that, in hindsight, this was the case.

Mr Durcan put it to Dr Walsh that, even at the time, if someone had addressed the situation it would have been seen to be extraordinarily unsatisfactory. Dr Walsh said people were doing their best to meet the situation as they saw it. Mr Durcan asked Dr Walsh if the product from Drogheda could be returned and heat treated, could this not have been done with the rest? Dr Walsh said he could not answer that question.

Mr Durcan said that since heat-treated BTSB product issued to St. James' Hospital since October 1985 could this not have been done for other hospitals? It would appear the reason other hospitals were not issued with heat treated product, and non-heat treated product recalled, was that they were not as proactive as Drogheda, and there were no guidelines to instruct them as to what should happen. Dr Walsh said the guidelines were there. Heat treated product should be made available, but he believed that certain clinicians wished to have their independence and would not be instructed as to what product they should use.

Mr Durcan put it to Dr Walsh that, ultimately, this was a BTSB product, and as such was there not an obligation on the BTSB to ensure that it should be put into a condition that was as safe as

possible? Dr Walsh agreed that this was the case. He also agreed that there was no policy as to how that was to be brought about.

PROCEEDINGS: TUESDAY, 25th JULY 2000 - DAY 35

Gerry Durcan S.C. continued his cross-examination of Dr Terry Walsh, formerly of the BTSB.

Mr Durcan referred Dr Walsh to a management meeting of the 25th March 1986. The Executive Consultant, Mr Keyes, informed the meeting that the cost to the Board of the return of non-heated products, together with stock held of dried cryoprecipitate, would result in a deficit to the Board of approximately £80,000, which would have to be written off in the 1985 accounts.

Mr Durcan asked Dr Walsh to clarify the reference to unheated products. Dr Walsh said this was a combination of non-tested products and unheated products which were returned to the Board, and credit had been given for them. Mr Durcan asked, was it not the case that the recall of January 1986 was neither intended, nor did it operate as a product recall of un-heated products? Dr Walsh said that was his understanding of the documents at the time.

Mr Durcan referred Dr Walsh to a minute of the BTSB Board meeting of 26th March 1986, wherein it deals with HTLV-III testing and says, products not heat-treated, following direction of the Minister, have been withdrawn. The minute goes on to deal with the value of these products.

Mr Durcan asked Dr Walsh, was there any direction from the Minister to withdraw non-heat treated products that he was aware of? Dr Walsh said he did not recall seeing any such direction. Mr Durcan put it to Dr Walsh that, insofar as the Board minutes record Ministerial direction on unheated products, they were talking about something that hadn't happened. Dr Walsh said that some confusion seemed to exist between testing and non-heat treatment.

Mr Durcan said it would appear that the confusion resulted in the words “testing” and “heating” being used interchangeably. It would appear, therefore, that the Board was under the impression that a withdrawal of *unheated* products had taken place, whereas in fact the Ministerial direction referred to *untested* products. Dr Walsh said he was not on the Board of the BTSB at the time; Dr Barry was on the Board and Dr Barry should have clarified the position for the Board.

Mr Durcan referred Dr Walsh to a letter from Prof. Temperley of 24th April 1986, concerning the HIV seroconversion of haemophilia B patients. Dr Walsh said he got in touch with Prof. Temperley, and that investigations into the seroconversions would take place on 28th April 1986. It is noted in Mr Cann's diary that Prof. Temperley was in attendance at Pelican House. Dr Walsh said he may have seen him at the time. Dr Walsh said it was his impression that Prof. Temperley was of the opinion that the newly heat-treated products were the source of the HIV seroconversion.

In May 1986 Dr Walsh attended the Council of Europe Committee of Experts meeting at Berne, Switzerland. Solvent/detergent technique was discussed at this meeting. Mr Durcan asked Dr Walsh, was this the first time he had come across the solvent/detergent technique of viral inactivation. Dr Walsh said he could not recall if it was the first time. Dr Walsh said he was a relative lay person with respect to viral inactivation, but the solvent/detergent technique was of interest to him on the basis that a solvent and a detergent could be added to a blood product.

Mr Durcan referred Dr Walsh to an inter-office memo from him to the chief medical consultant Dr Barry and the executive consultant Mr Keyes. The memo contained a note of a conversation that Dr Walsh had had with Prof. Temperley, where the professor points out that the most likely source of infection, with respect to the five, possibly six, haemophilia B patients who had antibodies to HTLV-III, was BTSB non-heat treated factor IX.. Dr Walsh said that, to be on the safe side, he immediately sent a note to hospitals to say that non-heat treated products should not be used, and any product still remaining in the hospital should be returned. Mr Durcan said that, when Dr Walsh referred to "safe side", wasn't it absolutely imperative that there should be a recall at this stage, because it had now become clear that BTSB product in all probability was the source of infection?

Mr Durcan referred Dr Walsh to the formal withdrawal notice of the same day, 25th June 1986. Mr Durcan put it to Dr Walsh that this was not just advice, but was in fact a firm instruction to withdraw the product. Dr Walsh agreed that this was the case. Given that this was the case, said Mr Durcan, why did the BTSB not engage the anti-D mechanism of calling hospitals and telling them on the telephone to withdraw the non-heat treated product from circulation? Dr Walsh said that in his view there was a very limited likelihood that any factor IX unheat treated remained in circulation. Mr Durcan asked Dr Walsh was he saying that the risk in June 1986 was less than that in October 1985? Dr Walsh said he was taking the initiative in this particular recall. He consulted with Dr Barry the next day, as urgent action was required.

Mr Durcan referred Dr Walsh to a memorandum of a meeting that took place on 1st July 1986. The memorandum notes that Dr Walsh is on holiday, however he is part of a Committee set up to look at the question of factor IX needs within the BTSB. The memo notes that Mr Keating has just returned from Paris, where he attended a conference on AIDS. Mr Keating returns with the news that 60 degrees by 72 hours is the appropriate heat treating protocol for factor IX. It is also noted that an agreement has come into existence between Dr Walsh and Prof. Temperley to use re-heated factor IX, and that in future only tested factor IX would be used. Mr Durcan asked Dr Walsh, did this imply that the BTSB and Prof. Temperley were prepared to use factor IX from non-tested donations as late as July 1986? Dr Walsh said this was a question for Prof. Temperley.

On 26th August 1986, Prof. Temperley contacted Dr Walsh setting out the dates of seroconversions among haemophilia B patients. The document included details of late seroconversion of a patient in Cork, referring to a late positive test result in August 1986. Mr Durcan asked Dr Walsh, was he surprised at such a late seroconversion? This particular person had a negative test in March and tested positive in August. The likelihood, therefore, was that the BTSB product which caused the infection, went into circulation sometime in 1986, said Mr Durcan. Did that cause concern? Dr Walsh said he did not particularly pick up on this matter.

Mr Meenan, Counsel for Dr Walsh, then intervened and pointed out that the witness had done an analysis of the various seroconversions, which analysis was contained at page 120 of the documents. Dr Walsh's analysis indicates that he knew that the BTSB product was the likely source of infection. Dr Walsh's own note shows that he analysed Prof. Temperley's letter. Mr Durcan asked, were you then concerned about the late seroconversion? Dr Walsh said he was concerned. Mr Durcan asked Dr Walsh, given that the BTSB product was now clearly the source

of infection, did any action take place on the part of the BTSB? Dr Walsh said there was no evidence of any action being taken by the BTSB at this time. Mr Durcan asked Dr Walsh, why was no action taken? Dr Walsh said he could not answer that question.

Mr Durcan asked Dr Walsh, did the BTSB tell the patients that they had tested positive due to their treatment from BTSB product? Mr Durcan asked Dr Walsh, "Do you know whether the patients involved were told what had happened to them and what had caused their infection?" Dr Walsh said: "I have no knowledge of that; I wasn't treater." Dr Walsh said he referred the matter to the chief medical consultant and the chief executive at the time, and did not know if any further action took place. Dr Walsh said that the patients were under the care of the Haemophilia Treatment Centre and Prof. Temperley.

Mr Durcan asked, was it the case that the National Drugs Advisory Board were not told of the infection, and neither were the patients told of the infections? Dr Walsh said the BTSB took no steps to tell them because, in the situation where the treating doctor is prescribing a particular product, and the patient knows which product they are on, he was sure the patient would be informed by the treating doctors what products they were receiving and where the products came from, and what the products were likely to have infected them with. Dr Walsh said there was no reason why the treating doctors could not have told the infected persons of their position. Mr Durcan asked, were any steps taken by the BTSB to ensure that the treating doctors had told the patients? Dr Walsh said that was a matter for the chief medical consultant.

Dr Walsh was referred to a letter from Dr Egan in Galway, where Dr Egan complained that a third party had told him of the problems concerning the seroconversion of haemophilia B patients. Dr Walsh said he believed that he had informed Prof. Egan in June of the problem. He also believed that he had communicated these difficulties to him again in August. Dr Walsh said that Prof. Temperley was the proper person to tell Prof. Egan of the problems with factor IX. Mr Durcan said Prof. Egan seemed to think that this was a job for the BTSB. In reply to Prof. Egan, Dr Walsh said he thought he had told Prof. Egan of the factor IX problems on a visit to Galway. If not, he had intended to, and apologised to Prof. Egan for not having so told him.

Mr Durcan then referred Dr Walsh to a visit from a delegation from BPL, Elstree. The Elstree delegation was seeking to source Anti-D, and the purpose of the visit was to discuss the fractionation of Irish plasma. BPL was not in a position to fractionate Irish plasma until the end of December 1988. The visit took place on 29th October 1986, when it was not possible for Elstree to offer fractionation facilities to the BTSB for factor VIII. It was possible that factor IX could be obtained from Elstree. This factor IX was heated to 80 degrees Centigrade for 72 hours. Dr Walsh said this was a new thing at the time; it was a different heat treating protocol.

In a memo of a conversation, Dr Walsh talked to Prof. Temperley about factor IX from Elstree. The memo records a conversation where Prof. Temperley says the price being asked for the Elstree factor IX was too high. It was noted that the Elstree product had been in use for 18 months, and during that time no case of Non-A, Non-B Hepatitis had been recorded. Mr Durcan put it to Dr Walsh that, it would appear from the documents that the Elstree product, with respect to factor IX, was available, so it was not a supply problem that prevented the BTSB taking factor

IX from Elstree. Dr Walsh agreed with this proposition. With respect to its viral inactivation record, it appeared to be safe? Dr Walsh agreed that this was the case. So the only difficulty, therefore, would appear to be the price. Dr Walsh said there may have been other difficulties with Elstree factor IX, but he could not say what they were. The price in question was 20p per international unit.

Mr Durcan referred Dr Walsh to an interview of the 4th January 1987, in the *Sunday Tribune.* The article quoting Dr Walsh, says there have been no new AIDS cases in Irish haemophiliacs. All the precautions were working and the BTSB was protecting the blood supply for transfusions. Dr Walsh is quoted as saying that no Irish person ever got AIDS from a transfusion, and they won't either. This article, published in 1987, does not refer to the HIV infection of haemophilia B patients in 1986.

Dr Walsh was also referred to the Armour A28306, and said he had formed the view that A28306 had been a source of infection with HIV of a haemophilia A patient on 21st February 1986.

Mr Durcan referred Dr Walsh to the Armour contract. On 14th June 1988 Prof. Temperley wrote a letter addressed to Mr Keyes, wherein he states that a balance had to be drawn between the cost of product and infection dangers associated with blood products. Prof. Temperley outlined a treatment regime for previously untreated patients in his letter. This thrust of Professor Temperley's letter is to assure the board and Armour that, if the company continues with heat treated product for the BTSB, such product will not be used in the treatment of PUPs.

Dr Walsh said at this time he wanted to switch to solvent/detergent or monoclonal product as quickly as possible. He was present at the Board meeting at which the letter was discussed, and had talked to Prof. Temperley prior to Prof. Temperley writing the letter. It would appear from the letter that a safer product was available to the BTSB, but for financial considerations a choice was made to go with the Armour product. This choice was likely to be driven by financial consideration. Dr Walsh said he did not disagree with this. The only other consideration was continuity of supply. Factor IX was not mentioned in the letter. As for Haemate P, designated for PUPs, the Board did not supply this product. Further, the Armour contract would allow the Board to source its own factor IX., said Dr Walsh.

PROCEEDINGS: WEDNESDAY, 26th JULY 2000 - DAY 36

John Trainor S.C. cross-examined Dr Walsh of the BTSB.

Mr Trainor directed Dr Walsh to a memo by Mr Cann of meeting between a deputation from BPL, Elstree and senior BTSB personnel at Pelican House on 29th October, 1986. The memo notes that heat treatment for 72 hours at 80 degrees Centigrade is effective for Non-A, Non-B Hepatitis. Mr Trainor noted that at this time, Dr Barry was the chief medical consultant and Dr Walsh was consultant haematologist.

Mr Trainor asked Dr Walsh, was it the case that both Dr Walsh and Dr Barry advised Mr Keyes. Dr Walsh said Mr Keyes was primarily advised by Dr Barry, however he agreed that he (Dr Walsh) was keeping up with medical matters and would acquaint himself with recent medical developments.

Mr Trainor referred Dr Walsh to an article by Schipp and Manucci in the *New England Journal of Medicine* of April 1987. The article notes that 60 degrees Centigrade for 72 hours applied to factor concentrates leaves the product highly infectious for Non-A, Non-B Hepatitis.

Mr Trainor asked Dr Walsh, was it the case that the Travenol contract which commenced in July 1985, and ran for approximately two years until December 1987, when contract fractionation was taken over by Armour, utilised the 60 degrees by 72 hours heat treatment protocol? This was agreed by Dr Walsh.

Mr Trainor noted that for a general run of the Armour contract, factor IX was being returned as an unfinished paste from to the BTSB and processed at Pelican House. Dr Walsh agreed that this was the case. Mr Trainor put it to Dr Walsh that the first date upon which factor IX was returned for processing by the Board was mid May of 1988.

From May 1988 factor IX was returned from Armour to Pelican House for processing. Dr Walsh agreed that from the start of 1988, when he was appointed as chief medical consultant, he was responsible for medical aspects of product safety within the BTSB. Mr Trainor put it to Dr Walsh that as chief medical consultant it was his responsibility to take whatever executive steps were necessary to ensure safety, and to report to Mr Keyes and the Board on safety issues with regard to the Board's product? Dr Walsh said it was part of his job to see that the product was available and standards were observed. Mr Trainor put it to Dr Walsh that, among these standards, was ensuring the product was safe.

Dr Walsh agreed that the Travenol heat treatment protocol was 60 degrees Centigrade for 72 hours. This information is contained in a letter from Dr Walsh to Prof. Temperley dated 23rd January 1987.

Mr Trainor referred Dr Walsh to a meeting between Travenol and the BTSB on 2nd April 1987. The meeting was attended by Dr Walsh among others, and the heat treatment of factor IX was discussed. Travenol told the BTSB personnel present at the meeting that the heat treatment protocol then employed for factor IX was 72degrees centigrade for 96 hours. Dr Walsh said he

recalled the meeting, but his recollection of the meeting was that it was a discussion over Travenol's failure to achieve agreed yields. He did not recall the discussion on heat treatment of factor IX.

With regard to the Armour contract Dr Walsh said it was his understanding that factor IX paste would be returned from Armour and would be heat treated by the BTSB using the Travenol's heat-treatment protocol. Dr Walsh said he was generally aware of this arrangement, but was not aware of the technical details attaching to it.

Mr Trainor referred Dr Walsh to a record of heat-treatment employed by the BTSB in relation to factor IX from August 1985 onwards. The information was recorded by Mrs Cunningham and a number of heat treatment protocols are noted.. The BTSB appears to have settled on heat-treatment of 60.6 degrees Centigrade for 152 hours in air and that heat treatment protocol was applied from February 1988. Mr Trainor said he understood from Dr Walsh's answers that when Mrs Cunningham heat-treated the product at 60.6 degrees for 152 hours she did not do so pursuant to any instruction from him as chief medical consultant. Dr Walsh said this was correct. He said he did not specifically direct Mrs Cunningham in which heat treatment to use. Dr Walsh said it was his understanding that the product was being heat treated to the Travenol protocol. He did not direct Miss Cunningham in her work. He assumed the product was being treated to the correct protocol.

Mr Trainor put it to Dr Walsh that he was the person, the chief medical consultant, within the Board with specific responsibility for product safety. Dr Walsh said it was his responsibility to advise the Board to the best of his ability, and the Board could take his advice or from other suitable sources.

Mr Trainor put it to Dr Walsh that, as chief medical consultant, he bore the responsibility of ensuring that the products of the Board were safe. Dr Walsh said he accepted that he had responsibility to advise the Board on particular aspects of product safety but, he said, other members of the Board with a medical background were also in a position to offer advice. Dr Walsh said it was his duty to advise the Board, but it was the Board which carried ultimate responsibility.

Mr Trainor put it to Dr Walsh that in the Spring of 1987, Dr Walsh knew that 80 degrees Centigrade for 72 hours would virally inactivate factor IX against Non-A, Non-B and HIV as far as anybody could tell at the time. Dr Walsh agreed that this was the case.

Mr Trainor asked Dr Walsh, did he advise the Board that the BTSB should take steps to virally inactivate factor IX it was producing, by heating it to 80 degrees Centigrade for 72 hours? Dr Walsh said he did not specifically advise the Board along these lines. He was advising the Board around this time of other options that were becoming available. Dr Walsh said he could not specifically remember advising the Board to heat treat factor IX to 80 degrees for 72 hours. Dr Walsh also agreed that he did not advise Miss Cunningham to utilise 80 degrees for 72 hours to virally inactivate BTSB factor IX. Dr Walsh said his concern was to supply a product that was acceptable to the user, the user being the treating doctor. Dr Walsh said if the user had requested 80 degrees for 72 hours, that would have been given consideration.

Mr Trainor said, as the person responsible for ensuring product safety, knowing that 80 degrees Centigrade for 72 hours was a safe protocol, was it not the case that Dr Walsh had a duty to advise the Board of that fact, and instruct Mrs Cunningham to implement it? Dr Walsh said he did not know the specific details of the viral inactivation heat treatment protocol utilised by the BTSB with respect to factor IX. Mr Trainor said the point of the foregoing was that, among the factor IX produced, that this Tribunal has heard about under Mrs Cunningham's system, and under Dr Walsh's direction as chief medical consultant, batch no. 9885 issued in July of 1989 was responsible for infecting with Hepatitis C, at least four people, three of whom were children. He asked Dr Walsh, was he aware of this.

In this regard, Mr Trainor referred to the evidence of Dr Lawlor given on Day 18, (July 8th, question 77) when Dr Lawlor spoke at some length about the probabilities that batch 9885, made from Armour plasma, processed by Pelican House using the Travenol method, was responsible for the infection of at least four people. Dr Lawlor said that in all probability batch 9885 was responsible for the Hepatitis C infection of those concerned. Infection was due to the fact that insufficient heat-treatment to inactivate Non-A, Non-B, (Hepatitis C) was employed. Dr Walsh said he had only become aware of these infections since the Tribunal started.

Mr Trainor put it to Dr Walsh that, had the batch been treated to 80 degrees Centigrade for 72 hours, the infections would not have occurred, and those children who had become infected would not have done so? Dr Walsh said the heat treatment protocols being applied were those acceptable at the particular time. Dr Walsh agreed that he had left it to others, namely Ms Cunningham, to find out what heat treatment protocol should be used.

Mr Trainor put it to Dr Walsh that the one heat-treatment protocol that Dr Walsh knew to be safe, was not advised to Ms Cunningham by him, and insofar as it was suggested that batch 9885, was heated by a BTSB heat treatment method and was not virally inactivated for NANB, the buck stopped with Dr Walsh? Dr Walsh said he accepted this to some extent. But, the raw material for the product was not ALT tested, and it wasn't Hepatitis C tested. Dr Walsh said he urged the Department of Health to adopt these technologies. Dr Walsh said he was not ultimately responsible for the choice of any product. It was his duty to advise the board and he had done so.

Mr Trainor directed Dr Walsh to the HIV infection of persons with Haemophilia A by Armour batch A28306.

Mr Trainor put it to Dr Walsh that by the Spring of 1987 a fair measure of scepticism arose in dealings with Armour, particularly in relation to blood products. Dr Walsh agreed with this proposition. In January 1987 the Board opened negotiations with Armour as an alternative contract fractionator for its plasma. Mr Trainor put it to Dr Walsh, was it not extraordinary that the BTSB would get into a contract fractionation arrangement with Armour, given the fact that it had just been involved in a recall of blood products?

Dr Walsh said he, in the company of others from the BTSB, travelled to the plant in Germany owned by Armour, and were satisfied with the facilities under which the plasma gathered in Ireland would be contract fractionated by the company. The BTSB at this stage was dissatisfied

with the Travenol contract fractionation arrangement on the basis of poor yield. Dr Walsh said Travenol was not obtaining from the BTSB's plasma what it had promised it could obtain.

The BTSB entered into its contract fractionation arrangements with Armour in late 1987. In January 1988 Armour sought an indemnity from the BTSB regarding to the product it proposed to make for the BTSB, and which it would be heat treated at 68 degrees for 72 hours. The indemnity meant that the BTSB was accepting full responsibility for any problem that might arise using the product. Dr Walsh agreed that this was the effect of the indemnity, however he said that the only way that the BTSB could possibly hope to achieve self sufficiency at this time was by opting for the heat-treated Armour product rather than the safer but more expensive monoclonal product. Dr Walsh agreed that the BTSB would strike a balance between product safety and the yield being achieved by contract fractionation.

With respect to the indemnity, Dr Walsh said the request by Armour for an indemnity caused concern, and also aroused interest in the new product. Mr Trainor referred to the product warning literature to accompany Armour BTSB factor VIII. The product warning literature indicated that it was known that concentrate prepared by Armour was not virally inactivated for Non-A, Non-B Hepatitis. Dr Walsh said that the issue of the indemnity was discussed with the treaters.

Mr Trainor then referred Dr Walsh to letter by Prof. Temperley on June 14th 1988. In the letter addressed to Mr Keyes and to the Board of the BTSB, Prof. Temperley says that a balance must be drawn between the cost of product and the risk of infection associated with blood products.

Dr Walsh said at this time he wanted to switch to monoclonal or solvent detergent products as quickly as possible. Dr Walsh said he was present when the letter was discussed at the BTSB board meeting. He agreed with Mr Trainor's suggestion that it would seem to be the case that while safer products were available it was decided to go with the Armour product. Another consideration would have been continuity of supply, said Dr Walsh.

The Armour contract employed 68 degrees centigrade by 72 hours for its heat treatment protocol. Mr Trainor asked Dr Walsh was the 80 degrees by 72 hours employed by BPL ever considered in relation to the Armour contract. Dr Walsh said this was not considered as it was not the Armour protocol, it may have led to licensing difficulties and it would have reduced the yield.

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Mr John Trainor, SC, for the I.H.S. continued his cross examination of Dr Walsh.

Mr Trainor referred Dr Walsh to the issue of final batch testing of batch number 90753. He noted that all batches of this vial had been issued by the 29th October 1985. Mr Trainor asked Dr Walsh, was it the case that a test was carried out on a reserve vial following the issue of the batch? Dr Walsh said that while he did not see anything wrong with the testing of a residual vial from a batch which had been fully issued, it would not be very helpful for antibody detection.

Mr Trainor then referred Dr Walsh to a meeting between Dr Walsh and Prof. Temperley on 25th June 1986, where they discussed the issue of non-heat treated BTSB factor IX. It was agreed the BTSB non-heat treated factor IX would not now be used. In a memo of the meeting between Dr Walsh and Prof. Temperley, it is noted that, "With regard to the future, Prof. Temperley has indicated that he will use heat-treated material already prepared." Mr Trainor asked Dr Walsh, was it the case that Prof. Temperley had therefore agreed to use heat-treated material, albeit that it wasn't tested?

Mr Trainor then directed Dr Walsh to his recall notice of 25th June 1986, where non-heat treated material was recalled by the BTSB, and the instruction issued that non-heat treated material should not be used. At this point, Mr Trainor directed Dr Walsh to a meeting which occurred following the return of Mr Keating from Paris, whereupon it was decided that the BTSB heat-treatment protocol would be changed to 60 degrees for 72 hours.

Mr Trainor then referred Dr Walsh to Ms. Cunningham's note, where various BTSB heat treating protocols are recorded with respect to factor IX. The note records the fact that from September 1985 to June 1986, all batches of BTSB factor IX were heated for 20 hours at 60 degrees centigrade. From 1st July 1986 to September 1986, BTSB factor IX was heated for 72 hours at 60 degrees Centigrade.

Mr Trainor then referred back to Mr Keating's note of the Paris International AIDS Conference, where Mr Keating recorded that HTLV-III could not be completely inactivated in lyophilised material when heat treated at 60 degrees centigrade for 20 hours. Mr Keating related this news to his colleagues in the BTSB when the factor IX situation was discussed. Although Dr Walsh was on holidays for this meeting, he was nevertheless included on the Committee to produce a policy for the BTSB with regards to the factor IX. Mr Trainor put it to Dr Walsh that in June of 1986, the BTSB was in possession of the knowledge that experts at a major conference had expressed the view that 20 hours by 60 degrees centigrade would not inactivate HIV. Dr Walsh agreed that this was the case. That being so, said Mr Trainor, was it not therefore the case that the BTSB in July of 1986, knew that 60 degrees for 20 hours would not virally inactivate its factor IX for HIV if the donor pools had been exposed to an infected donor?

Mr Trainor said that, given that this was the case, was the Board concerned for the fact that BTSB factor IX heated at 60 degrees centigrade for 20 hours, was in circulation and in the hospitals? Dr Walsh said that, when this product was prepared initially, it was believed that 60 degrees centigrade for 20 hours was effective for HIV. Mr Trainor said that he appreciated that

fact, but now in July of 1986, was it not the case that the Board realised that its heat treatment protocol was ineffective for HIV?. Dr Walsh said the BTSB's factor IX was in the same category as commercial concentrate in circulation at this time.

Mr Trainor asked Dr Walsh, why did the BTSB reheat its factor IX which had not been issued to the hospitals when, at the same time, it did not recall factor IX which was issued under the old heat treating protocol? It would appear that only product immediately available to the BTSB was heat treated to the new standard. Dr Walsh agreed that this appeared to be the case. It would therefore appear that BTSB factor IX, heated to 60 degrees centigrade for 20 hours, which was realised in January 1986 to be inadequate for inactivating HIV, was left in the hospitals after this date and may have been issued to patients.

Mr Trainor directed Dr Walsh to a letter from Prof. Temperley, where Prof. Temperley instructed treaters not to use BTSB factor IX until further notice. Mr Trainor said it would appear that Prof. Temperley had a different understanding of what had transpired at the meeting between himself and Dr Walsh than that contained in Dr Walsh's memo. Dr Walsh said he would not like to second guess Prof. Temperley on this matter.

It would therefore appear that when the BTSB changed its factor IX heat treatment protocol on safety grounds in July of 1986, it did not recall potentially infectious product from hospitals around the country. The BTSB went on to heat treat unscreened donations in the expectation that this product would be used.

Mr Trainor put it to Dr Walsh that in October of 1986, Prof. Temperley made his decision clear that he would not use untested and inadequately heat-treated BTSB factor IX. However, apart from the stock returned by Prof. Egan from Galway, for almost the entire of 1986 that there had been on hospital shelves BTSB factor IX heated to the old protocol of 60 degrees for 20 hours. Dr Walsh said he was satisfied that no-one was infected with this material. Mr Trainor put it to Dr Walsh that this was simply an act of good fortune. At this point Mr Meenan objected on Dr Walsh's behalf, on the basis that the witness could not deal with an opinion. Mr Trainor put it to Dr Walsh that, as far as he was concerned, was it the case that there was no recall by him or anybody else on the Board in the period from the beginning of July 1986 onwards of heated factor IX heated by the Board to the old protocol of 60 degrees for 20 hours. Dr Walsh said there was no evidence of such a recall.

Dr Walsh was then cross-examined by Mr McGovern for Prof. Temperley.

Mr McGovern said that Prof. Temperley would give evidence that he received information in June of 1986 which startled him, and was to the effect that the BTSB was using unscreened plasma in the manufacture of factor IX concentrate, and on account of this he sought information from Dr Walsh. Dr Walsh said his recollection of the meeting was in relation to seroconversions.

Mr McGovern said Prof. Temperley will give evidence that he has no recollection of ever saying that he would use untested reheated factor IX, and he believes that, insofar as Dr Walsh's memo purports to suggest otherwise, the memo is a misinterpretation of his position. Mr McGovern

said Prof. Temperley would be clear in his evidence that the meeting of 25th June 1986 was about the use of unscreened plasma being used for the manufacture of BTSB factor IX. Dr Walsh said that his memo would indicate that it took until October of that year before Prof. Temperley finally said that unscreened BTSB factor IX would not be used.

Mr McGovern drew Dr Walsh's attention to the Department of Health memorandum of 26th January 1986, where the Department directs that only plasma from donors tested for HIV should be used for blood products. Mr McGovern put it to Dr Walsh that the only logical position for anyone to adopt who received this notice, was to conclude that henceforth only tested plasma would be used in the production of factor IX concentrate. Dr Walsh agreed that the note meant what it said. Prof. Temperley's position, said Mr McGovern, was when he agreed to use heat treated product already prepared, he though the material was from tested donations, and was very alarmed when he discovered otherwise.

Mr McGovern then referred Dr Walsh to Prof. Temperley's letter of 14th October 1986, addressed to the chief executive and members of the board of the BTSB. Mr McGovern said that the position was that the letter was sent to the chief executive and the board of the BTSB at the request of Mr Keyes. The letter was written and contains suggestions made following discussions with a number of people, including Dr Walsh. Dr Walsh agreed that this was the case. Mr McGovern asked Dr Walsh that, insofar as Prof. Temperley dealt with various products in the letter, would Dr Walsh be in agreement with his assessment of the situation? Dr Walsh said he agreed that Prof. Temperley was an expert in the area, and that he would have no particular disagreement with him.

With respect to the sentence contained in the letter that: “The Board should understand that in a present period of financial stringency, the hospitals could not be expected to meet a doubling of the cost of concentrates in 1989. Some balance would have to be struck between cost and the infection dangers associated with blood products.” Mr McGovern said that when talking about dangers, Prof. Temperley was referring to the danger of Non-A, Non-B Hepatitis, and not AIDS or HIV. Dr Walsh said that, to the best of his knowledge at this time, products were safe for HIV. It was also known at this time that the Armour product was inadequate for Non-A, Non-B. Dr Walsh agreed with this. Therefore, said Mr McGovern, the recommendations contained in Prof. Temperley's letter for the treatment of virgin patients were entirely appropriate, in that they would not therefore be exposed to Non-A, Non-B Hepatitis. Dr Walsh agreed that this was the case, providing the product and the method used to administer the product were effective.

Mr McGovern put it to Dr Walsh that the BTSB would supply product and would pay for the product via the hospitals, and if there was a concern for cost then this was a legitimate concern? Mr McGovern said that Prof. Temperley's evidence would be that from November 1985, Prof. Temperley was using only heat treated factor IX, and that the changeover from non-heat treated BTSB factor IX concentrate to heat treated product, was a somewhat gradual process. He would say that during the period from October to November 1985 the BTSB, in conjunction with the National Haemophilia Treatment Centre, conducted a trial of the new heat treated product. Dr Walsh said he did not recall this. He said he was not involved at that particular time. Mr McGovern said the purpose of the test was for thrombogenicity. The trials were successful and heat treated factor IX only was used from November 1985, said Mr McGovern.

Dr Walsh was cross-examined by Mr George Birmingham S.C. for Cecily Cunningham. Dr Walsh agreed that Ms Cunningham was not a policy maker, she had received instructions in the manufacture of BTSB factor IX from the chief technical officer and carried out her duties diligently.

The National Drugs Advisory Board had no questions for Dr Walsh.

Mr Ian Brennan, SC, cross-examined Dr Walsh on behalf of the Department of Health. Dr Walsh agreed that the BTSB's membership of the American Association of Blood Banks would not be given to a blood centre on the nod - it was subject to an all-encompassing inspection, and any inadequacy within the BTSB would be noted in this inspection. Dr Walsh agreed that, as far as he was concerned, he had done his job and that he was a professional person doing a professional job. Mr Brennan put it to Dr Walsh that his evidence could be broken into three phases, namely those of Travenol, Armour and Octapharma. Mr Brennan also put it to Dr Walsh that there was no shortage of consultants within the BTSB, as was witnessed by the testimonial from the AABB. Dr Walsh agreed that he had done his job. He had done it competently and had not made any incorrect decisions as far as he was concerned.

Dr Walsh was cross-examined by Mr McGrath for the BTSB.

On the basis of the examination and cross-examination, new documents were admitted to the cross-examination of Dr Walsh on behalf of the BTSB. These documents included return notes which indicated to Dr Walsh that contact was made with the hospitals prior to January 1986 from within the BTSB, following a meeting with Department representatives. Mr McGrath asked Dr Walsh who would issue such return notes. Dr Walsh replied that this would be the chief technical officer. The changeover from the Travenol to the Armour contract was discussed particularly with relation to factor IX difficulties.

Dr Walsh was examined by his own counsel, Mr Meenan and was re-examined by Mr Durcan for the Tribunal.

The Tribunal then adjourned until 10.30 a.m., September 12th, 2000.