IRISH HAEMOPHILIA SOCIETY

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CONTENTS:

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TRIBUNAL OF INQUIRY

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

PROCEEDINGS: TUESDAY 21st NOVEMBER, 2000 – DAY 71

Mr James Connolly S.C. continued his examination of Dr Lawlor on behalf of the Kilkenny health worker. With respect to the introduction of look-back as recommended by the AABB, Dr Lawlor said such look-back was not in place before June 1986 at the earliest. Dr Lawlor said by mid 1987, when the BTSB had compiled a list of HIV positive donors, a look-back should have taken place. Up to five donors had been identified as being HIV positive by this time.

Mr Connolly referred Dr Lawlor to Mr Hanratty's report of the ISBT conference in Sydney in May 1986, at which it appeared that the only real obstacle to introducing look-back were ethical considerations. Dr Lawlor agreed that this appeared to be the case. Dr Lawlor said that in July 1987 the BTSB appeared to consider all aspects of look-back but did not take it on board.

In the month of July 1987 Dr Walsh, on the instruction of Dr Barry, compiled a list of previous HIV positive donations. This was the list kept in a safe at the BTSB. Dr Lawlor said it was kept in a safe in order to maintain donor confidentiality. Dr Lawlor said that Dr Barry and Dr Walsh would have had access to this document. Dr Lawlor agreed that the limited pool of HIV positive donors, and the fact that the paper trail with respect to these donors was still intact, meant that the look-back could have taken place. Mr Connolly put it to Dr Lawlor that the situation was crying out for a look-back. Dr Lawlor agreed with this proposition.

At a board meeting of the BTSB in September 1989, it was agreed that look-back would be conducted on any donations proving positive henceforth, however no retrospective look-back was agreed at this stage.

Dr Lawlor said she thought that look-back had been carried out at this stage, and worked on this basis. Dr Lawlor said that a report to the Council of Europe, that the variability of hospital records was preventing look-back by the BTSB, was a matter for Dr Walsh.

It was eventually decided to conduct a look-back at the board meeting of 20th September 1989. Mr Connolly put it to Dr Lawlor that from 1987 to 1989 matters had simply drifted on with respect to conducting look-back. Dr Lawlor agreed that this was the case. Mr Connolly asked Dr Lawlor had any look-back taken place into hepatitis B donors. Dr Lawlor said that no look-back on hepatitis B donors took place anywhere, that she was aware. Dr Lawlor said she became aware in April 1985 of the existence of donors who subsequently tested positive and who had made previous donations before testing was introduced in October 1985.

Dr Lawlor was then cross-examined by Mr Martin Hayden on behalf of the Irish Haemophilia Society. Mr Hayden referred Dr Lawlor to her evidence of the previous day when, in response to Mr Connolly, she indicated in her defence of the BTSB a distinction should be made between the U.S. position and the Irish position, with respect to the introduction of testing and look-back,. The US was seen as a source of contamination and Ireland was seen as a safer source of product. In that context Mr Hayden asked Dr Lawlor, did she see her position at the Tribunal as defending the BTSB or assisting the Tribunal in establishing what in fact happened? Dr Lawlor said she

saw her position as defending the BTSB where it was defensible, and assisting the Tribunal in either event.

With respect to the BTSB selecting a test kit in 1985, Mr Hayden referred Dr Lawlor to publicity material from Abbott Laboratories where the company indicated that HTLV-III test kits were available in March 1985. Dr Lawlor had previously indicated that the BTSB had difficulty in receiving kits because they were not available on this side of the Atlantic. Mr Hayden put it to Dr Lawlor that Abbott Laboratories, with its offices in Santry, Co. Dublin, was advertising the fact that it had kits available for use in March 1985. He further pointed out that when testing was eventually introduced in October of 1985, the BTSB in fact used the Abbott kit as an in-house confirmatory test and cited the fact that it had the advantage of using equipment already in use at the BTSB. This being the case, Mr Hayden asked Dr Lawlor should the BTSB not have introduced some form of testing with Abbott or other available tests, earlier than October 1985?

Dr Lawlor said the issue of false negatives and false positives, and the magnet effect of attracting potentially infected donors who might avail of a test, prevented the introduction of testing in March 1985. Dr Lawlor said false negatives and false positives were a major problem. Dr Lawlor said that the BTSB kept itself up to date with these matters in the medical literature.

With respect to the issue of false negatives and false positives, Mr Hayden referred Dr Lawlor to Council of Europe observations on the introduction of testing in Germany, where the Abbott test in use showed that 1:3 of the false positives was in fact a true positive. Mr Hayden put it to Dr Lawlor that as such, would it not be a safe and reasonable option to adopt such a test at that time in Ireland? Further, the issue of false negatives did not arise in the report?

Mr Hayden put it to Dr Lawlor that a reduction in the amount of blood available which would be the upshot of introducing testing and of having to suffer false positives, was in fact the more likely reason why the BTSB was slow to introduce testing?

When the BTSB's commercial fractionators and those to whom it sold plasma insisted on the introduction of testing, it was only then that the BTSB developed a sense of urgency on the issue of testing? Mr Hayden put the above to Dr Lawlor.

Dr Lawlor did not agree with Mr Hayden's views on this.

With respect to when she became aware of when BTSB factor IX infected people with haemophilia B, Dr Lawlor said she was not aware of this until 1996 when she conducted her enquiries. With respect to earlier observations that Dr Walsh had indicated that BTSB product probably hadn't caused difficulties in respect of HIV infection of haemophilia B patients, Dr Lawlor said that it was possible that a linkage was discussed, but it was not known for sure if BTSB factor IX had caused the difficulties.

Dr Lawlor said some had had commercial product and BTSB factor IX. Dr Lawlor said she thought the issue of BTSB factor IX had been closed in 1991. There was no consideration of a look-back on haemophilia patients at any time. Dr Lawlor said the final investigation into the issue was opened when the Tribunal of Inquiry was pending. This investigation took place in 1997. All the information at her disposal at that stage then established the link.

Dr Lawlor was then cross-examined by Mr Charles Meenan, who appears for Dr TJ Walsh, Dr Power, and Dr Egan. Mr Meenan referred Dr Lawlor to a document upon which a hand written note appears, indicating that a policy decision by the board was required on the issue of look-

back. The note is written by Dr Walsh. With respect to the issue of the variability of hospital records causing a problem, Mr Meenan put it to Dr Lawlor did this not in itself constitute a form of look-back, in that the difficulties raised by the hospital records had been encountered further?

Mr Meenan said that in September 1989 Dr Walsh, as the chief medical consultant, had initiated the discussion on a look-back programme at the board, and said such a programme would have to be implemented. Dr Lawlor said she was under the impression that look-back had been conducted previously with respect to Donor F, who tested positive in August 1990.

Mr Meenan asked if it was the case at this time five years was regarded as sufficient for lookback. The five year rule applied in 1990, said Mr Meenan. Dr Lawlor agreed that this was the case. This being the case, Donor F's previous donations in the period before August 1985, would not be examined. Mr Meenan said that Dr Walsh would say that he did not say BTSB product probably had not caused the seroconversions in 1986.

Dr Lawlor was then examined by Mr Ian Brennan for the Department of Health. Mr Brennan discussed the issue of HIV screening and the provision of alternative sites for screening in 1985. Mr Brennan said Mr James Walsh will say he met the BTSB on three or four occasions, in the summer and autumn of 1985, with respect to the topic of alternative sites. Dr Lawlor agreed that this was the case. Dr Walsh would say that alternative sites were to be located in STD clinics, and this was the obvious place for the location of such facilities. Mr Brennan pointed to a BTSB board minute which suggested that STD clinics be used as alternative sites. Further, Mr Brennan said the Department of Health would say that alternative sites were in place in STD clinics with over 500 patients testing positive in the first year of operation. Further, when testing was introduced by the BTSB, the alternative sites issue did not materialise as a difficulty.

Dr Lawlor was then examined by Mr Frank Clark for the BTSB.

PROCEEDINGS: WEDNESDAY 22nd NOVEMBER, 2000 – DAY 72

Mr Gerry Durcan re-examined Dr Emer Lawlor.

Mr Durcan took Dr Lawlor through the list of HIV positive donations, starting with Donor A. Mr Durcan examined the "Important Message to Donors" leaflet. In the early version of this BT1 form the acknowledgement by the donor of having read the important message to donors, is not prominent on the form. Mr Durcan also noted that there was a difference in how the form was completed in its various sections.

In his examination of the various donations which proved HIV positive, Mr Durcan noted that a delay occurred between the time the donation was tested and the time in which the BTSB contacted the affected donor. With respect to donors A, B and C, Mr Durcan noted that a delay of between three and four months in testing positive and informing the donor, exemplified the fact that no system was in place in the BTSB for contacting infected donors.

With later positive donations, such as that of Donor F, which was made on 31st August 1990, Mr Durcan noted the letter issued from the BTSB concerning this donation, on 11th September 1990 however no look-back took place even though a previous donation had been made on 11th December 1984. The explanation as to why no look-back occurred, seems to lie in the fact that the previous donation was outside the five year period which had been recommended as the relevant period upon which a look-back should occur.

With respect to previous assertions that there was a 1: 50,000 chance that a donation might be positive. Mr Durcan pointed out that within three months of testing, three positive donors had turned up. Dr Lawlor agreed that by late 1986 and into 1987, there should have been a look-back programme established by the BTSB. She also agreed that the most hazardous donations with respect to HIV infectivity, were those made just prior to the introduction of testing.

Mr Durcan asked if in mid-1987 through to 1989, did anyone suggest in the BTSB that pre-testing donations should be examined. Dr Lawlor said that she was not aware that this was done. Mr Durcan asked Dr Lawlor was there any logic in holding a look-back and not dealing with the most risky period? Dr Lawlor agreed that there was no logic in this position.

Mr Durcan referred Dr Lawlor to two alternative views as to the efficacy of look-back contained in the medical literature.

Mr John Keating of the BTSB was then examined by Mr Durcan.

With respect to tests available in May 1985, Mr Keating said these tests were non-specific and they were not 100 per cent sensitive. Mr Keating said that sample test kits were requested at the end of June. In late August the tests became available and he evaluated each of the tests with respect to ease of use. Mr Keating said he did not evaluate the Wellcome test at this stage because it was not available. It did not become available until July. The test kits were ordered in late June. Mr Keating said the equipment also had to be supplied by the companies, and the companies were reluctant to make a test available without the dedicated equipment. Mr Keating agreed there was no reason why the equipment needed to conduct the tests could not have been ordered in April or May, however he said the equipment was expensive.

With respect to his investigations in January 1991 into batch 90753, Mr Keating said he had no recollection of conducting this investigation. He had no specific memory of the investigation. He said he was often asked to conduct investigations into various batches, and this one was no different from other tests he was asked to conduct, and consequently he had no memory of it.

In response to cross-examination by Mr Raymond Bradley of the Irish Haemophilia Society, Mr Keating said the issue of HIV surrogate testing was not considered by the BTSB. With respect to batch testing factor IX, Mr Keating said the logic of batch testing was that these issues were in stock before testing was introduced, and any test on the batches was considered better than no tests. Mr Keating said he did not ask for test kits in March of 1985.

Mr Gerry Durcan then examined Dr Terry Walsh of the BTSB.

With respect to letters issued to positive donors, Dr Walsh said that hepatitis B donor letters may have been the model for the later letters to HIV positive donors. With respect to a letter to Donor A in September 1986, Dr Walsh said Donor A telephoned him and Dr Walsh contacted the donor's GP. Mr Durcan asked Dr Walsh did he look at the donor's form for a donation made on 16th July 1985? Dr Walsh said he did not recall looking at such a form, and there was no policy there in the BTSB at the time that required him to examine such a form.

Mr Durcan asked Dr Walsh did the absence of such a policy prevent him from looking at the form? Dr Walsh said he could not recall.

With respect to the donation received on the 8th September 1986, Mr Durcan noticed that the virus reference laboratory was still working on a sample of this nine months later. Dr Walsh said he did not know why such a sample would be under examination in May 1987. The VRL test results were available on the 10th September 1986.

With respect to Donor F, who tested positive on a donation given on 31st August 1990, and who had previously donated on 11th December 1984, Dr Walsh said there was no clear policy on positive donors in the autumn of 1985. Dr Walsh said this was for the national director to determine. He did not think there was a written policy, even though three positive donors appeared within two months of testing being introduced.

Dr Walsh said he could recall no discussion about issues regarding testing. Dr Walsh said information on positive donors was kept by Dr O'Riordan's secretary. Any medical member of the BTSB had access to these records, said Dr Walsh. If access was needed it was available.

By 15th July 1987 Dr Walsh had prepared a list of HIV positive donors. Dr Walsh said he knew at this stage it was time to review HIV positive donors, and he knew in a general sense there were a number of positive donors in existence. The timeliness of this review arose with respect to the incidence of HIV, the patterns of infection, and the need for a look-back. Dr Walsh said at this stage part of the reason for a timely review was the need for look-back. He would have preferred if look-back had been done. Dr Walsh said he put the information together and presented the document to Dr Barry. He could not remember any discussion with Dr Barry, or other form of memo, arising from the review conducted by him in July 1987.

With respect to Donor A, Mr Durcan put it to Dr Walsh that he [Dr Walsh] had clinical responsibility for Dublin. Dr Walsh said his clinical responsibility extended to blood transfusion, not look-back policy. Dr Walsh said a decision on lookback was a decision for the board. He said was there was no policy forthcoming. Dr Walsh said that Dr Barry was as capable as him

when it came to making the decision regarding look-back. No-one came back to him concerning a policy on look-back in July 1987, or thereafter.

Dr Walsh agreed that he became chief medical consultant on 1st January 1988. In July 1987 he had favoured a look-back. Mr Durcan asked Dr Walsh when he did become chief medical consultant, did he institute a look-back at that stage? Dr Walsh said he did nothing about look-back in 1988 because he felt it had been decided not to have a look-back. Mr Durcan put it to Dr Walsh it was nevertheless his view that a look-back should have been done? Dr Walsh agreed that this was the case.

Mr Durcan put it to Dr Walsh, if that was the case why did he not, at the earliest opportunity, institute a look-back, since he was of the view that this should be done? Dr Walsh said he did not institute a look-back because it had been dealt with, ie. It had been decided not to do it.

Dr Walsh said he brought the subject of look-back to the board in 1989, when he thought it was appropriate. Mr Durcan put it to Dr Walsh that the risk from previous donations had not abated in any way? Dr Walsh said he agreed that look-back should take place, but other people had differing views. Dr Walsh said he presumed there was a policy not to have a look-back. Further, he had other things to deal with in 1988, and he now regretted he had not instituted a look-back when he took over as chief medical consultant. Mr Durcan put it to him that he should have instituted a look-back in 1988. Dr Walsh said he had given his explanation.

In September 1989 Dr Walsh said he told the board that a positive donation may indicate the existence of previous infections. Dr Walsh said he had provided a reasonably detailed account of this, and he recommended that a look-back take place. Mr Durcan asked Dr Walsh, did he tell the board it was medically necessary to conduct a look-back? Dr Walsh said there was resistance from the board to look-back. They were concerned about the public relations and potential liability aspects of instituting look-back.

Dr Walsh said he was of the view that look-back should be done, but he could not recall whether he recommended that it should still be done. Mr Durcan asked Dr Walsh what was the logic of agreeing that future positive donations should be the subject of a look-back, but previous positive donations should not? Dr Walsh said he could not give a rationale for the decision. Mr Durcan put it to him, would he accept that this decision made no sense? Dr Walsh said this was the case but he was told by the board to stop overstating his case, and was told to desist from causing scare stories. He was told this in dramatic terms at the board meeting. With respect to the decision to institute look-backs at future HIV positive donations, Dr Walsh said he was relieved that at last something was happening.

In September 1989 it was decided that a five year look-back period should be instituted, which would have taken the board back to the time when testing started. Dr Walsh agreed that the fact that there was no look-back at the previous donations of positive donors in the period prior to the introduction of testing, meant the most at-risk donations were left without look-back..

Mr Durcan asked Dr Walsh, when the board arrived at this wrong decision did he attempt to dissuade them? Dr Walsh said there was no further attempt to introduce retrospective look-back. When he set out to explain the risks of this course, Dr Walsh said he was told to stop digging up the past and proceed into look-back from here on. Dr Walsh said he told the board that previous look-back should take place. He agreed that he believed the board policy was wrong, however there was no document setting out these views and this view was never put in the record.

Mr Durcan put it to Dr Walsh that the board was going against medical advice, and this was contrary to the position previously adopted by the board that it never rejected the medical advice it was offered? Dr Walsh said this was putting things in rather stark terms, but he agreed that this was what the upshot of his exchange with the board meant. He said the board went against medical advice on other occasions with regards to other issues like blood packs.

Mr Durcan said that up to now, the Tribunal has been told that when medical matters were under consideration and a recommendation was made to the board on the basis of medical advice, this course was adopted. Dr Walsh said this was one occasion when it was not adopted.

Mr Durcan put it to Dr Walsh that the reason there was no look-back for the Kilkenny health worker, is because of this board decision in September of 1990? Dr Walsh agreed that this was the case. This being so, the Kilkenny health worker went for seven years without treatment for HIV, because of this decision. Dr Walsh said that detailed discussions had taken place at the board meeting; it was not a theoretical discussion, and he found it difficult to talk about but he had done his best at the meeting.

Dr Walsh said he made it clear to the board that of the five previous donations, only three required look-back. Dr Walsh said, however, the decision taken by the board was only in respect of future HIV positive donations.

PROCEEDINGS: THURSDAY 23rd NOVEMBER, 2000 – DAY 73

Mr Gerry Durcan S.C. for the Tribunal, continued his examination of Dr Terry Walsh of the BTSB.

Mr Durcan put it to Dr Walsh that, in the summer of 1989 the issue of litigation and personal liability of board members of the BTSB was raised. Dr Walsh said he was not sure about the exact date of the litigation, but he was aware that the issue of personal liability had been raised at the board. With respect to a comment recorded during a visit of Dr Hoppe, at which a participant had noted that "you could take your luck with the odd platelet", Dr Walsh said these words were not attributable to him.

With respect to Donor F, Dr Walsh said this matter was dealt with in August and September of 1990. The donation of 1984, made by the same donor in December of that year, was outside the look-back period by a number of months. However, Dr Walsh agreed that the look-back could have been extended to include Donor F's December 1984 donation.

Mr Durcan referred Dr Walsh to a memo of 28th January 1991. The memo notes: "I have carried out a search of the available records of donations found to be HIV positive since testing commenced in October 1985. Two donors were identified who had given donations prior to the introduction of testing, and from whose donations cryoprecipitate had been prepared. A search is now in progress to determine the disposition of these units." Mr Durcan put it to Dr Lawlor that this memo to Mr Keyes in January 1991, was connected to the on-going litigation. Dr Walsh agreed that this was the case. Dr Walsh also agreed that this memo was written during the exercise which had taken place in a look-back at the donations of Donor F. In and around the same time, on 11th January 1991, Mr Keating was conducting his investigation into batch no. 90753. Mr Durcan asked Dr Walsh did he recall asking Mr Keating to conduct this search. Dr Walsh said he did not recall this happening, but agreed that it was highly likely that Mr Keating's investigation was the search referred to in his memo.

Mr Durcan asked Dr Walsh had he previous information concerning BTSB factor IX causing infections with HIV in and around August 1986. Dr Walsh agreed that this was the case. In January 1991 it would therefore appear that Dr Walsh had information to hand that showed the donation of Donor F in January 1984 was in batch 90753. Dr Walsh now had a positive donor in the year 1990, whose donation had gone into batch 90753 which was manufactured sometime in 1985. Dr Walsh also knew that he had six haemophilia B patients who were positive for HIV in 1986. Dr Walsh said he agreed that these things were now obviously connected, but he had made no connection along these lines at the time. Dr Walsh agreed that the look-back which had occurred took place for legal reasons; it was not a medically induced look-back. Dr Walsh said he didn't make the connections in 1990 concerning the 1984 donation and the 1985 manufacture of factor IX, and the 1986 infections with the same batch. The look-back was held for legal reasons.

Mr Durcan asked Dr Walsh did he ever find the cryo referred to in the memo? Dr Walsh said he could not recall the final outcome of the search as the litigation was settled around this time.

Mr Durcan asked Dr Walsh that, in connection with the litigation, was it not the case that Donor F had been found to be infectious in 1990. He had made a donation in December 1984. This was a period of high risk just before the introduction of testing. The donation had been traced to a batch

of BTSB factor IX, and the actual batch number had been found. Mr Durcan put it to Dr Walsh that the batch number could be used to trace those into whom the product had been administered.? Dr Walsh agreed that if anybody had gone to the trouble to examine the record to see where the batch had gone, they would have found that the batch had in fact gone to the people who in August 1986 had been identified as having seroconverted. However, Dr Walsh said that the recipients of the red calls had been tested and these tests were negative for HIV. Dr Walsh said this may have indicated that this donor wasn't responsible for the HIV infection and the fact that those who were infected using factor IX had also used commercial products, may have indicated that it was not the BTSB factor IX..

Mr Durcan put it to Dr Walsh that, had the recipient of the red cells or the recipient of 90753, who was a patient in the Mater Hospital and did not suffer from haemophilia, should these recipients have been subjected to a look-back and tested where possible? Dr Walsh agreed that all recipients of clotting factors should have been tested.

Mr Durcan put it to Dr Walsh that the level of information which had been garnered in the month of January 1991 was such, in regard to donation 901600, that there was no doubt about what should have happened. Was it not the case, said Mr Durcan, that any blood product that had been made from that donation, or into which that donation had gone, should have been traced, and the red cells should have been traced, and the factor IX should have been traced? Dr Walsh said it was a different situation in that the information was scattered, and it was not brought together in the way it had been brought together today.

Mr Durcan put it to Dr Walsh that someone had compiled the information. Would he quibble with the assertion that a look-back should have taken place.? Dr Walsh said, no, he would not disagree with that. Mr Durcan put it to Dr Walsh that, wasn't part of the problem that the look-back that was taking place was taking place in a legal rather than a medical context?

With regard to Dr Walsh's conversation with Dr Lawlor in 1991 concerning possible infections from BTSB FIX. Dr Walsh said he would never have declared to Dr Lawlor that the BTSB product probably hadn't caused HIV infection. He had said in 1986 that Pelican House factor IX could be involved. Dr Walsh said that where people were treated with both Pelican House factor IX and commercial products, there was a possibility that they may have been infected with the commercial product, and as he hadn't done an investigation into this issue, therefore he couldn't say for sure that it was BTSB product that caused the infection.

Mr Durcan asked Dr Walsh, was he still entertaining doubts that BTSB factor IX had caused the infection of seven people with HIV, as described by Dr Lawlor? Dr Walsh finally agreed that he had no doubts as to this source of infection.

Dr Walsh was then cross-examined by Ms Una McCrann for the Kilkenny health worker.

Mr Martin Hayden cross-examined Dr Walsh on behalf of the Irish Haemophilia Society. Mr Hayden referred Dr Walsh to the issue of members indemnity. Members of the board of the BTSB sought to obtain assurance that they would not be held individually liable for any actions of the board in the face of claims from people with haemophilia. The board discussed the legal and public relations aspects of these claims.

Mr Hayden referred Dr Walsh to the meeting of 20th September 1989. The BTSB board meeting was told that meetings had taken place with the board's insurance company with the board's solicitor present. The insurance company solicitor had been asked to confirm in writing that the

insurance company would indemnify members of the board. This issue was also raised with the Department of Health.

Mr Hayden asked Dr Walsh, was this discussion taking place in the context of claims lodged by members of the Irish Haemophilia Society? Dr Walsh said that could be the case, or it could be that the board was concerned about its liability to donors or a transfusion recipient who may be injured by perceived negligence. Mr Hayden put it to Dr Walsh that, was it his position that the board suddenly started considering its position as to whether somebody injured themselves in a clinic or were they really talking about the degree of liability? Dr Walsh said he had no specific recollection of the discussion concerning indemnity.

Mr Hayden asked Dr Walsh about his 1991 discussions with Dr Lawlor concerning factor IX infections. The issue of look-back. The issue of whether all documentation was forwarded to Mr Keyes as a result of the discovery required for litigation. In January of 1990 Dr Walsh said he furnished all documents in his possession to Mr Keyes in respect of the discovery order arising from the litigation then being pursued by members of the I.H.S., and which litigation was settled in the summer of 1991.

Mr Hayden asked Dr Walsh if he could recollect the meeting of September 1990 at which it was decided to conduct a look-back on the future infected donations? Dr Walsh said he could remember the tone of the meeting, and was told to stop digging up the past, and was told to desist from scare stories. Dr Walsh said he was told this in dramatic terms.

Mr Hayden asked Dr Walsh, could he remember if the fact that BTSB factor IX had caused infections in 1986, had this fact been brought up at that board meeting? Dr Walsh said the 1986 infections had not been discussed. He also said he could not remember who at the meeting had instructed him to stop digging up the past.

Mr Hayden asked Dr Walsh, had Mr Keyes or Prof. Temperley brought up the 1986 factor IX infections. Dr Walsh said this was not the thrust of the meeting. The meeting was discussing look-back, and that the BTSB factor IX infections had already been identified, and in that context look-back wasn't particularly relevant to the factor IX infections.

Mr Hayden asked Dr Walsh, was it credible that he could remember what was said at the meeting but could not remember who said it?

With regard to Dr Walsh's conversations with Dr Lawlor in 1991 concerning the likelihood of BTSB product causing HIV infection among haemophilia B patients, Mr Hayden referred Dr Walsh to a document completed for the Council of Europe. Dr Walsh noted that no transfusion-associated HIV infection has been found to date in Ireland other than in haemophiliacs who received commercial clotting concentrate. Dr Walsh said he now realised that this statement contained an error on his part, in that he should have mentioned that BTSB factor IX, ie. non-commercial product, had caused infections.

Mr Hayden put it to Dr Walsh that, given he had made a mistake on the Council of Europe form and had told the Council of Europe that only commercial concentrates were the source of infection among the haemophilia population, could he not have also made the same mistake when he was talking to Dr Lawlor in 1991? Dr Walsh said he didn't think so.

With respect to a further observation by Dr Walsh that variability of hospital records was causing problems with look-back, such information being provided to the Council of Europe in May

1988, Mr Hayden asked Dr Walsh how did he know that hospital records were causing such a problem prior to the introduction of any look-back? Dr Walsh said he knew that the variability of hospital records was causing a difficulty with look-back from his position as a blood transfusion expert who visited various facilities and talked to the people who worked in the hospitals.

Mr Hayden then referred Dr Walsh to the board minute of 17th January 1990, where the issue of indemnity is again discussed. Mr Hayden read a copy of a letter received by the board from the Department of Health. "The board considered the following letter of 21st December 1989 from the Department of Health regarding the indemnification of board members in respect of actions taken against the board. The letter read, "Dear Mr Keyes, I wish to refer to your letter of 4th August 1989 concerning our query raised in relation to the personal position of board members in their indemnification in actions taken against the board. The understanding of this department is that, as the board is established under the Health Corporate Bodies Act 1961, in common with other bodies so established, a body corporate with perpetual succession with rights to sue and be sued in its corporate name, there would appear to be no reason why any actions would be taken against individual members in relation to the position of their office, unless extreme incompetence and negligence or other corruption was alleged. In view of the above, the question of indemnification of the board members does not arise. Dr Walsh said he only had a vague memory of the matter being discussed.

Mr Hayden referred Dr Walsh to the preparation of documentation on the instruction of Mr Keyes, in anticipation of forthcoming litigation in 1991. Dr Walsh said his specific query that he set out to answer was in relation to particular units of cryo. Mr Hayden asked Dr Walsh, did this investigation include the investigation into batch 90753? Dr Walsh also agreed that he was aware, from August 1986, that the BTSB factor IX had probably caused infections among haemophilia B patients.

In the context of litigation, Mr Hayden asked Dr Walsh did he pass all the documentation he had assembled as a result of his investigations, to Mr Keyes? Dr Walsh said that would be his recollection. Dr Walsh said he was aware that this information was being furnished for the purposes of discovery in the existing HIV litigation. Mr Hayden asked Dr Walsh, was he looking at the documentation from the point of view of litigation at that stage? Dr Walsh said he wasn't looking at the documentation; he was merely compiling it. Mr Hayden asked Dr Walsh, if he was compiling the documentation for the purposes of litigation, hadn't that everything to do with liability? Dr Walsh agreed that that was the case. Mr Hayden put it to Dr Walsh that liability had everything to do with what caused something to happen?

Dr Walsh's counsel, Mr Meenan, objected to this question on the basis that Dr Walsh was being asked to comment on a legal matter. Mr Hayden said he was sure Dr Walsh was able to answer the question of whether or not he understood what he was looking at from the litigation viewpoint. Mr Hayden said that, whilst Mr Meenan would prefer that he didn't ask these type of questions, he thought the witness was well able to answer them.

With regard to an Affidavit of Discovery, Mr Keyes made a request to Dr Walsh and others to furnish all documentation in their possession to him to be added to the schedule for discovery in respect of an order made, arising out of pending HIV litigation in January 1991. Mr Hayden asked Dr Walsh had the investigation conducted by Mr Keating, been undertaken in respect of this order? Dr Walsh said he could not recall anything other than that he had provided all the relevant documentation in his possession to Mr Keyes.

With regard to these events, Mr Hayden asked Dr Walsh did he, when he came into possession of information on donor F and the infected donation in 1990, and his knowledge that Donor F had made a donation in 1984 and infected BTSB product had gone into circulation in 1985 resulting in infections in 1986; Dr Walsh, as the chief medical consultant and a trained medical professional, not make any connection between the 1984 donation and the potentially infected batches of 1985? Dr Walsh said that, as the cryoprecipitate was mentioned, such a possibility must have been considered, but he did not investigate it further at the time.

With regard to the donation made by Donor F in 1984, and the fact that the same donor was positive for HIV in 1990, and that the BTSB was conducting an investigation into batch 90753 which had been made from the cryo supernatent which had been investigated by Dr Walsh, Mr Hayden made the point that within a short space of the exercise conducted by Mr Keating into batch 90753, that the BTSB settled the HIV litigation. The Tribunal Chairperson said it was unfair to impute onto Dr Walsh knowledge of the litigation. Dr Walsh had said he prepared documents for discovery, and that was it said the Chairperson. Mr Hayden said this question arose with regard to Dr Lawlor' assertion previously that the litigation brought about by members of the Irish Haemophilia Society in respect of HIV infection, had been settled without admission of liability. The Chairperson said this was an entirely different question.

The Chairperson informed Dr Walsh that his cross-examination by the BTSB would be taken up on the following Tuesday, when the BTSB had had time to consider his evidence and take instructions on the issue of whether or not the board of the BTSB had gone against the medical advice of Dr Walsh at the September 1990 board meeting with regard to the need for a retrospective look-back.

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Ms Grainne Clohessy for the Tribunal of Inquiry, examined Mr Michael J Ryan, formerly chief technical officer of the Limerick Blood Transfusion Service. Mr Ryan told Ms Clohessy that he gained his blood transfusion service experience in the U.S. Air Force from 1957 to 1977, and worked for the Limerick Blood Transfusion Service from 1977 until 1990.

Mr Ryan explained that the Limerick Blood Transfusion Service was a private company run by two doctors Kelleher. The organisation gathered between 8,000 and 10,000 units of blood annually. Mr Ryan said the Blood Transfusion Service in Limerick prided itself on being up-to-date and first with innovations concerning blood transfusion. Mr Ryan said he kept himself up-to-date with blood transfusion matters through his membership of the AABB and in this regard had written to a Dr Holland in the United States in September of 1985, seeking Dr Holland's views on the efficacy of various anti-HTLV-III tests. Mr Ryan said the Limerick Blood Transfusion Service introduced testing in August of 1985, some two months prior to the introduction of such a service by the BTSB.

Mr Ryan was also examined by Mr Jim McCullough for the Irish Haemophilia Society. Mr Ryan confirmed that the Limerick Blood Transfusion Service had indeed introduced testing in the month of August 1985. He said he found nothing extraordinary in his actions in writing to Dr Holland in the U.S., seeking Dr Holland's views on the efficacy of various kits that Dr Holland had tested. Mr Ryan said that he had no difficulty in receiving test kits from Wellcome from its Dublin based facility, and agreed that his communication to Dr Holland was part of the on-going re-evaluation of the testing regime introduced by the Limerick Blood Transfusion Service.

Mr Ryan said the issue upon which the test kits were evaluated was on the matter of false positives. The issue of false negatives did not arise. Mr Ryan agreed that, in common with Dr Holland, a pragmatic view had been taken in Limerick of the issues unfolding in blood transfusion. A test was implemented at the earliest opportunity by the Limerick Blood Transfusion Service, said Mr Ryan.

Mr Gerry Durcan for the Tribunal then examined Dr Joan Power, regional director of the BTSB in Cork. Dr Power described the activities of the BTSB in Cork in collecting blood, in collecting plasma, in distributing haemophilia products to the regional hospital, and dealing with people with haemophilia. Dr Power said the Cork BTSB dealt with approximately 71 persons with haemophilia in the Munster region. Dr Power described various look-backs which the Munster region of the BTSB had conducted into the previous donations of positive donors. None of these donations concerned people with haemophilia.