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TRIBUNAL OF INQUIRY

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

PROCEEDINGS: WEDNESDAY 15th NOVEMBER, 2000 – DAY 68

Mr Gerard Durcan, for the Tribunal, opened Part 2 of the Tribunal of Inquiry. Mr Durcan said in this part of its work, the Tribunal will be concerned with matters set out in paragraphs 9, 10, 11 and 12 of its Terms of Reference. In general, these Terms of Reference concern the adequacy and timeliness of donor selection and donor screening procedures adopted by the BTSB in the period from 1980 until October 1985, and whether the Board took adequate and timely measures to identify persons who may have been infected from blood and blood products during that period.

Mr Durcan said the Tribunal will in particular look at two cases, the first being that of the Kilkenny health worker who has adopted the pseudonym Mary Murphy, and who was infected with HIV virus as a result of receiving a blood transfusion. The other case being the circumstances in which platelets which had not been tested for the HIV virus, were issued by the BTSB and given to a patient in Wexford General Hospital in December 1985.

The Terms of Reference for this part of the Inquiry concern infection with the HIV virus only, and not with infection with Hepatitis C. The period under investigation with respect to donor testing and screening is the period from 1980 until October 1985. The Tribunal's investigations in this part of the Inquiry are therefore confined to blood and blood productS derived from donations made before the introduction of testing in October 1985.

Mr Durcan then set out the circumstances which led to the infection of the Kilkenny health worker with HIV. Mr Durcan told the Tribunal that this woman was transfused with whole blood in the month of July 1985, and that this blood had been donated by Donor A on 16th July 1985 prior to the introduction of HIV testing of blood donations in mid-October of that year.

Donor A made a further blood donation on 1st September 1986 and an anti-HTLV-III test carried out by the BTSB showed that he was positive for the virus antibodies. Following the positive test in September 1986, it would appear that no step was taken by the BTSB to establish whether Donor A had made any previous blood donations, nor was there any attempt to trace persons who had received any such donations. The BTSB did not initiate any such enquiries until September of 1996.

Quite independently of those enquiries, the Kilkenny health worker was diagnosed as being HIV positive in early December 1996. The BTSB accepts that this person was infected with HIV virus as a result of a blood transfusion which was received in July 1985. Mr Durcan said the circumstances of this infection raised issues as to the adequacy

of the measures taken by the BTSB in the early to mid 1980s to protect recipients of blood and blood products from infection with the HIV virus.

Mr Durcan raised the following matters:

1) Did the Board take adequate measures to attempt to ensure that persons who had been exposed to HIV virus did not donate blood?

2) Did the BTSB act with sufficient expedition in introducing testing of blood donations for HIV? Mr Durcan said this issue raised very distinct matters with respect to the Kilkenny health worker, since at the time of her infection in mid July 1985, commercial tests for the HIV virus were available but their use was not adopted by the BTSB for a further three months, that is in mid-October 1985.

3) Should the BTSB have taken steps at an earlier time, ie. before September 1996, to identify persons who may have been infected by a previous blood donations of a donor who was subsequently found to be HIV positive.

With respect to donor selection and screening, Mr Durcan said that it was clear by the start of 1983 that HIV virus could be spread by blood or blood products. Mr Durcan referred to the Council of Europe recommendations of June 1983, and AABB recommendations in March of that year. Mr Durcan said that, against the realisation that HIV was blood-borne, the Irish situation remained that of a voluntary non-remunerated donor panel and a lesser number of infected persons would be expected within that panel.

Mr Durcan referred to the BTSB's message to donors in July 1983, which was published along the same lines as the AABB leaflet. The screening available to the BTSB at this point relied on the leaflet and was a donor self-exclusion screening process. The donor leaflet contained no question as to specific symptoms of HIV infection which were alluded to in leaflets recommended by the AABB.

Mr Durcan said that Ireland was among the first European countries to introduce such a donor leaflet. As time progressed, it was realised that the risk groups identified earlier as being potential carriers of HIV, were expanding.

A review of the BTSB's leaflet was first mooted in November 1984. The review procedure continued throughout 1985. It appeared to be the case that the BTSB felt the delay in revising the leaflet was justified on the basis that screening was to be introduced, and that the new leaflet should coincide with the introduction of screening.

Mr Durcan referred to the donation of Donor F who made a blood donation on 11th December 1984, the plasma from which went into BTSB factor IX Batch 90753, which it is believed infected six haemophilia B patients. The information available to the Tribunal would suggest that Donor F was an intravenous drug abuser prior to his donation, or was

in a relationship with such a drug abuser. Donor F died from an AIDS related illness in 1996.

Mr Durcan also referred to another HIV positive donor who made a donation on 7th July 1988. This man donated twice yearly from March 1981 until July 1985 at an industrial clinic. This donor believes he may have seroconverted any time between 1982 and 1985, and it was believed he had a homosexual contact source. The significance of these donors with respect to the BTSB's leaflet is that both donors made their donation at a time when the leaflet was in use.

With respect to donor testing, Mr Durcan referred to the Atlanta conference of the World Health Organisation in April 1985 which discussed AIDS and recommended screening. In Manchester the Committee of Experts of the Council of Europe in May 1985 also discussed screening. The AABB introduced screening on July 1st 1985 at its blood collection centres. In Britain screening was introduced in September of 1985. The BTSB introduced screening in October 1985. The matter was under consideration by the BTSB from March 1985, but it appeared that the BTSB did not introduce screening until tests through which screening could take place had been evaluated.

Mr Durcan noted that, while screening was under consideration by the BTSB from March 1985, it would appear that the BTSB would not introduce testing until it had evaluated all the tests. Dr O'Riordan wrote in this regard to the Department of Health commenting that the Abbott test then available in March of 1985 was unreliable, in that it recorded a number of false positives and the results were difficult to interpret.

By September of that year Dr O'Riordan was again writing to the Department of Health saying that it was imperative that testing now be introduced. By 29th October 1985 all donations of blood being received by the BTSB were being tested.

Mr Durcan said it would be a matter for the Tribunal to decide, having regard to all the factors which delayed the introduction of testing, whether the BTSB acted in a suitable or timely manner by introducing testing in October of 1985. In this regard the Tribunal will have evidence from Mr Michael Ryan, the Chief Technologist at Limerick Blood Transfusion Service, as to how and when testing was introduced in that service. Mr Durcan said that as events had unfolded, the issue of the date of the introduction of HIV testing was of considerable practical importance, especially with regard to the donation which infected the Kilkenny health worker which was given by Donor A on 16th July 1985.

Mr Durcan then considered the issue look-back. He defined look-back as a system whereby a blood bank finds a donor to be HIV positive and looks back to see whether that donor has made any previous blood donations, and if so, checks to see where those donations have gone and whether they have caused infection.

At the time of the introduction of testing the BTSB discussed the necessity of having a look-back system. The Committee of Experts of the Council of Europe in May 1986

noted that 8 of the 25 member states had look-back in place. In January 1986 the AABB initiated look-back procedures, and in May 1988 the Council of Europe directed that look-back should take place. With the introduction of testing in 1985 the BTSB discussed the issue of look-back with Dr Gunson, a director of the regional transfusion centre in England who, it would appear, suggested that a previous donation from a positive donor should be traced back for a period of five years.

The BTSB did not initiate a look-back scheme until the Autumn of 1989.

With respect to donations made prior to 1985 by persons who were later found to be HIV positive, the BTSB did not initiate any look-back until the Autumn of 1996. BTSB medical consultants, in the summer of 1996, decided that it was then necessary to conduct a look-back into HIV positive donations which may have been made prior to October 1985. The BTSB had a list of seven such donors.

At the end of September 1996 a list of 31 blood products made from donations from these donors was circulated to hospitals around the country, with a view to tracing these products and to ascertain whether they had caused infection. The list of 31 HIV suspect products was attached to three other lists of blood donations or blood components which were being traced in the context of the on-going hepatitis C virus look-back. The letter did not state that the 31 products on the list were being sought as a result of a fear that the donors from whose donations such products were made, may have been infected with HIV.

Among the blood products on the list was donation number 979909 which had been given on 16th July 1985 by Donor A. Whole blood from this donation was given to the Kilkenny health worker who, on her own initiative in early December 1996, discovered she was HIV positive.

A further donation on the list, number 901600, was given by Donor F on 11th December 1984. The plasma from this donation was made into a batch of cryoprecipitate, the supernatent of which was fractionated into BTSB factor IX batch number 90753. Batch 90753 is believed to be responsible for the infection of six persons with haemophilia B with HIV.

Mr Durcan said the Tribunal will have to consider whether the look-back produced in respect of the donations made from the seven donors prior to October 1985, should have taken place at an earlier time, ie. earlier than 1996. If such a look-back should have taken place in the determination of the Tribunal, the question will be asked as to why such a look-back did not take place. The Tribunal will consider whether such an earlier look-back would have reduced the risk of onward infection. The Tribunal will also examine as to whether or not the look-back of 1996 was carried out in a proper and satisfactory manner.

A question to be considered here is whether or not the BTSB was correct in conducting a HIV look-back under the auspices of a Hepatitis C look-back which did not put those concerned on notice that HIV was under investigation.

The final issue to be dealt with by the Tribunal on this part of the investigation, is the administration of platelets to a patient in Wexford General Hospital. These platelets were derived from a blood donation made by Donor C on 9th December 1985. Upon testing, the donation was found to be HIV positive, however the platelets had been issued and administered to the patient prior to the test taking place.

Mr Durcan then examined Dr Emer Lawlor of the BTSB.

Mr Durcan referred Dr Lawlor to early BTSB screening leaflets in use in the early 1980s. Dr Lawlor said the BT1 form asked a number of questions, but was not as detailed as later versions of the leaflet.

Mr Durcan referred Dr Lawlor to MASAC recommendations issued in January 1983 that recommended direct questioning be introduced. Dr Lawlor agreed that direct questioning was introduced in the U.S. but such questioning was not recommended and was not in use in Ireland. Council of Europe documents containing recommendations that donors be monitored for the symptoms of AIDS, such as night sweats and weight loss, were not adopted by the BTSB.

Dr Lawlor said by the beginning of 1983 the threat of AIDS was not seen as an Irish problem. The BTSB partially implemented the Council of Europe recommendation R(83)8, in that it produced a donor leaflet. When the BTSB introduced a donor leaflet on the back of R(83)8, it did not adhere to all the Council of Europe recommendations contained in this document. Dr Lawlor said the BTSB's leaflet had to be filled in, and contained general questions; they were not specific to AIDS, but were generally in line with the U.S. approach, said Dr Lawlor.

Mr Durcan asked Dr Lawlor, did BTSB doctors who were taking blood, at any stage ask donors questions in regard to possible AIDS risks. Dr Lawlor said she was sure this was being done.

Dr Lawlor said with respect to Ireland's place in the AIDS epidemic, it was sensible for the BTSB to identify at risk categories and attempt to exclude them by a donor leaflet. Dr Lawlor agreed that the introduction of the leaflets did not result in any adverse repercussions for the BTSB. With respect to whether or not the leaflet provided a call-back option, ie. an option whereby a donor could call a centre and instruct them not to use his donation, Dr Lawlor agreed that no explicit call-back service was offered by the BTSB. Dr Lawlor said the facility became more explicit at a later date.

In November 1984 a revision of the leaflet was under consideration. This remained the case for most of 1985. Draft updates of the leaflet were prepared and Dr Lawlor agreed that recommendations from the U.S. public health service indicated that a revision of the

leaflet was due. Mr Durcan asked Dr Lawlor what was holding things up at the BTSB? Dr Lawlor said it may have been a case of the best holding out the good. Mr Durcan asked Dr Lawlor, did the delay arise on the basis that the BTSB should not revise the leaflet, having regard to what was happening with testing. Dr Lawlor agreed this may have been the case and that because of that the leaflet stayed the way it was.

Mr Durcan referred Dr Lawlor to the situation in Britain where the British authorities updated their leaflet in May 1985. Mr Durcan pointed out that the British revised the leaflet even though they had the same questions with respect to testing as did the BTSB. Dr Lawlor agreed that this was the case.

The BTSB's amended leaflet finally emerged in December of 1985. Dr Lawlor said one of the big worries for the BTSB was the fact that alternative testing sites were not available. Dr Lawlor said the lack of alternative sites was a tremendous worry for the BTSB. Without an alternative site the BTSB was concerned that people at risk would use the BTSB's services to avail of a test under the guise of giving a donation. Dr Lawlor said people were not inclined to go to sexually transmitted disease clinics.

Mr Durcan asked Dr Lawlor, could it be justified to have a period of a year going by when it was accepted that the leaflet needed to be updated, and that it wasn't updated? Dr Lawlor said she was not actually sure that it made any difference to the particular person they were talking about, but it was regrettable that it took so long. Dr Lawlor said the fast moving scene and the temptation to wait for the next bit of information to become available, may offer explanations as to why there was a delay.

Donor A, whose donation infected the Kilkenny health worker, donated on 16th July 1985. Donor F donated on 11th December 1984 and his donation went to the manufacture of cryoprecipitate and BTSB batch number 90753. Both these donors were screened by the leaflet which went unrevised from November 1984 until December 1985. Mr Durcan put it to Dr Lawlor that the bottom line was that the revision of the leaflet was delayed for a period of over one year. Dr Lawlor said this was so, but she did not know what the practical effects of that were. Dr Lawlor said Donor F had been exposed to drugs. The leaflet covered that, and that would not have changed. Mr Durcan said, would it be fair to characterise Dr Lawlor's evidence to say that the delay was excessive, but on the other hand no ill effects were caused. Dr Lawlor agreed that this was her evidence.

With respect to the introduction of testing, Dr Lawlor agreed that in February 1985 Dr O'Riordan had considerable doubts about testing. Dr Lawlor said this was a common view in Europe and it was regarded that testing was a U.S. problem. In March 1985 the AABB informed its members, including the BTSB, that tests were now licensed in the U.S. Tests on persons with haemophilia had already been conducted. Dr Lawlor agreed that this was the case and that tests had been carried out in British labs.

Dr Lawlor said the tests carried out on the samples provided by people with haemophilia were not tests applicable to blood banks. The tests now becoming available were licensed in the U.S. and were blood bank type tests. In March 1985 Dr Lawlor agreed

that viral tests were in being, but she said there was a shortage of kits. It was 2-6 weeks for tests to be used in blood centres. Dr Lawlor agreed that from the time of this announcement, an increasing number of kits should be available in circulation. However, Dr Lawlor said there was a delay in getting such test kits across the Atlantic.

In March 1985 Dr O'Riordan wrote to the Department of Health regarding the Abbott test. The Abbott test, said Dr O'Riordan, was unsatisfactory in that it recorded false positives. He informed the Department that he would wait until the Council of Europe had examined the matter, and would revert to the Department with further information.

Mr Durcan referred Dr Lawlor to a board minute of the BTSB, where the Department of Health has been informed that false negatives and false positives arising from tests provided grounds for a decision to defer the introduction of testing. This appears to be the first mention of false negatives. It is known that false positives provide a big problem for the Abbott test and there is no confirmatory test available. Dr Lawlor said the problem with false positives was that it led to a loss of blood, in that the donation could not be used, and also presented problems as to what action to take with regard to subsequent donations. Dr Lawlor said the presence of false positives was not a good enough reason for not introducing testing, but combined with other factors and the perceived wisdom that Ireland had a low risk population, it was understandable why testing did not proceed. With respect to false negatives, Dr Lawlor agreed that the problem here was that infections could be allowed into the blood pool, and also the existence of a test would attract potentially infected donors, increasing the likelihood of false negatives.

Mr Durcan put it to Dr Lawlor that the HTLV-III test was a useful tool for blood screening, but could not be regarded as an AIDS test as such. Dr Lawlor said the utility of the HTLV-III test at that time, was very much directed at the U.S. blood supply. Dr Lawlor said the magnet effect of attracting potentially infected donors outweighed any benefits that the introduction of testing might have offered at that time. Dr Lawlor said in April 1985, Ireland was a low risk population and it was important to assess all the tests. Mr Durcan put it to Dr Lawlor that, while it maybe the case that the BTSB thought the risk was low, it was not low enough. Dr Lawlor agreed that the perception of low risk may have engendered unjustified feeling of confidence in the blood system by the BTSB.

Mr Durcan referred Dr Lawlor to a document prepared by Mr Keating in May of 1985. The document deals with issues such as donor consent to testing and psychological repercussions of reporting a positive test to a donor. The document notes that a priority for the blood transfusion services must be to disassociate themselves from any publicity linking them with the transmission of AIDS, otherwise a considerable number of low risk donors will be lost and the blood supply may become less safe through participation of high risk donors. Mr Durcan put it to Dr Lawlor that the reality was that there was a possibility that blood transfusion could transmit AIDS at this time. Dr Lawlor said that this was the case, but transfusion-associated AIDS was a much lower risk than other ways of contracting the disease. Dr Lawlor's explanation for this comment was that

donors may have had concerns that they could become infected by giving a donation, and while this was an impossibility, the BTSB tried to distance itself from the AIDS issue.

On 6th June 1985 Mr Cann notified the national director, Dr O'Riordan, that kits were available and that testing of the kits would commence. Mr Durcan put it to Dr O'Riordan that testing of the kids wasn't to evaluate the efficacy of the kit but to test whether or not it was possible for the BTSB to use the kit, and for the ease of use of the kit. Dr Lawlor said the BTSB was not in a position to evaluate the test *per se*, and what the BTSB sought to do in testing the kits was to evaluate it for ease of use by the BTSB.

On 1st July 1985 the AABB set its deadline for the introduction of HTLV-III testing. Mr Durcan put it to Dr Lawlor that what had been desirable now became mandatory, according to the AABB. Dr Lawlor agreed that this was the case. Mr Durcan put it to Dr Lawlor that any test would have been better than none at this stage, from an absolute safety view point. Dr Lawlor said, no, the magnet effect would make the situation worse, in that the availability of a test would attract infected donors. Dr Lawlor said in this situation no transfusion would be safe. Dr Lawlor said that it was worth getting the test right, and in this sense the BTSB took an understandable course of action.

Mr Durcan asked Dr Lawlor, did the BTSB put the infrastructure for administering the test in place while awaiting the outcome of its evaluation results? Dr Lawlor said it would have been a good idea if the BTSB had taken steps to allow it to introduce testing quickly once it was decided on which test to use.

On 19th June 1985 the BTSB board was informed that information regarding testing would be available in 3-4 months time. Dr Lawlor agreed that this suggested a lack of priority with respect to testing. Mr Durcan said that putting it all together, in that Dr O'Riordan was not convinced about the necessity of testing; there being no application as regarding grants or money to put testing in place; in June of 1985 the board being informed that testing would be available in 3-4 months time - all of this suggested a rather casual approach to the issue of testing by the BTSB? Dr Lawlor said that Ireland and Europe generally were slow to introduce testing. She said that testing was introduced here at the same time as testing was introduced in the UK. She agreed with Mr Durcan that the low risk population meant that testing was not a matter of absolute priority with the BTSB.

Mr Durcan referred Dr Lawlor to the manufacture of factor IX. Mr Durcan pointed out that it would appear that the BTSB was wrong in its thinking regarding the viral inactivation properties of the factor IX process. Mr Durcan said that the thinking on all these things appeared to be wrong. Mr Durcan put it to Dr Lawlor that the introduction of early testing, and the introduction of heat treated FIX earlier, would have given an element of protection. With regards to why testing was not introduced, Dr Lawlor said the issue of false negatives, false positives and the magnet effect, and a genuine concern about the alternative testing sites contributed to the delay.

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Mr Gerard Durcan S.C. continued his examination on behalf of the Tribunal, of Dr Emer Lawlor of the BTSB. Dr Lawlor agreed with Mr Durcan that the BTSB could have commenced testing as soon as test kits became available. Dr Lawlor said the Wellcome test kit did not become available as early as other test kits, but the BTSB could have looked at putting the infrastructure for testing in place, and obtaining funding from the Department prior to the actual introduction of testing. Dr Lawlor said the issue of funding may have been addressed in the usual ritual between the BTSB and the Department of Health, but she did not believe the lack of funding delayed the introduction of testing.

On 16th September 1985 Mr McCartney of the Department of Health wrote to Dr O'Riordan, referring to Dr O'Riordan's letter of 12th September of that year and their subsequent telephone conversation. Mr McCartney confirmed to Dr O'Riordan that it was now imperative that the Blood Transfusion Service Board introduce routine testing of all blood donations immediately. Representatives of the Department of Health were available to talk to the BTSB regarding any funding required. Dr Lawlor said the imperative nature of the Department of Health's instruction arose because Britain was about to introduce testing. Dr Lawlor agreed that in September 1985 the issue of testing suddenly took on an urgency that simply wasn't there before.

Mr Durcan referred Dr Lawlor to a letter from Mr Ryan of the Limerick Blood Transfusion Service. The letter was sent on the strength of an article in AABB to Dr Holland in the United States. Mr Ryan was enquiring as to Dr Holland's findings regarding test kits. Dr Lawlor said this letter was extraordinary and Mr Ryan should have contacted the BTSB or someone in Britain. Mr Durcan asked Dr Lawlor, was it not reasonable for Mr Ryan to contact someone in the U.S., given that the U.S. had more experience in administering tests? Dr Lawlor said that the U.S. did not use the Wellcome test because it was not FDA approved, so there was no point in contacting sources in the U.S. to discuss the test proposed to be used by the BTSB. Dr Lawlor said she did not think contacting U.S. sources was the best way to deal with the problem. Dr Lawlor said the U.S. population was quite different from that of Ireland. Dr Lawlor agreed that she found it extraordinary that Dr Ryan had contacted the U.S. to discuss testing, rather than writing or contacting the BTSB in Dublin. Dr Lawlor said Mr Ryan should have been contacting his own side.

On 18th September 1985, upon the directive of the Department of Health, testing commenced. No alternative sites had been put in place at this time, however Dr Lawlor said the tests had now been evaluated and the need was now greater, and it would have been wrong not to introduce testing.

Mr Durcan asked Dr Lawlor, was it a fact that no alternative sites had been provided at this point, and would this not indicate that alternative sites were not an absolute reason for delaying testing? Dr Lawlor said it was necessary to introduce the test even though Ireland remained a low-risk population; there was a 1:50,000 risk of getting an infected

donor at this time. Dr Lawlor said the risk of infection was much greater in the U.S. than in Europe, and given the concerns about attracting HIV positive donors with the availability of a test, Dr Lawlor indicated that the magnet effect was a genuine concern with the BTSB. However, Mr Durcan said that even with the magnet effect, was it not the case that the BTSB introduced testing without alternative sites being available? Dr Lawlor agreed that this was the case.

Mr Durcan then referred Dr Lawlor to a document prepared by Mr Cann containing questions arising upon the introduction of testing. Dr Lawlor said no policy emerged from these questions. With respect to informing HIV donors of their status, Dr Lawlor said the questions remained unanswered. It was not known who was going to tell donors how much information they were to be given, whether they would be told directly or whether their doctor would be told. Dr Lawlor said things were moving fast and a policy had not been worked out. No written policy existed. Dr Lawlor said that not just the BTSB held these views of testing. Dr Lawlor said such views were also entertained by the Department of Health and experts such as Dr Freidman. Dr Lawlor said the urgency to introduce testing in Ireland was less as the risk of infection was less.

Mr Durcan then referred Dr Lawlor to the look-back section of the Tribunal's investigation. In the first instance, Mr Durcan referred Dr Lawlor to Council of Europe minute of 7th July 1985, which had been sent to Dr O'Riordan. This document recommended a follow-up of five years on positive donations. However it did not recommend any follow-up with respect to persons with haemophilia A and haemophilia B who may have been infected with blood concentrates. With respect to notification of recipients it was recommended that donations of positive donors should be traced for a period of five years, and any recipients within this period should be notified. This recommendation was reiterated by Dr Gunson.

By mid 1986 look-back along these lines was introduced in the United Kingdom, however it was not introduced by the BTSB. In June 1986 the AABB introduced a look-back and provided a definition of the process. A look-back policy is the tracing of donations of blood from donor to recipient. If a current donation is found to be positive for antibodies to HTLV-III (ELISA positive repeatedly reactive and confirmed by western blot) then a look-back should take place.

A document from Mr Hanratty arising from his attendance at the Sydney IBTS conference in May 1986 notes that the AABB look-back system is in operation in the U.S. By 13th July 1987 the BTSB had identified a number of HIV positive donations. A memo generated by Dr Walsh to Dr Barry details various cases of persons whose donations had been found to be positive, and who had donated on previous occasions. Dr Lawlor agreed that this appeared to be so. Dr Lawlor said she presumed that this document was generated in respect of an anticipated look-back by the BTSB. Dr Lawlor said that if a look-back was going to be done, this was the time it should have been done.

Mr Durcan referred Dr Lawlor to Council of Europe documents of March 1988, concerning the effectiveness of look-back. In these documents a Dr Hogman of Sweden

examined a period from 1980 to 1984 and noted the increasing risk of HIV infection. Dr Hogman's research shows the risk increasing from 1980 to 1985. It was agreed that the latter part of this period presented a peak risk in which donations were infectious. These were the years 1984 and 1985.

Mr Durcan asked Dr Lawlor should it not have been obvious at the time that these were indeed the high risk years, and should have been looked at in an organised look-back? Dr Lawlor agreed that this should have been done but wasn't. She said she does not know why it wasn't done. She said they may not have thought about it.

Mr Durcan asked Dr Lawlor, was it not obvious that a look-back should have been done? Dr Lawlor agreed that a real risk emanated from the positive donations recorded. With respect to looking for HIV infected components, Dr Lawlor agreed that the records concerning these components were in being at that point. The despatch records were there to show where various products went, and would have facilitated a look-back had such an exercise taken place at the time. Dr Lawlor agreed that had such a look-back taken place at the time, it would have cut down the risk of onward infection.

When look-back was introduced by the BTSB it took the form of contacting the donor and then contacting his or her GP. The BTSB did not address the issue of previous donations. Dr Lawlor said there was reluctance to tell the recipients of previous donations due to the trauma which would ensue upon being told such news. Dr Lawlor agreed that the situation was that donors were being told but recipients were not being told. She agreed with Mr Durcan that this situation was completely unsatisfactory.

In a document completed for the Council of Europe on 3rd – 6th 1988, Dr Walsh reported to the Council of Europe that the variability of hospital records was causing problems in conducting a proper look-back. Mr Durcan asked Dr Lawlor, was it the case that hospital transfusion records were causing problems with respect to look-back, and if so, how could such problems be caused given that the BTSB still had its own despatch records in its possession? Dr Lawlor said she did not know the answer to these questions.

Mr Durcan referred Dr Lawlor to a look-back request from Dr Mulcahy concerning positive donations from Donor H into the Anti-D pool. Dr Walsh responded by saying that no evidence of HIV infectivity had been found among recipients of Anti-D, and a look-back as requested by Dr Mulcahy was therefore unnecessary. He reminded Dr Mulcahy that there are ethical implications of testing for HIV without permission.

In response to a questionnaire from the Council of Europe, the BTSB reported that no transfusion-associated HIV infection had been found to date in Ireland other than in haemophiliacs who received commercial clotting concentrate. Dr Lawlor agreed that this was incorrect as there had been seroconversions from BTSB product at this stage, ie. not commercial concentrates.

Mr Durcan then referred Dr Lawlor to the donation of Donor F. Donor F was found to be positive on 31st August 1990. He had previously donated in December 1984. The

BTSB did not carry out a look-back on the 1984 donation as it had been made five years prior to the donation which subsequently tested positive. Donor F's donation of December 1984 was infected with HIV. Donor F's donation was made into cryoprecipitate, the supernatant of which went into BTSB batch 90753. In order to determine the disposition of Donor F's cryo, Mr Durcan asked Dr Lawlor had a look-back actually taken place in January 1991? In addition to cryo and factor IX, red cells from donor F were also used. Mr Durcan referred Dr Lawlor to a document which indicated Mr Keating investigated factor IX used by the NHTC. The document is entitled: information sought on 21st August 1990 - confidential. Dr Lawlor said that this was prepared in anticipation of litigation. Dr Lawlor said she had no knowledge of an investigation which took place into this matter in January of 1991.

Mr Durcan asked Dr Lawlor, would the investigation of January 1991 indicate that a process had been followed through to ensure that donation 901600 had in fact gone into batch 90753? This was the donation of Donor F. Dr Lawlor agreed that this was the case. Mr Durcan put it to Dr Lawlor that the person conducting the investigation, putting the information at his disposal together, would have seen that it was highly likely that 90166 was an infected donation and this had gone into a batch of cryo, and had gone into a batch of factor IX? Dr Lawlor said this may have been the case if it had been thought through at the time. However, there was an element of denial with respect to Irish factor IX, and it was also an element of hindsight in what Mr Durcan was saying.

Mr Durcan said was it not also an issue of foresight, as the Tribunal had already heard in August of 1986 that the BTSB was aware that BTSB factor IX had caused HIV seroconversions in six or seven haemophilia B patients? Dr Lawlor said it appeared to her that this was something that had never actually been accepted by the BTSB. Mr Durcan pointed out that both Dr Walsh and Mr Keyes had accepted that by August 1986 there was absolutely cogent evidence that BTSB factor IX had caused the infections.

With respect to the investigation that took place in January 1991, it would appear that 90753 had been identified, and the cryo therefrom had been identified as being derived from donation 906100. Mr Durcan asked why no look-back had taken place at that stage? Dr Lawlor said it should have taken place. Mr Durcan put it to Dr Lawlor that in January 1991 a look-back was not only desirable, but absolutely necessary. Dr Lawlor agreed that this was the case. She also had agreed that the despatch records of the BTSB were intact and available to assist in any look-back at this time.

Mr Durcan referred Dr Emer Lawlor of the BTSB to the case of the Kilkenny health worker. Dr Lawlor said an investigation into the HIV positive donations was taking place. A list of 31 HIV positive donations and products therefrom had been attached to a hepatitis C look-back. Of the 31 suspect donations, 15 were prior to 1991, 16 were of real concern, and 3 related to the period of greatest infectivity in 1984/1985.

Dr Lawlor said the destruction of despatch records meant that when the list of HIV positive donations became available to her in April 1995, it was very difficult to trace where these products had gone. Dr Lawlor said that when she looked in the BTSB safe and found the record of HIV positive donations prior to 1986, she was dismayed, because at this stage she knew that the despatch records for this period had been destroyed and that it would prove very difficult to look back on these donations in the absence of the despatch records.

Mr Durcan put it to Dr Lawlor that if there was ever to be a look-back to the pre-1985 donations, that the very act of destroying the despatch records was going to make it infinitely more difficult? Dr Lawlor agreed that this was the case. With regard to the Kilkenny health worker, the records at St. Luke's Hospital were in good order and no difficulty arose in tracing from them. Further, at Wexford no difficulty arose in tracing platelets. Dr Lawlor said that the platelet issue was facilitated by the fact that a name was available on a platelet request form and that, matched to the hospital record chart, enabled tracing to take place. The Kilkenny health worker's hospital record containing the infected transfusion was presented to the BTSB on 13th December 1996. In and around the same time the Kilkenny health worker independently learned that she was suffering from HIV.

Mr Durcan referred Dr Lawlor to her discussions with Prof. Temperley concerning the HIV outbreak in 1986. This discussion took place prior to the Medical Advisory Committee meeting in January 1997. At that meeting Prof. Temperley indicated he wished to place on the record that he suspected an outbreak of HIV in haemophiliacs in 1986 was related to blood products received from the BTSB. Mr Durcan asked Dr Lawlor in what context did Prof. Temperley wish to place this comment on the record?

Dr Lawlor said that Prof. Temperley had told her in that summer that he felt the BTSB had never accepted that factor IX infections were related to the Irish product. Dr Lawlor said she told Prof. Temperley what she had found in the summer of 1996, that BTSB products had in fact infected people with haemophilia B in 1986. Dr Lawlor said that 1996 was not the first time she had heard that BTSB product may have been involved in the infection with HIV of people with factor IX deficiency. However, Dr Lawlor said that any time the issue was discussed, it was always said that the infection was not related to BTSB product, and as she had not done any investigation she accepted what was said. Mr Durcan asked Dr Lawlor when was the first time that she became aware that BTSB

product had caused seroconversions in haemophilia B patients, which had manifested itself in 1986? Dr Lawlor said it may have come up at a MAC meeting in 1991, at the time of the litigation. Mr Durcan asked Dr Lawlor when the issue came up in discussions in 1991, was it accepted that BTSB product had caused seroconversions, or was it suggested that it was probable that the BTSB product hadn't caused the seroconversions. Dr Lawlor said it was suggested that it probably hadn't. Mr Durcan asked Dr Lawlor who had made this suggestion. She informed Mr Durcan that it was Dr Walsh. Dr Lawlor agreed that from that time onward she was under the impression that seroconversions in haemophilia B patients had been caused by commercial products.

Dr Lawlor said when she looked at the files in 1995 she did not know BTSB factor IX had caused infection. She became aware of this fact upon conducting her investigations in the summer of 1996.

Mr Durcan asked Dr Lawlor what was her reaction when she became aware that some of the infected donations had made their way into the factor IX pool and had gone on to infected people? Dr Lawlor said her reaction was obviously that this was bad, but this was at a time when HIV was being transmitted through blood products and it wouldn't be entirely surprising if BTSB product, rather than commercial concentrates, had actually caused a problem. Dr Lawlor said there wasn't anything that could be done about that at that time. Mr Durcan asked Dr Lawlor had no-one ever told her about the events that took place in the spring and summer of 1996? Dr Lawlor said, no.

Mr Durcan asked Dr Lawlor, was it the case that there was a lot of information concerning the events of 1986 which might have thrown light on the material she was reading in the files? Dr Lawlor agreed that this was the case, but that she didn't know it and obtained her information by a separate route. Dr Lawlor said when herself and Prof. Temperley sat down to assess the information, he had knowledge which tied up the story in terms of the patients. Dr Lawlor said this information may have been in the BTSB's files but she hadn't seen it at that stage. Dr Lawlor said herself and Prof. Temperley sat down in 1997, when it was clear there was going to be a Tribunal, and that the whole issue needed to be sorted out, and it was then going to be done.

Mr Durcan then referred Dr Lawlor to a minute of the Medical Advisory Committee of the BTSB of 11th March 1997. The minute states, "IT outlined the history of positive HIV seroconversions in haemophilia B patients after May/June 1985, when the vast majority of haemophilia A patients were infected by commercially infected factor concentrates. Factor IX concentrates produced by the BTSB could not be excluded in the case of haemophilia B patients. Investigations by Emer Lawlor discovered that a donor who was positive for HIV in 1990, donated in late 1984. The plasma had been included in a pool which was used to product unheated factor IX concentrate." This concentrate was issued from August 1985.

Dr Lawlor said that of 32 suspect donations, three have never been traced. With respect to factor IX made from the donations of the infected Donor F, Dr Lawlor said factor IX from this donation was infectious, but the red cells made from the donation were not

infectious. Dr Lawlor said the investigation conducted by her was only into the red cell portion and the cryo portion; the factor IX portion was not circulated, said Dr Lawlor, because the BTSB knew where that product had gone.

Of three infectious donations traced by the BTSB, one went into the Kilkenny health worker and caused infection, the other one was traced to the red cells of donation number 901600. Dr Lawlor said the red cells didn't cause infection and the cryo from this batch didn't cause infection, as far as she knew, because it went into somebody who was already unfortunately infected. That was the most likely explanation. However, the cryo supernatant which went into the factor IX, did cause infection. Dr Lawlor agreed that two out of the three donations traced by her caused infection. Dr Lawlor agreed that if the look-back procedure had taken place earlier, then more of the donations would have been traced. As it was, three out of six high-risk donations remained untraced. Mr Durcan put it to Dr Lawlor that the failure to hold a look-back at the earliest possible time, had real consequences in the context of the success of the look-back exercise. Dr Lawlor agreed that this was the case.

Dr Lawlor was then cross-examined by Mr James Connolly S.C. for the Kilkenny health worker. With respect to look-back, Dr Lawlor agreed with Mr Connolly that a look-back should have taken place in 1987, and that the information available to those within the BTSB, including Dr Barry, Dr Walsh and Mr Keyes, should have been acted upon in that year. Dr Lawlor agreed that it was unconscionable that such a look-back did not take place at that time.