IRISH HAEMOPHILIA SOCIETY

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TRIBUNAL OF INQUIRY

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

PROCEEDINGS: JUNE 26th, 2000 – DAY 16

John Finlay S.C. continued his examination in chief of Dr Emer Lawlor of the BTSB. Mr Finlay said he would deal with:

1) Self sufficiency from 1st January 1985 until 1990.
2) Viral inactivation, with particular regard to the risk of Hepatitis C during the period 1985 to 1990.

Mr Finlay noted, and Dr Lawlor agreed that, with the exception of one haemophilia A patient who seroconverted in 1986, and the haemophilia B patients who seroconverted in1985 and 1986, no further infection of a person with haemophilia with HIV occurred during the period 1985 to 1990. Mr Finlay said he would also examine the issue of the effectiveness of dry heat treatment against the risk of infection with Non-A, Non-B Hepatitis.

1) <u>Self Sufficiency</u>

It was noted that, at the start of 1985, the Department of Health authorised the recruitment of staff to allow the Board achieve self sufficiency. Dr Lawlor pointed out it was noted in the Minutes that such recruitment should take place whilst at the same time complying with the national embargo relating to public sector recruitment.

In July 1985 the first consignment of BTSB plasma was despatched to Travenol's factory at Lesine, Belgium. The Tribunal referred Dr Lawlor to an article cited in her statement of evidence, concerning the recent evolution of clotting factor concentrates for haemophilia A and B. This article is by Kasper, Lusher et al of Transfusion Practices Committee, published by In Transfusion of 1993. This article provides a retrospective on the period in question.

Returning to the period under examination, Mr Finlay referred Dr Lawlor to the National Haemophilia Services Co-ordinating Committee Meeting of the 15th February 1985. At this meeting, the proposal to contract fractionate BTSB plasma was discussed. Discussion took the form of considering a 16-point plan where the various elements of the plasma procurement and contract fractionation programme were detailed. Directors of the National Haemophilia Treatment Centres voted against the proposals, the directors of the Haemophilia Service being Prof. Temperley and Dr Cotter. Prof. Temperley continued to protest at being excluded from the negotiations surrounding contract fractionation, and directed his protests to Dr O'Riordan.

The process under which Travenol came to be selected as the contract fractionator was examined. The fractionation would take place at Travenol's plant in Belgium. A high purity product was to be produced. The specific activity of the proposed product, Hemofil, was 1.6 units/mg. Dr Lawlor agreed that this was a good level of concentration.

The product would be dry heated at 60^0 Centigrade for 72 hours. Standard packaging home care kits would be provided. A batch size of 3000 litres was required.

A critical aspect of Travenol's proposals was a predicted yield of 20%-22%, which Dr Lawlor agreed was high for a heat treated product. Another crucial factor was that Travenol would pay the BTSB £23.00 per litre for plasma. The Travenol contract therefore became the basis of the BTSB's newly defined self sufficiency programme.

Dr Lawlor agreed that the heat treatment protocol used in the Travenol fractionation contract was not directed towards the viral inactivation on Non-A, Non-B, but was designed to inactivate HIV.

At the same time as the BTSB was coming to its arrangements with Travenol, *The Lancet* of June 1985 published an article by Hay, Triger and Preston, entitled "Progressive liver disease in haemophilia: An understated problem". The article noted that recent publicity about AIDS and haemophilia has overshadowed the problem of liver disease. The article noted that, in an eight year study of 79 unselected patients with haemophilia who had received clotting factor concentrates, there was evidence of chronic liver disease in 17. Eight patients had chronic, active Hepatitis and nine had cirrhosis. The thrust of the article was that Non-A, Non-B Hepatitis was not as benign as was previously thought.

At a BTSB Board Meeting on 17th July 1985, the National Director, Dr O'Riordan, reported the first consignment of plasma had been despatched to Belgium. When it was put to Dr Lawlor by the Tribunal, that a profit of £266,000 would accrue on an annual basis to the BTSB from the fractionation contract. Dr Lawlor described this as a self financing project. The Tribunal agreed that a small operating profit would be derived from this arrangement.

In a letter of 4th June 1985, from Prof. Temperley to Prof. McCann, Prof. Temperley indicated that he was in agreement with the contract fractionation arrangement entered into by the BTSB with Travenol. However, he appeared to have some reservations. He noted that the commercial company decided upon does not have a high reputation in Ireland or Britain in the field of concentrate production. Opposite this remark, someone has added the word "extraordinary comments".

By the end of 1985 no improvement had occurred with respect to Non-A, Non-B Hepatitis. The Haemophilia Centre Directors Hepatitis Working Party Reports for 1984/1985 note that Travenol dry heated concentrate showed little or no reduction in associated cases of Hepatitis.

In 1986 the Travenol product was on stream, but the yields predicted were not achieved. At this point Mr Keyes has been appointed Executive Consultant of the BTSB, and reported the situation to the Department of Health with respect to failure to achieve self sufficiency. The target date for self sufficiency of January 31 1986 would not be met.

The decision to use only heat-treated products, and the discontinuance of cryoprecipitate, has increased the plasma requirement from 12,000 to 18,000 litres. The combined problems of a low yield and a difficulty in meeting the target for

plasma, made self sufficiency difficult to attain. Dr Lawlor agreed with this proposition from Mr Finlay.

At this stage, the BTSB was looking round for other possible contract fractionators for its plasma. On 29th October 1986 a delegation from Elstree fractionation centre in London visited the BTSB. The delegation met Mr Keyes and Mr Hanratty, and informed them that the Elstree centre was fractionating factor VIII and using a heat treatment protocol of 80^0 centigrade for 72 hours. It was noted that in 18 months of use, no evidence of Non-A, Non-B Hepatitis had emerged. Previously all recipients of factor concentrates had developed Non-A, Non-B. The product was also presumed safe for HIV.

In addition to producing factor VIII, the Elstree plant was also producing factor IX heat treated. It was also indicated by the Elstree delegation that they would not be in a position to carry out contract fractionation until 1988 at the earliest. Dr Lawlor said that the BTSB would not be in a position to undertake the heat treatment regime utilised by Elstree with regards to factor IX.. Dr Lawlor said she was not aware of any further enquiries made with Elstree at the beginning of 1988, as to whether or not they could fractionate for the BTSB.

The Minutes of a BTSB Board Meeting on 20th November 1986 noted that the Board was not making progress towards the Government's policy on self sufficiency. In this regard, two companies were to fractionate plasma for the BTSB – the companies being Cutter and Armour. At the same Board Meeting it was noted that the visitors from Elstree had been seeking Anti-D material, and it had been agreed to make some available to them. They were to quote a price for factor IX fraction for consideration of plasma. It was noted that Elstree was not taking any outside work until 1st January 1988. Thereupon the entire plasma programme would have been reviewed.

2. Viral Inactivation – Hepatitis C

While the BTSB continued its project towards self sufficiency, debate concerning viral inactivation with respect to Hepatitis intensified. At a scientific meeting on 23rd March 1987, Miss Cunningham, in a discussion about various methods of heat treatment, noted that the British protocol of 80^0 Centigrade for 72 hours was effective for Non-A, Non-B and AIDS. In an assessment of the state of knowledge with respect to Hepatitis Non-A, Non-B at the start of 1987, it was noted that pasteurisation was effective against transmission of the Non-A, Non-B virus. Dry heat-treating was less effective. Therefore in 1987 it was known that dry heating was ineffective in preventing Hepatitis, and other methods of viral inactivation were more successful in varying degrees, in eliminating Non-A, Non-B.

In April 1987, Dr Walsh contacted the Swiss Red Cross, with a view to investigating alternative fractionation arrangements, the Swiss Red Cross informed Dr Walsh that it used a solvent/detergent method with respect to viral inactivation for Non-A, Non-B.

Dr Lawlor said the BTSB was not in a position to use solvent/detergent as a viral inactivation for its own factor IX solvent/detergent was not an end stage procedure. Solvent/detergent inactivation is added to the product in the course of manufacture. Without large scale capital investment, the BTSB would not be in a position to undertake a project of this nature.

At a meeting of the NHSCC, the issue of pasteurised viral inactivation was discussed, as was monoclonal viral inactivation. Dr Lawlor noted that both these methods would have problems in terms of yield.

Under the BTSB's contract fractionation arrangement with Armour, the BTSB agreed to take back all the product made from its plasma. Under the arrangement, Armour would supply the BTSB with factor IX. The BTSB would carry out viral inactivation on this factor IX, and proposed to do so using Travenol's heat treatment method.

The Tribunal noted that in September 1987, and experiment was carried out by Miss Cunningham, in which factor IX was heat treated in water at 60^0 centigrade for 72 hours. Mr Finlay noted that this was not a form of heat treatment that had been encountered elsewhere. Dr Lawlor indicated she was unable to assist the Tribunal as to the purpose of this experiment.

On 18th November 1987, Mr Keyes analysed the costs of doing business with Armour. The cost to the Board of the Armour contract fractionation arrangement would be a total of £900,000. Mr Finlay contrasted this arrangement with that which pertained in the contract with Travenol, whereby the Board stood to make a profit of about £200,000. Dr Lawlor indicated she could not help the Tribunal with regards to financial matters. It was indicated that Mr Keyes would be giving evidence in due course, and that he will deal with this matter.

In December of 1987 it was indicated, in a Report of the Chief Executive, that Travenol had agreed to allow the BTSB to use its patent for factor IX production. He also indicated that an arrangement had been entered into with Armour. The contract fractionation arrangement with Armour did not feature a written contract. The Tribunal noted that, almost as soon as the arrangement had been entered into with Armour, the company sought to change the arrangement. In January 1988, Armour voluntarily withdrew heat-treated factor VIII which was suspected of causing seroconversion in Canadian haemophiliacs.

On 27th January 1988, Armour wrote to the BTSB and indicated that the parent company had made a decision that it would not be involved in either custom fractionation or toll manufacture of any factor VIII products, other than its own current product, Monoclate. In these circumstances, Armour sought an indemnity from the BTSB, under which the BTSB shall indemnify and hold harmless Armour Pharmaceutical and its affiliate companies (Armour) and Officers, Directors and employees of Armour, from and against all and any third party liability in respect of HIV, Hepatitis or other viral infection arising from the sale, handling, promotion, or use of factor concentrate including, but not limited to, settlement costs, judgements and attorney's fees. This indemnity shall be indefinite in duration and shall survive expiration of the agreement. Armour indicated it would not manufacture factor VIII beyond the end of December 1988. Furthermore, the BTSB was to supply only plasma tested for Hepatitis B surface antigen and HIV antibody. All Armour trademarks and company names would be removed from product supplied to the BTSB.

In response, Dr Lawlor said the request for an indemnity arose because there was a move in the U.S. away from dry heated treatment, from intermediate purity to high

purity product. Obviously the company would not want to manufacture two different products. She noted that Armour did in fact continue to fractionate for the BTSB for some time. So obviously they came to terms with it.

The request from Armour for an indemnity from BTSB was discussed at the BTSB Board Meeting on 17th February 1988. The CEO explained this request had very serious implications for the Board. The production of factor VIII would cease on 31st December 1988, and thereafter the Board would be faced with a choice of Monoclate or pasteurised product. Both products had implications for the goal of self sufficiency. The CEO also indicated that the matter of the indemnity would be dealt with strictly in accordance with advice from the Board's solicitors, and that any final indemnity would be approved by the Board before it was actually signed.

In May of 1988, the BTSB was faced with three options, according to Mr Keyes:

1) To continue production of factor VIII. It was noted that this would be possible for only a limited time, as Armour had indicated it would cease production of factor VIII for the BTSB at the end of the year.

2) Change to monoclonal derived factor VIII. It was noted that this option would at least double the cost of producing factor VIII. Additional plasma would also be required, but this may be compensated for by improved patient response to this treatment.

3) A change to pasteurised product. It was noted that self sufficiency could not be achieved with a change to pasteurised product.

It was also noted that the continuation of factor VIII may present product liability problems.

Dr Lawlor said these product liability problems arose because Armour wanted to transfer product liability to the BTSB, and also product liability acts were about to become law.

The Tribunal examined the UK Haemophilia Reference Centre Directors document of 16th May 1988. The purpose of the document was to present the view of the Reference Centre Directors on the relative merits of therapeutic products which were available in the UK, or likely to become available in the near future. The document evaluated the various products on offer, and said that least risk products were recommended for use on previously untreated patients and those not previously exposed to regular therapy. The purpose of the assessment was to reduce the risk of Hepatitis infection among children, and those who required occasional therapy only.

In 1988, Armour Pharmaceutical Co. was fractionating plasma for the BTSB. The arrangement, however, was uncertain, as Armour had indicated that it would not continue fractionating beyond the end of that year. Armour had indicated it wished to produce only monoclonal product, and was reluctant to supply the BTSB with heat-treated product. Armour was so uneasy about continuing to supply heat-treated product that it sought an indemnity from the BTSB as to any liability which may arise from the use of such products.

In continuing his examination of Dr Emer Lawlor, Mr John Finlay S.C. for the Tribunal, put it to Dr Lawlor that the Board had, at a previous Board meeting, asked that Prof. Temperley's views be sought in relation to what was to happen about the fact that Armour was no longer willing to continue production beyond the end of 1988. Dr Lawlor agreed that this was the position the BTSB found itself in at the time.

The Tribunal then read a letter which set out Prof. Temperley's views. The letter, dated June 14th, 1988 was from Prof. Temperley for the benefit of the Board, and was addressed to Mr Keyes. The Tribunal described this as a document of some importance and read the letter in full, as follows:

> "Dear Mr Keyes, I regret I will be unable to attend the Board meeting on 15th June 1988. I trust, however, that the contents of this letter will assist in arriving at a satisfactory decision regarding factor VIII production in 1989. The included suggestions are made following discussions with representatives of the Board, including Dr Walsh, UK Directors of the Haemophilia Reference Centre Directors, and other experts in the world-wide haemophilia community.
>
> All products mentioned are considered to have a negligible risk of HIV infection. Factor VIII concentrates, following the AIDS disaster, may be regarded as belonging to first, second and third generation products. The present product, using Irish plasma fractionated by Armour, is heat treated for 72 hours at 68^0 centigrade, and belongs to the first generation group. This group is being rapidly removed from the world market, partially because of previous HIV disasters, and also because dry heat treatment seems inadequate to destroy Non-A, Non-B Hepatitis virus.
>
> There are likely to be commercial considerations, also. Only one first generation product has retained its reputation in relation to HIV infection and remains on the market. Cutter Koate HT is a product which, until recently, was used intensively by the National Haemophilia Treatment Centre. The heat treatment conditions of this product are those insisted upon by the Board and the Centre when the recent contract to fractionate Irish plasma was granted to Armour.
>
> The Board is aware that Armour is only producing a first generation product for the Irish market, as it has a strong first generation product from the world market. The Board is also aware that Cutter only fractionate in the U.S., and Irish plasma is not permitted to enter the U.S. Thus, the Board is dependent upon a unique concession from Armour to produce a first generation product for Irish haemophiliacs.
>
> Second generation products are either wet heat-treated or dry heated to 80^0 centigrade, rather than 68^0 centigrade, as for the first generation products are solvent/detergent

treated. These products decrease the risk of Non-A, Non-B Hepatitis infection. Of those, Haemate P (Boeringer), a pasteurised product, and NHS 87 treated to 80^0 centigrade have been given adequate trials. The former is available commercially and will be used by the National Haemophilia Centre for infants and young children who have not come in contact with blood products.

The problem with second generation products is the price. Pasteurised products are at least twice the price of dry heated products. Third generation products are monoclonal purified Armour and Baxter. They are as yet unlicensed and still involved in clinical trials. They would appear to be associated with minimal risk of Non-A, Non-B Hepatitis transmission. There is no definite idea of cost, but they are likely to be at least twice the cost of dry heated products.

The Board should understand that, in the present period of financial stringency, the hospitals could not be expected to meet a doubling of the cost of concentrate in 1989. Some balance will have to be struck between cost and the infection danger associated with blood products.

Using Cutter Koate HT and the Irish plasma Armour products, no new HIV seroconversion has occurred for at least twelve months. Virtually all our treated haemophiliacs have had Non-A, Non-B. There is no definite evidence that crude products such as Irish plasma, Armour factor VIII products produces immune deficiency, despite their large content of protein. In my view, therefore, the logical conclusion for the Board is to make every effort to obtain Armour's agreement to take on production of factor VIII concentrates using Irish plasma for 1989 in the same manner as for 1988. This would have my support as Director of the National Haemophilia Centre. For virgin patients, that is usually infants, Haemate P will be used to protect them from Non-A, Non-B."

On the basis of this letter the BTSB continued its fractionation arrangements with Armour into, and up to the end of, 1989.

The Tribunal noted that Dr Temperley's letter did not touch upon the supply of factor IX. Dr Lawlor said the supply of factor IX was part of the Armour contract, and may be one of the reasons that favoured its continuation.

The Tribunal noted the difference between the factor VIII being supplied by Armour and the factor IX being supplied to the BTSB and heat-treated by the BTSB. The difference being the fact that the Armour factor VIII was heat treated according to the Cutter method at 68^0 for 72 hours, whereas the BTSB factor VIII was now being heat treated at 60^0 for 152 hours. 68^0 for 72 hours was effective for HIV. Neither heat treatment regime was associated with the prevention of Non-A, Non-B Hepatitis.

Mr Finlay said that Dr Temperley's advice appeared to be based on the idea that if a person had already been exposed to Non-A Non-B Hepatitis by previous treatment such a person was not at any greatly increased risk by taking product which was not virally inactivated for Non-A Non-B. Dr Lawlor agreed with this proposition.

With respect to those who had not been exposed to Non-A, Non-B, such as young children and those not exposed to previous therapy, Dr Temperley advised that special arrangements

would be put in place for them, namely that they would be treated with Haemate P. Dr Lawlor further agreed to this proposition.

The Tribunal then noted that similar arrangements did not appear to have been referred to concerning those using factor IX for the first time, or non-regular users of factor IX. In which case, they would be newly exposed to the risk of Non-A, Non-B Hepatitis infection. Mr Finlay put it to Dr Lawlor, in relation to the policy suggested by Prof. Temperley and accepted by the Board, that it was absolutely critical to that policy that special arrangements would be made for previously untreated patients. Dr Lawlor said that was certainly an element in it. Dr Lawlor agreed that it was central to the policy that special arrangements would be made for persons who had previously received no treatment. The policy with regard to previously untreated patients was crucial to the whole rationale of Prof. Temperley's advice to continue with dry heated product. Dr Lawlor agreed with this proposition, and she said that she was not sure why the factor IX's were not included in it. She said, "I think you are going to have to ask him".

Dr Lawlor said she did not know who had full responsibility implementing the policy with respect to factor VIII and previously untreated patients.

The Board of the BTSB approved the advice of Prof Temperley and decided to continue with the Armour arrangement. Mr Keyes wrote to Mr Bishop of Armour Pharmaceutical on 16th June 1988, and noted that there had been no further seroconversions to HIV since blood products from Irish plasma had been fractionated by Armour. While cognisant of Armour's desire to switch to monoclonal product, Mr Keyes nevertheless asked Armour to continue the existing arrangement until the end of 1989. Mr Keyes said, "There is still concern about Non-A, Non-B Hepatitis but, taking everything into consideration, a continuance of factor VIII to the end of 1989 is considered most appropriate". Mr Keyes said that he was aware that the request may cause some concern among the Board at Armour, but the Director of the National Haemophilia Treatment Centre was prepared, together with the BTSB management, to meet the Company's Directors and explain reasons for the above request to Armour Pharmaceuticals.

In conjunction with the Board's attempts to persuade Armour to continue with the existing contract fractionation arrangement, the BTSB entered into preliminary discussions with Octapharma for the supply of a solvent/detergent product. The contract with Octapharma was negotiated during 1988 and all details were agreed during the currency of the Armour arrangement. The Tribunal noted reports in the publication "Haemophilia and Blood Products Newsletter". This newsletter said Dr Lawlor was distributed and supported by Armour Pharmaceuticals. The publication raised questions about the efficacy of solvent/detergent methods with respect to Non-A, Non-B.

In September 1988, Mr Keyes, Mr Walsh and Mr Hanratty from the BTSB, met Armour Pharmaceutical Co. executives. The company again indicated that it was its wish to move to monoclonal product and it was unwilling to continue fractionating Irish plasma using heat-treated methods.

Mr Keyes said his Board had requested that the present arrangement continue up until the end of 1989, and he prevailed upon the Company to continue with the arrangement. The Company finally agreed to continue with the arrangement, but distanced itself even further from the product. Part of the arrangement was that Armour's trade name should be removed from labels and a product licence variation would be required.

At the same time the issue of contract fractionation by Octapharma was being put to the Board of the BTSB. The advantage claimed by Octapharma was that its product would eliminate Non-A, Non-B Hepatitis. Prof. Temperley and three officers of the Board were to visit contract fractionation facilities in Norway and France, to assess the Octapharma product.

The Tribunal referred to a note written by Mr Hanratty to Mr Keyes, following the trip to Norway and France. The tenor of the note was that Prof. Temperley would agree to the Octapharma project, but in the long-term a research and development fund would be established to conduct research, with respect to fractionation applied to the procurement of plasma and clinical aspect of the therapy. Mr Hanratty suggested that price reduction be negotiated with Octapharma, and a price increase be negotiated with the hospitals to produce a fund of approximately £20,000-£25,000 to conduct a trial. In the long term, a 1p increase to factor VIII and factor IX should be considered to create a £50,000 research fund. Mr Hanratty commended this course of action to Mr Keyes.

In November 1988, on the recommendation of Mr Keyes, the Board accepted that preliminary contract fractionation arrangements be undertaken with Octapharma. Mr Keyes noted that this course of action would involve careful handling of existing arrangements with Armour.

In July 1989 the BTSB finalised its arrangements with Octapharma. In 1990 satisfactory results regarding yield from Octapharma were reported.

The last batch of plasma was despatched to Armour in 1989 and delivered in January or February of 1990. By 1995 the BTSB had moved to recombinant products.

The afternoon of Day 17 was taken up with a long discussion concerning surrogate testing with regard to the Hepatitis C, and the merits and demerits of ALT and Hepatitis B core testing were debated at length. The conclusion which appeared to be drawn from the debate, was that no testing was introduced because it couldn't be decided if one or other or both tests should be used, and in any event no funding from the Department of Health was forthcoming to allow a testing regime to be put in place. As a result, the issue was overtaken by the availability of a Hepatitis C test in 1989.

PROCEEDINGS: WEDNESDAY JUNE 28th, 2000 – DAY 18

Mr John Trainor S.C., opened the proceedings with an application on behalf of the Irish Haemophilia Society, re: application under the provisions of Clause 7(8) of the Memorandum of Procedures, for a direction that certain additional documents be included in the core bundles.

Mr Trainor said that it was anticipated that the I.H.S. would be the first party to cross-examine Dr Lawlor. Mr Trainor said the need to add additional documents only came to light when the evidence that had been given was considered. This testimony appeared to take a somewhat different form from the statement of evidence given by Dr Lawlor to the Tribunal. In light of this departure, the I.H.S. now wished to add a number of documents to the core bundles. Mr Trainor said he did not believe it would be possible to conduct a proper examination from the perspective of the I.H.S., without being allowed to have the additional documents considered. In these circumstances he applied for a direction that the I.H.S. be permitted to add the additional documents, or at least that they be considered for addition.

Mr John Finlay S.C. for the Tribunal, said he did not accept that the evidence given by Dr Lawlor took any unexpected turn. He said the evidence followed the books of documents collected by the Tribunal, and which had been made available to the I.H.S. since April 10th last. In addition, all parties had available to them Dr Lawlor's narrative statement which, in effect, contained a comprehensive summary of most of the documents.

Mr Finlay said the Tribunal would be anxious to consider, and he placed emphasis on consider, any additional documents which the Irish Haemophilia Society wished to suggest may be relevant to the work of the Tribunal. The documents in question should therefore be submitted to the Tribunal by close of business Thursday, June 29th. The Tribunal would then look at these documents, and those considered relevant and appropriate would be included in the Books of Evidence.

Therefore, matters which might be referred to in cross-examination of Dr Lawlor would be chosen by the Tribunal on Friday, and made available to Dr Lawlor's solicitors and other relevant parties on Friday evening. The cross-examination to commence on Monday morning.

Mr Trainor said that certain matters had arisen in evidence which made this application necessary.

The Chairperson said she would accede to the application and allow the documents to be handed in to the Tribunal by close of business on Thursday 29th June, and once the Tribunal has had an opportunity to investigate them, the documents would then be disseminated to the various parties for the commencement of Dr Lawlor's cross-examination on Monday, July 3rd.

The Tribunal then continued with the cross examination of Dr Lawlor.

With regard to Hepatitis C infection among persons with haemophilia, information from the National Haemophilia Treatment Centre indicated that, when tested after June of 1991, a total of 191 persons with haemophilia were found to have Hepatitis C antibodies. Dr Lawlor agreed with these figures.

Mr Finlay said that reliable testing for Hepatitis C became available in June 1991. Dr Lawlor agreed with this observation. Dr Lawlor said the 191 persons infected with Hepatitis C, were infected by exposure to non-heat treated or non-virally inactivated products from the early 1970's, down to when solvent/detergent products became available.

With respect to which blood products were regarded as infective for Hepatitis C, Dr Lawlor said: "With Hepatitis C, if you have had frequent exposure to blood products it doesn't matter whether you are getting commercial concentrates or home produced concentrates, or indeed even cryoprecipitate. If you get enough of it, you are going to – 90% of haemophilia patients will be infected if the product isn't treated."

Dr Lawlor said that the Hepatitis C was an indigenous risk in every community. Those who were frequently exposed to blood products ran the risk of contracting Hepatitis C. Those using concentrates are at risk from first exposure, she added.

Dr Lawlor told the Tribunal that she had examined the records of children born since 1985 who had haemophilia A. She had condensed this information into a chart. Dr Lawlor said that two haemophilia A patients born since 1985 had a weak positive test result for Hepatitis C virus. Dr Lawlor agreed that these persons would have been treated with Hemofil supplied by Armour.

With regard to children with haemophilia B born since 1985, a similar examination was also carried out. Of these 15 children, 11 were Hepatitis C negative, four children were Hepatitis C positive.

Dr Lawlor said that one of the four haemophilia B children who tested positive for Hepatitis C was unlikely to have been infected by a BTSB product. She based this statement on the fact that this particular child was infected with Hepatitis C, Genotype 4 virus. Genotype 4 virus usually originates in the Middle East or Egypt, said Dr Lawlor. In addition to receiving BTSB product, this child had been in receipt of regular therapy by way of concentrates. Dr Lawlor said that although this boy had received treatment from BTSB factor IX, in the circumstances it was unlikely that he was infected with BTSB product.

The other three haemophilia B children who were positive for Hepatitis C were treated with Batch No. 9885 BTSB factor IX. Dr Lawlor said this was the likely source of infection for these children. Batch 9885 was derived from Irish plasma fractionated by Armour and heat treated by the BTSB, said Dr Lawlor. Dr Lawlor said Armour was manufacturing factor IX for the BTSB. The BTSB's role was to heat treat and bottle factor IX. Only one batch of frozen supernatent was returned to the BTSB from Armour under the fractionation arrangement. Thereafter, finished factor IX was returned. Batch 9885 was issued in July 1989.

In July 1989 the oldest of the three children infected would have been four or five years old. Dr Lawlor said that these children had had a lot of different exposures, but she had been able to identify 9885 as the infected batch, as this batch had been administered to an adult on a once off basis and he had become infected with Hepatitis C. Dr Lawlor said that all four Hepatitis C children received batch 9885.

Mr Finlay asked Dr Lawlor if she had heard the evidence of the woman who appeared under the pseudonym of "Felicity". Dr Lawlor agreed that she had, and confirmed that the three of the children she had been talking about were Felicity's children. Dr Lawlor said that two of

these children had Genotype 3 Hepatitis C virus, and one child had Genotype 4 Hepatitis C virus.

With respect to the adult who became infected with one exposure to Armour BTSB factor IX in 1990, Dr Lawlor agreed with Mr Finlay that he was a person who did not receive much in the way of product. This man had mild haemophilia B and was undergoing a procedure when the concentrate was administered. He was initially treated with Octapharma factor IX, a solvent/detergent product safe for Hepatitis C virus. About one month later, in October 1990, this man received BTSB factor IX, batch 9885 – an infected batch from which he contracted Hepatitis C.

The Tribunal then adjourned until Monday 3rd July at 10.30 am.