IRISH HAEMOPHILIA SOCIETY

TRIBUNAL NEWS

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TRIBUNAL OF INQUIRY

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

PROCEEDINGS: MONDAY 10th JULY, 2000 – DAY 24

John Trainor, S.C. continued his cross-examination of Dr Emer Lawlor of the BTSB. Mr Trainor referred Dr Lawlor to the BTSB's home-produced Factor VIII project which took place between 1981-1983.

Dr Lawlor told the Tribunal that a person who had been working in another hospital was brought into the BTSB to work on the factor VIII project. Ms Cunningham also worked on the project but was not principally involved in it. The project worker was under the supervision of Mr Hanratty. Dr Lawlor said she was not in a position to say how the salary or remuneration of the person working on the project was met. Dr Lawlor said the name of the person involved could be made available to the Tribunal. Details of the project worker's remuneration could also be made available. Dr Lawlor said she did not know who paid the person's salary, and she did not know whether it was a full time job. She did not know whether the project was funded by a research grant.

The Lawlor said that the only expenditure of which she was aware, connected to the project, was that discharged by the I.H.S. in relation to the purchase of equipment which was used to assay Factor VIII at St. James' Hospital.

Dr Lawlor said some documents relating to the Factor VIII project had been contained in the Board's discovery. These documents had been presented to the Tribunal and could be examined at a later date. Mr Trainor asked if any report or record of the project was maintained. Dr Lawlor said the arrangement was quite informal in terms of reports. The experiment was of a practical nature and no reports appear to have been made. Neither was there any record of the terms of employment of the person engaged on the project.

At this point, the Tribunal intervened and Mr Finlay said the person involved would be contacted by the Tribunal, if possible, and may well give evidence. Mr Trainor would therefore be in a position to speak directly to this person, and get answers to his questions.

With regards to the amount of factor VIII made during the course of the project, Dr Lawlor said she had no immediate figure, but up to 15 patients were treated. Mr Trainor returned to a question he had asked the witness on Friday last. Mr Trainor had put it to Dr Lawlor that the factor VIII project was perfectly viable, and the only reason it didn't proceed was when the Board realised it could make more money by selling plasma and getting concentrate back, rather than making it itself. Dr Lawlor had disagreed with this proposition.

Dr Lawlor had said that, if the project worked, a commercial company would have taken it up, but none had done so. If it had worked, people could have taken a patent on the project and done very well, said Dr Lawlor.

Mr Trainor noted that factor VIII from small plasma pools, did not lend itself to economics of scale. Mr Trainor noted that in the U.S. concentrates sold for between 4p-6p, while in Ireland it cost 12p per international unit. For the factor VIII project to be attractive to a commercial

company, it would have to come in below the price of manufacturing factor VIII from large plasma pools, as was practised in the U.S.

Dr Lawlor said that any improvement in yield would have been attractive to a commercial company, and anything that would improve yield of factor VIII would interest a commercial company. Dr Lawlor said she was quite sure that when Gail Rock's paper was published, major commercial fractionators would have examined it, but they didn't pursue it. The fact that the project was not pursued probably meant that it was not commercially viable, said Dr Lawlor.

Mr Trainor said that an obvious port of call for the BTSB in seeking funds for such a project, would have been to seek a grant from a drug company. Dr Lawlor said she did not know whether or not this happened, but she could see nothing wrong with it. However, she had no evidence that this was the case.

Mr Trainor referred Dr Lawlor to a letter from Mr Barrell of Travenol, to Mr Sean Hanratty of the BTSB. It concerned the use of heparin bags, Sag-M and mock-up packs. Dr Lawlor said that this letter related to how the project was being conducted. Dr Lawlor referred to Ms Cunningham's visit to the BPL in October 1983, where Dr Smith advised Ms Cunningham that the heparinised plasma factor VIII production method did not work.

Dr Lawlor said, if the heparin bag had worked as set out in the methodology, as described by Gail Rock, Baxter, the company supplying the heparin bags, would have had a new product to sell, if it had been viable the company would have gone on to do so.

Mr Trainor said he noted that Dr Lawlor regarded the factor VIII project as alchemy, ie. An attempt to turn lead into gold, and he wanted to know why she said this. Dr Lawlor said all sorts of projects were mooted when it came to manufacturing factor VIII, and it was even suggested within the I.H.S. discovery that it might be possible to manufacture a factor VIII in weightless conditions, ie. on board a space ship. She said that, while this may have been suggested with some degree of humour, it was nevertheless indicative of the many different projects put forward for factor VIII production. She said that what most of these projects had in common, was that they didn't work.

Mr Trainor put it to Dr Lawlor that, with the benefit of hindsight, the project was misguided. Dr Lawlor agreed that she was operating in hindsight. Mr Trainor said that, if one was to look at the documents for 1981, 1982 and 1983, one could not express the view that the project was doomed to failure.

Mr Trainor said it was not apparent from the documents that the project would not work. Mr Trainor also noted that, after 1984, when the project went out of sight, no mention was made of it being misguided. Mr Trainor established that Dr Lawlor, as a Haematologist, was not in a position to give expert evidence on whether the factor VIII project was a misguided effort. Dr Lawlor agreed with this proposition. Mr Trainor said it was also his understanding that the Board was not offering a witness to testify as an expert that the factor VIII project was misguided. Dr Lawlor said she was sure that the Tribunal would call witnesses to this effect.

Mr Trainor then asked Dr Lawlor, had documents from before and after 1984 not established that the factor VIII project to be a misguided effort, and that Dr Lawlor herself didn't have an expert view. If the Board did not offer professional expertise to support this opinion, then on

what basis could the Tribunal find that the effort between 1981 and 1983 was misguided? Dr Lawlor said she saw no reason why she should change her mind on that.

Mr Trainor asked, was this simply a view point that Dr Lawlor had formed for herself on reading the documents in some way or other. Dr Lawlor agreed with Mr Trainor. Mr Trainor asked Dr Lawlor when she had formed this view. Dr Lawlor said she was always of that particular viewpoint. Dr Lawlor said that a small blood bank, strapped for cash, would be very unlikely to be able to produce gold out of lead or gold out of straw, and was not surprised that the factor VIII project did not work. Mr Trainor asked, was this a view that Dr Lawlor had before she came to read the documents discovered by the Board. Dr Lawlor replied, yes, that it was most unlikely that the BTSB would have been able to produce factor VIII on its own.

Mr Trainor asked, was Dr Lawlor not then surprised when she came to read the BTSB's documents, that there was nothing to support her view that the factor VIII project was not tenable. Dr Lawlor said it had come as a huge surprise to her, and she also said that she thought Prof Temperley would agree with her point of view that this was a misguided effort.

Previously, Dr Lawlor had mentioned that she had had a two minute conversation with the person who worked on the factor VIII project. Mr Trainor asked when the conversation took place, and Dr Lawlor replied, it took place sometime last Autumn. Dr Lawlor had called this particular person on the telephone, after identifying her through the BTSB. Three or four people had vague memories of the factor VIII project and were able to identify the worker to Dr Lawlor. Dr Lawlor inquired as to what work had been done, but the person concerned did not remember much about the time.

Dr Lawlor said she had had a very brief conversation with this person, who was actually just either going into hospital, or had just come out of hospital. Mr Trainor asked Dr Lawlor, was she resiling from the idea that the project was misguided. Dr Lawlor said, no, she was not taking back that idea. Dr Lawlor said that, on a scientific basis, the project may not have been misguided, but it didn't work.

Mr Trainor asked did Dr Lawlor put it to the person who worked on the project that it wasn't going to work. Dr Lawlor said she did not put such a view to the person as it was not appropriate to do so.

From the above, it would appear that Dr Lawlor formed the view that a project which lasted for three years, from 1981 to 1983, producing BTSB factor VIII, was misguided. However, there are no documents in the BTSB to support this position. Documents within the BTSB Discovery say that the project will work.

On 9th October 1981, the NHSCC carried out a survey of the costs of the factor VIII project, the capital outlay required and the savings it would deliver.

In 1983 Dr O'Riordan announced a break-through was imminent on factor VIII production. On 1st October 1983 Dr O'Riordan, addressing the Irish Haemophilia Society, stated that the Board had reached an end stage of research with regard to factor VIII production. Clinical trials were to be held in the near future, and home production of factor VIII would save £100,000 per annum. Dr Lawlor said that the difficulty at this stage was that, while the heparin factor VIII project appeared to be getting very good yields, the problem was that the heparin was interfering with the assay.

Mr Trainor referred Dr Lawlor to an article in the *New England Journal of Medicine* for 1984 by Rock and Palmer *et al*, outlining success encountered in manufacturing factor VIII using heparinised plasma. The Chairperson said that, as Dr Lawlor had not seen the documents, it was not appropriate to examine her there and then. An examination on the documents would continue the following day, after Dr Lawlor had had a chance to read the documents concerned, said the Chairperson.

Mr Trainor continued his cross-examination of Dr Lawlor on the BTSB's attempts to achieve self sufficiency. He examined the plasma procurement programme initiated by the BTSB. Mr Trainor pointed out that it soon became apparent that contract fractionation was potentially a very profitable operation. Between the end of 1983 and the end of 1984, the BTSB and the Department of Health engaged in lengthy correspondence concerning the costs associated with savings which may accrue from the factor VIII project.

In November 1984 a young man with haemophilia A was being treated at St. James' Hospital for AIDS. This event galvanized the BTSB into action, said Dr Lawlor. contract fractionation got under way in 1985; during this time commercial concentrates remained in use. Mr Trainor asked, was it not inevitable in using commercial concentrates, that it was only a matter of time before some person would contract HIV from the products? Dr Lawlor agreed. Dr Lawlor said, people just did not believe it was going to happen.

Mr Trainor said of the BTSB's policy in circulating commercial concentrates: Wasn't it a bit like playing Russian Roulette, in that eventually someone would get hurt, and when someone did get shot, no-one should be surprised? Dr Lawlor said, yes, I think it was inevitable. Dr Lawlor said when it did happen, it came as a surprise, a shock and a horror to everyone.

Mr Trainor put it to Dr Lawlor that the discovery of AIDS in a person with haemophilia could not have come as a surprise to Dr O'Riordan? Dr Lawlor said it probably came as a shock and surprise to everyone. Mr Trainor asked, did this unfortunate discovery allow Dr O'Riordan to sweep aside all opposition to contract fractionation? Dr Lawlor replied that it did, but not in any pejorative sense. Would this project allow the Board to generate a substantial income, asked Mr Trainor. Dr Lawlor said there may have been income involved, but it was much more about self sufficiency.

Was it not a fact that the BTSB was exploiting this development to get the contract fractionation project through? Dr Lawlor said: no, I think it is a matter of waking up the Department of Health to get on with it.

PROCEEDINGS: TUESDAY 11th JULY, 2000 – DAY 25

Mr John Trainor S.C. continued his cross-examination of Dr Emer Lawlor of the BTSB.

ROCK PALMER, 1984

Mr Trainor referred Dr Lawlor to an article in the New England Journal of Medicine of the 2nd August 1984. The article was by Rock and Palmer on the operation of heparinsed plasma, and was contained in the BTSB Discovery. Dr Lawlor said the methodology contained in the article was very similar to that performed by Mr Hanratty and Prof. Temperley, and she said it was a pity that Prof. Temperley and Mr Hanratty had not submitted their letter to *The Lancet*.

Dr Lawlor said that the operation described in the article was not user-friendly. It took 5-10 minutes to dissolve the product in water at 37 degrees. The requirement to dissolve it in hot water made it a difficult product to use. Dr Lawlor said that Gail Rock, the author of the article, had been interviewed by Mr Justice Krever for his report on the Canadian blood system. Dr Lawlor said at no point did Mr Justice Krever decide the Rock Palmer method was suitable for use. Mr Trainor pointed out that Justice Krever, in his report, noted that the circumstances in Canada were markedly different from here.

The article referred to by Mr Trainor was published in August 1984. Mr Trainor asked Dr Lawlor if the document had received any consideration when it arrived at the BTSB? Dr Lawlor said by the time the article was received the decision to discontinue the factor VIII project had been made. Dr Lawlor said it was obvious that the Board had decided that the project was not a runner.

SELF SUFFICIENCY – 1980-1983

Was it the case, therefore, asked Mr Trainor, that from January 1980 until the end of December 1983, the Board's sole commitment to self sufficiency was contained within the factor VIII heparin project? And, was it also the case that the extent of the commitment of resources allocated by the Board to the project, which represented the Board's quest for self sufficiency, was the engagement, on some unknown terms, of a part-time project worker under the supervision of Mr Hanratty, and with the assistance of Miss Cunningham? Dr Lawlor said she would agree that adequate resources were not put into the project.

Dr Lawlor also said that the Department deflected any requests for assistance. The hospitals did not have money. The only funds forthcoming were those expended by the Irish Haemophilia Society when they paid for an expensive piece of equipment. Dr Lawlor said the whole project was being done on a shoestring. Mr Trainor asked Dr Lawlor, was it the case that, in introducing a new step to the process, the possibility of patent rights accruing arose? Dr Lawlor said there was no evidence of that whatsoever.

Mr Trainor directed Dr Lawlor to the examination of a work book on the heparin project, dated 7th August 1981. In Ms Cunningham's handwriting it was noted that some of the work was being carried out for S. Hanratty. Dr Lawlor said there was no significance in this. Mr Trainor asked, was it significant that Mr Hanratty was the director of a company in 1982, a company in the business of supplying blood bags? Mr Trainor asked Dr Lawlor, did she know whether or not Mr Hanratty was a Director of Accuscience, a medical supplies

company? Dr Lawlor said she was unsure of this, and suggested that one of the financial witnesses would deal with this matter.

Mr Trainor put it to Dr Lawlor that it seemed to follow, from what she had said, that if adequate resources had been put into the project that, at the very least, the Board would have become aware sooner that the project was not viable?

Dr Lawlor said if more resources had been put into the project, the Board may well have found out earlier that the project was not viable. The Board could not get resources for the project until it determined whether or not the project would work, and in this sense a catch-22 situation prevailed, ie. the Board could not get funding until it got the results of the project, and it could not get the results of the project until it got the funding.

Mr Trainor said, was it not the case that Dr O'Riordan was not prepared to sanction what he regarded as an extravagant divergence of resources for the treatment of haemophilia? Dr Lawlor said that this wasn't the case. A balance of need must be struck. In terms of what the Board could do, it just wasn't possible. A lot of resources were not forthcoming, and it was not a lack of enthusiasm on Dr O'Riordan's part it was simply the reality of the case, she said.

In late 1984, the BTSB was still considering who would get the plasma fractionation contract, and was still engaged in ongoing discussions with the Department of Health as to funding the project. Mr Trainor asked Dr Lawlor if it was the case that the Board was attracted to contract fractionation by the financial benefit it could bring? Dr Lawlor said that, while the Board's decision may have been dressed up in financial terms, the contract fractionation project was directed at realising self sufficiency.

Mr Trainor said there was no evidence that the Board was particularly interested in safety. It was apparent when one considered the Board's response to treating its own products. Mr Trainor noted that the advent of a haemophilia A patient with AIDS being treated at St James' Hospital, galvanised the Board into action. Dr Lawlor said the occurrence of this unfortunate patient galvanised the Department, not the Board. The Board was ready and able to get going at all times. It was the Department of Health which was causing delay.

Mr Trainor noted that, when contract fractionation was in the offing in December 1984, the Board was still discussing the production of intermediate purity factor VIII, as if such product was within the competence of the Board. It appeared from this discussion that the factor VIII project was still under discussion, suggested Mr Trainor. This was particularly so, as the Board continued to discuss the cost of capital equipment required for the factor VIII project. Dr Lawlor said that the factor VIII project was being terminated at this point.

Dr Lawlor said that contract fractionation may have been thought of sooner. This point could be argued. Mr Trainor suggested that, from the discussions and the documents contained in the Board's discovery, it appeared that a major reason for contract fractionation was the prospect of making money. Dr Lawlor said that the money made the project more attractive for the Department. The project would make sense to the Department if it made money, said Dr Lawlor.

FRACTIONATION CONTRACT

Mr Trainor referred Dr Lawlor to the business plans and proposals from various companies pitching for the contract fractionation business. These plans were contained in a spreadsheet prepared by the BTSB, in which the pros and cons of various companies are set out. One of the headings for consideration in this plan was whether or not the product on offer was heat treated. The company finally selected for heat treatment Travenol, which offered optional or dry heat treatment programme. Mr Trainor suggested that this would indicate that the BTSB did not prioritise this aspect of their contract. Dr Lawlor noted that undue reliance was placed on the fact that the Irish population did not have HIV.

Mr Trainor noted the communications to the Board from Prof. Temperley. The Professor protested at not being informed of the Board's plans for contract fractionation. Prof. Temperley told the Board that, if he and his fellow Directors were not involved in the selection of the product finally on offer, the Directors would by all means maintain competition, ie. they would import their own products. Dr Lawlor endorsed this course of proposed action by Prof. Temperley.

Travenol was finally selected as the company chosen to contract fractionate the Board's plasma. Mr Trainor suggested that Travenol was favoured for the contract by virtue of the yield on offer and the price it offered for the plasma. Travenol offered £23.00 per litre, giving the Board a projected surplus of £250,000 per annum. Travenol further offered a yield of 20 per cent.

In July 1985 the first consignment of plasma was despatched to Travenol. Previous projections prepared by Mr Hanratty were based on a price being charged by the Board of 10p per international unit for factor VIII. Mr Trainor noted that Mr Noel Fox, a leading accountant, who at this time was on the Board of the BTSB, declined to decrease the price to 10p. Mr Trainor said, was it not worthy of comment, and was it not worthy of comparison, that from the discovery of a haemophilia person with AIDS in St. James' Hospital in November 1984, to the completion of the fractionation contract, that a period of some seven months had elapsed while a period of three years had passed on the Heparin factor VIII project with a further year passing from the start of 1984 until a sense of urgency could be detected in the BTSB's attitude to achieving anything like self sufficiency?

A sense of urgency now attended the Board's actions. Dr Lawlor said this was because they now had a haemophilia patient with AIDS in St. James'. Mr Trainor said that it should not have taken the realisation of AIDS in the haemophilia population to motivate the Board to provide a safe factor concentrate.

In addition to being motivated by the arrival of AIDS, the Board also stood to make substantial returns for its efforts, said Mr Trainor. The Board's documents reveal that plasma turnover for 1986 amounted to £947,000. Dr Lawlor said that, even in a not-for-profit organisation, the bills and overheads had to be paid.

With regards to the significant sums accruing to the Board, Mr Trainor asked who would tell us what weight financial considerations were given by the BTSB in product selection? Dr Lawlor said the BTSB would provide a number of witnesses who could give such evidence. She hoped that they would be available to do so over the next few days.

Mr Trainor asked Dr Lawlor, was she still content that finance played no part in the deliberations of the Board. At this point, objections were raised by the Tribunal and by the BTSB legal team. However, Mr Trainor said that the witness could not have it both ways; on the one hand saying that saying finance played no part in the Board's decisions; and on the other the Board was simply motivated by self sufficiency.

If finance played no part in the Board's decision, the witness would have to show that. She could not refuse to answer questions on finance, and at the same time say finance played no part in the decisions of the Board. The Chairperson pointed out that the BTSB would provide a witness to give evidence on financial matters. This had already been stated on a number of occasions. Mr Trainor said that he may have submissions to make on this issue at a later date.

THROMBOGENECITY

Mr Trainor referred to the UK Centre Directors' Treatment Plan of 14th December 1984, which sets out treatment regimes for various haemophilia conditions with regards to the threat of AIDS. Following Prof. Temperley's letter of 17th November 1984, where he informed the BTSB of the presence of a person with haemophilia who was suffering from AIDS in St. James' Hospital, Cecily Cunningham of the BTSB contacted Dr Smith of BPL. In a note of her telephone conversation with Dr Smith, Miss Cunningham notes, with respect to the heat treatment of factor IX, that Dr Smith was more worried about thrombosis than AIDS, with regards to heat treating the factor IX.

Dr Lawlor referred to the BTSB's policy to wait and see with regards to what the UK was doing in heat treating factor IX. She also noted that in Scotland, the Scottish Blood Transfusion Service ceased production of its own factor IX and issued commercial heat treated factor IX for the duration of its investigation into thrombogenicity, and re-commenced the production of its own factor IX when it had satisfied itself that heat treated factor IX did not pose a thrombogenetic threat. Dr Lawlor said a huge debate on this subject took place in the UK. Mr Trainor suggested, while there may have been a huge debate on this matter in the UK, there was no debate here. There were no records of any debate taking place within the BTSB. A possible explanation for this, said Dr Lawlor, was that the country had just lost one quarter of its consultant haematologists when Prof. Temperley took his sabbatical, therefore there weren't too many people around to conduct a debate.

Dr Lawlor expressed surprise about the lack of debate that was apparent around the subject of heat treating factor IX. Mr Trainor noted documents from MASAC and from Dr Craske in the UK where it was noted that unheated factor IX transmitted HTLV-III to Hepatitis B patients. Dr Craske recommended a change to heat treatment of National Health Service factor IX as soon as possible.

Mr Trainor said, if the Board was giving consideration to potential problems in heat treatment of factor IX, was it not inconceivable that this would not be mentioned to the Department of Health when the BTSB was setting out its views on self sufficiency? Dr Lawlor said, not necessarily - Irish plasma was deemed to be clean, and it was possible that the Board would not mention this in its considerations. However, she now conceded that it was a fact that Irish plasma was not clean. Mr Trainor said, was it not a fact that heat treating factor IX would have adverse economic consequences for the Board. Dr Lawlor said it was not a money problem, it was a risk assessment problem – the Board was assessing the risk of using unheated factor IX against a perceived thrombogenic risk of using heated factor IX.

Would users of factor IX be exposed to dangers of thrombogenicity and the dangers of HIV? Dr Lawlor said the subject was left in the balance to see what would be sorted out in the UK, and Ireland would follow that. Mr Trainor said that there was nothing to show that the question of heat treatment was considered by the Board, except in the actions of Miss Cunningham in January. Other than this note of a telephone conversation by Ms Cunningham there was nothing to indicate that thrombogenecity was on the BTSB's agenda. Dr Lawlor said she was sure informal discussions took place between the relevant parties on this issue.

DR DALY'S LETTER

The heat treatment of factor IX took a dramatic turn in August of 1985, when Dr Helena Daly told Dr O'Riordan and Mr Hanratty that she would no longer continue to issue untreated factor IX, as it was unethical to do so. Dr Daly notes that losses would accrue to the Board as a result of having to adopt this course of action. Dr Daly's letter was followed by that of Prof. Temperley to Dr O'Riordan, and heat treatment of factor IX was put into operation shortly thereafter. It appeared at this point that all thoughts of thrombogenicity were set aside, said Mr Trainor. Dr Lawlor said, during this period nobody was too certain as to the dangers of thrombogenicity and the issue of un-heat treated factor IX. In this era of uncertainty, the Board continued to use both heated and unheated product. Mr Trainor said it seemed to be the Board's policy to plough on with the old way until it got a clear direction to stop. Again, objections were raised to Mr Trainor's suggestion from the Tribunal and from Dr Lawlor's BTSB legal team.

In summary, it would appear that the BTSB continued to issue un-heated factor IX made in Pelican House, for over 12 months after being warned that it could transmit AIDS. Given that the major project of the BTSB in 1985 was the achievement of contract fractionation, it appeared that the interests of people with haemophilia B were overlooked in a belated quest for self sufficiency.

Frank Clarke, S.C. noted that two further books of cross-examination documents had been delivered to the witness last evening. Mr Clarke said the witness was now 14 days in the witness box and into her eighth day of cross-examination, and it was unfair to her that matters had been left so late. It was his understanding that a reasonable advance opportunity was to be afforded to the witness to read documents. Mr Clarke said, while he felt entitled to ask for more time to allow the witness to read the documents, she had indicated she wanted to continue. Mr Clarke also noted that the documents in question had been available to the Irish Haemophilia Society for a very long time.

Mr Trainor, for the Irish Haemophilia Society, said he would not be reaching the additional books today, and the witness would therefore not be disadvantaged. He added that, when the original cross-examination books had been delivered, it was indicated that there may be more books. He further added that the I.H.S. had only been in a position from 14th April last, to engage Counsel. In the circumstances it could not be asserted that the I.H.S. legal team had been in possession of documents for a long time.

The Chairwoman said it was her ruling that documents should be delivered in advance, and this still applied. She said it was to the disadvantage of Dr Lawlor to give her two further books of evidence and expect that they be read overnight. However, she noted that Dr Lawlor wished to continue. But if she needed time to refresh her memory, she will get the time.

Mr Finlay then asked, were there any further documents forthcoming from the I.H.S. Mr Trainor said that, on one discreet issue, some further documents would be presented to the witness for cross-examination. The Chairperson said, since the I.H.S. had identified the documents, it should produce them. Mr Trainor said that the documents had not been identified; the issue had been identified, and the documents would be produced. Mr Finlay, for the Tribunal, inquired as to whether or not Mr Trainor could furnish the Tribunal with the documents by lunchtime today, or when?

Mr Trainor said it was clearly unrealistic for the Tribunal to expect the I.H.S. legal team to produce documents and attend the Tribunal at the same time. The Chairperson said the task of assembling documents could be handed over to junior Counsel, or whoever. Mr Trainor said that, whoever collected the documents, he would have to settle them and determine whether or not they were relevant to his cross-examination. In the circumstances, he would endeavour to have the documents presented to the Tribunal by lunchtime.

With that, cross-examination of Dr Lawlor proceeded.

Mr Trainor referred to Dr Helena Daly's letter of August 1985. She noted, in communication with Prof. Temperley, that she had told Dr O'Riordan and Mr Hanratty that it was “unethical” to continue issuing un-heat treated factor IX. Dr Lawlor said it was unlikely that a locum consultant would have the authority to direct the Blood Transfusion Service to change its policy. Dr Lawlor said Dr Daly was not the consultant in charge. Dr Lawlor said she was not saying Dr Daly wasn't experienced, but she was the locum consultant haematologist, and therefore didn't have the authority to deal with the issue.

At this point, Mr Trainor said he would like to put Dr Daly's statement to the witness. An objection was raised by Mr Finlay to this course of action. Mr Finlay said that Dr Daly's

statement had no status and, as she was to give evidence, she could answer any of Mr Trainor's questions in person.

The Chairperson agreed with this observation.

Mr Trainor said that Dr Lawlor was the BTSB's representative, and she is the only person on the Board to whom he could put these matters. He also said that Dr Lawlor was the only person, on behalf of the Board, who can answer the issues that arise on the evidence.

The Chairperson said she was ruling that Dr Daly's statement could not be produced at this point. However, should Mr Trainor require, the possibility of recalling Dr Lawlor at a later stage would be afforded to the I.H.S.

At this point, the I.H.S. legal team withdrew to consider the ruling and take instructions.

After a short adjournment, Mr Trainor indicated that he was now in a position to proceed.

Dr Lawlor said that in June 1985, knowledge of the effects of heat treating factor IX were coming into the public domain. Dr Lawlor referred to a memo of Dr John Craske of June of 1985, where Dr Craske urged that British National Health Service heat treated factor IX be brought into use as soon as possible, in order to avoid further HIV infection. Dr Lawlor also noted Prof. Bloom's article.

Mr Trainor asked Dr Lawlor, had the BTSB received this memo? Dr Lawlor said, no, the BTSB had not received the memo at the time. They had been aware of the debate going on, especially from Prof. Temperley who was on sabbatical at the Royal Free Hospital in London. This hospital had a large haemophilia unit. In these circumstances, Prof. Temperley would have been aware of the data, and particularly of the content of Dr Craske's memo, urging the use of heat treated factor IX.

Dr Lawlor said she did not wish to give the impression that the BTSB had been in receipt of Dr Craske's memo, but the debate was changing and moving. She also said that the risk of thrombosis was coming into the picture in a clear way. Dr Lawlor said that the risk of acquiring HIV from blood products had to be balanced against the risk of thrombosis in using heat treated factor IX.

Dr Lawlor said this was not just a theoretical risk, products were not purified. Mr Trainor said: was it not as clear as daylight that the BTSB, in considering the pros and cons of heat treating factor IX., would be aware that it was inevitable that a donor infected with AIDS would to show up?

Dr Lawlor said that, while she would now agree with Mr Trainor, it was not the view of the Board at the time. Mr Trainor said this was an issue to be considered by the Tribunal - i.e. the Executives concerned were no longer available to give evidence. Dr Lawlor said there are enough witnesses around who can deal with the issue in question.

Mr Trainor said his understanding of the evidence given by Dr Lawlor to the Tribunal was that in August of 1985 the BTSB was not expecting a case of AIDS to turn up on its doorstep. Dr Lawlor agreed that this was the case.

Mr Trainor asked Dr Lawlor, was it the case that the BTSB lacked a sense of urgency regarding the heat treatment of factor IX? Dr Lawlor disagreed, and she said there was undue complacency, but there was no lack of urgency on the part of the Board.

Mr Trainor put Dr Daly's letter to Prof. Temperley to Dr Lawlor. He also referred to Prof. Temperley's letter to Dr O'Riordan following upon his meeting with Dr Daly in London. The letter said that by November of 1984, the Board would have had 11 months to introduce heat-treated factor IX.

Mr Trainor put it to Dr Lawlor that Prof. Temperley's letter could not have been clearer. Dr Lawlor said the letter was obviously graphic but, as it happened, the treaters continued to use the product. Dr Lawlor said a genuine crisis prevailed at this time and things were not clear. Not only did the treaters keep using the product, the Haemophilia Directors also wanted to keep using the product. The problems with thrombogenicity had to be resolved.

Under the circumstances, the Board's position was, according to Dr Lawlor, that it was safer to continue using unheat treated factor IX. The position of the English Directors, according to Dr Lawlor, was to keep using the product. Mr Trainor asked, was it still the position in relation to factor IX which the Board was producing, that it was standing over on warranting safety of the product? Dr Lawlor agreed with this proposition.

Mr Trainor wanted to know, was it also the Board's position that it regarded as defensible the supply of a product that it was warranting safety of, namely unheated factor IX, in light of what it knew about the transmission to HIV through unheated product, and in the light of the letter from Prof. Temperley? Dr Lawlor said she was not speaking for the Board. She said she was reviewing the documents, and as such, it was regrettable that seven haemophilia B patients were infected with HIV. But, said Dr Lawlor, she could understand how it happened.

Mr Trainor asked Dr Lawlor, was it her view as a consultant haematologist, giving evidence on oath to the Tribunal, that the supply by the Board of unheated factor IX, which it was now underwriting, was a defensible position? Dr Lawlor said she could see how it happened. Mr Trainor said this is not the question he was asking. Dr Lawlor said, “I am not saying, that is not for me to say, that is for the Tribunal.”

Mr Trainor said that, as a haematologist giving evidence before the Tribunal, was it Dr Lawlor's evidence that it was regrettable that up to seven haemophilia B patients became infected? Dr Lawlor said it was regrettable. Mr Trainor said the answer to the question was, surely, yes or no. Either the Board was standing over the product or it wasn't. Dr Lawlor said that she could not answer this question. This was why we were having the Tribunal., said Dr Lawlor. Dr Lawlor said her role was to explain documents, and what the views of people were at the time. It was not for her to make a comment.

Mr Trainor pointed out that Dr Lawlor was the Board's witness. Who would deal with the documents when there was nobody else around, because Mr Hanratty and Mr O'Riordan were both deceased? In these circumstances, said Mr Trainor, he had no-one else to ask the questions of.

Dr Lawlor said that, with hindsight, the issuing of unheated factor IX was regrettable.

Mr Trainor said that by August 1985, a letter from Prof. Temperley to Dr O'Riordan, in the terms indicated, would have been regarded by Dr O'Riordan as a very serious document. Dr Lawlor said it could be seen from the letter that further delay was being contemplated when Prof. Temperley nominated November 1st, as the date upon when heat treating must finally start.

Mr Trainor noted that Professor Temperley pointed out in his letter that the BTSB would, by November 1st, 1985, have had 11 months to heat treat its factor IX. From this it could be inferred that Professor Temperley was of the view that heat treated products only should have been in use since January 1985.

Dr Lawlor said there was always a stand-off between fractionators and the people treating patients, to a greater or lesser extent. Mr Trainor asked Dr Lawlor who would have been involved in such a stand-off. Dr Lawlor said, Dr Peter Jones of Newcastle had been a person who was in a stand-off with blood products producers. Dr Lawlor said there always a potential conflict between these interests.

Mr Trainor asked Dr Lawlor, was it the case that the BTSB refused to move on the heat treatment of factor IX because, as yet, no case of AIDS had been reported from using factor IX.? Mr Trainor asked Dr Lawlor, was it fair to say that the Board was waiting until it discovered somebody with AIDS before it would act? Dr Lawlor replied, no.

At the start of 1985 the drug companies replaced unheated factor VIII at the instigation of Prof. Temperley. Should the BTSB have embarked upon a similar course of action for factor IX in August of 1985?, asked Mr Trainor. Dr Lawlor replied, yes, but at that stage it didn't have a concern regarding the safety of factor IX.

Mr Trainor put it to Dr Lawlor: was it not the case that treating doctors, advising of the dangers of using non-heat treated factor IX, were insisting on the issue of heat treated factor IX?

Mr Trainor asked, if there had been a detailed consideration of the issue of thrombogenicity, would it not have been brought to the attention of the Board? Dr Lawlor replied that there was no formal consideration of the issue of thrombogenicity, but she was sure such discussions had taken place.

Mr Trainor said it would appear that there was no formal assessment of risk whatsoever. Dr Lawlor agreed that this was not in the documents. She said other witnesses may be able to help Mr Trainor with this issue.

It would therefore appear that the BTSB decided to ignore instructions from the treating doctors to issue heat treated factor IX product, despite lacking the necessary knowledge and experience upon which they could accurately assess the risk. They were waiting to see what would happen in England.

Mr Trainor drew Dr Lawlor's attention to a letter from Mr Flanagan of the Department of Health, to Dr O'Riordan. Dr Flanagan advised that it was imperative that the BTSB finalised its arrangements to introduce donor screening. Dr Lawlor said screening was introduced on 15th October 1985, a day after it was introduced in the UK. However, even when the screening was introduced, it was still considered that Irish plasma did not present a danger.

Concerns for thrombogenicity still existed. Dr Lawlor said the BTSB was strongly relying upon what would happen in England to give them direction.

Dr Lawlor then turned to the issue of heat treatment of factor IX. When it was finally introduced a number of different heat treatment protocols were utilised – different batches being issued with different levels of inactivation.

Dr Lawlor said, when the decision was finally made to heat treat factor IX, things happened in a hurry. The BTSB settled on a heat treatment programme of 60 degrees for 20 hours, on the basis that it was a shorter time process, which expedited the delivery of the heat-treated factor IX. This heat treatment protocol was similar to that used by Armour. The reason for changing the heat treatment protocols was to speed up the production.

Between October and December 1985, equal amounts of heated and non-heated factor IX were in issue; about 100,000 units of each was in issue at the same time.

Mr Trainor also drew Dr Lawlor's attention to the purported recall of unheated factor IX in January 1986. Dr Lawlor said the BTSB's letter was intended to bring stocks back from the hospitals. However, the letter did not explicitly direct the hospitals to return BTSB unheated factor IX. Mr Trainor put it to Dr Lawlor that a loss would accrue to the Board as a result of such a recall, and that the Board would require some compensation from the Department of Health. Dr Lawlor agreed this was the case.

Following a letter from Prof. Temperley to Dr Walsh, that people with haemophilia B were seroconverting after the BTSB had agreed only heat treated products would be used the matter of recall was brought to the urgent attention of the Board. Further recall issued some two months later, in June of 1986. Mr Trainor asked Dr Lawlor, did it take the infection of a person with haemophilia B before the Board would act?

PROCEEDINGS: THURSDAY 13th JULY, 2000 – DAY 27

John Trainor S.C. continued his cross-examination of Dr Emer Lawlor of the BTSB. Mr Trainor directed Dr Lawlor to a letter from Prof. Temperley to Dr Walsh of the BTSB, concerning the seroconversion of haemophilia B patients following treatment with BTSB factor IX concentrate. Prof. Temperley informed Dr Walsh that six patients had tested positive for HIV antibody. Mr Trainor asked Dr Lawlor, was it the case that, had they remained on commercial product, they would have escaped infection? Dr Lawlor replied, yes.

In addition to the six patients reported by Prof. Temperley, a further patient who received product from batch 90633 was also seropositive, giving a total of seven HIV positive haemophilia B patients.

Mr Trainor directed Dr Lawlor to a letter from Dr Walsh to Dr Egan in Galway. It summarises the situation in relation to factor IX, and reminds Dr Egan that, in January 1986, the Board advised all hospitals that heat treated commercial factor IX was available, and that heat treated factor IX would shortly be available from Pelican House.

Heat treated factor IX became available between February and March 1986. A lot of difficulty appeared to occur with regard to quality control. Dr Lawlor was asked, did this not confirm the batches being delivered to St. James' Hospital between October 1985 and up to January 1986, and possibly into February and March of 1986, were in the nature of experimental or trial batches? Dr Lawlor agreed, saying she would regard these batches as trial, rather than experimental, batches.

Heat treated factor IX was available in February to March 1986. Mr Trainor pointed out that this was one year after the drug companies replaced factor IX with heat treated factor IX. Dr Lawlor agreed, but said that the BTSB had been waiting on a lead from England. It was not unreasonable to allow 6-8 months for the heat-treated product to become available, she said. Dr Lawlor said other difficulties also existed at the time. Dr Lawlor said one of these difficulties may have been the fact that the BTSB was taking a little bit more time than it would normally have done, to make sure of quality control.

She also said that perhaps undue reliance was put on the fact that these batches were testing negative for HIV. Mr Trainor said this was an issue he wished to address with Dr Lawlor. Mr Trainor said he noted the BTSB batches of heat-treated factor IX that had been produced from unscreened donors. Further, the BTSB was conducting tests on the final concentrate itself. Dr Lawlor said that if the BTSB found one positive test in a vial the whole batch would be withheld, and she assumed the BTSB got rid of it.

Dr Lawlor agreed that testing one vial from a batch would not confirm that all the vials within a batch were free of infection. She agreed with Mr Trainor that, if the vial being tested proved negative, then all the other vials in the batch were assumed to be negative and were released. Dr Lawlor said she agreed that this may have happened, but that Mr Trainor would have to ask the other witnesses. Mr Trainor asked Dr Lawlor, did any batch of a factor IX, tested by way of a sample, prove positive for HIV? “No, no batch proved positive, so they were all released,” said Dr Lawlor.

Mr Trainor directed Dr Lawlor to batch 90753. Mr Trainor asked, did the testing of 90753 take place on the finished product? Dr Lawlor agreed that it had. Mr Trainor asked, would it not have been preferable to test the donations? Dr Lawlor agreed that this would have been

the preferable course of action. Dr Lawlor also agreed it was possible to get different results on different vials within the same batch. This would explain why some recipients of 90753 remained HIV negative. Dr Lawlor said it is possible that the virus had degenerated in the particular batches, or it may have been that the person was resistant to infection. Dr Lawlor said this was a matter for expert evidence.

Mr Trainor directed Dr Lawlor to batch 90785. Dr Lawlor agreed that this was the first heat treated factor IX to be issued to St. James' Hospital. She also agreed that, between October and December 1985, 103,454 units of factor IX unheat treated were issued from the BTSB; at the same time the BTSB issued 206,190 units of heat-treated factor IX.

Dr Lawlor agreed that the recall of January 1986 was ineffective and, while some vials of unheat-treated factor IX were returned (517 vials had been issue and 318 returned), roughly 200 vials remained unaccounted for. Dr Lawlor agreed that she conducted an inquiry into this matter in 1997, 11 years after the 200 units were issued. Dr Lawlor said she could not trace who had received batches, but the BTSB was happy that anyone who had got the batch had been tested.

Mr Trainor said, was it not extraordinary that the BTSB had not conducted a look-back into the issue of factor IX from 1986 until 1997. Dr Lawlor said that look-back for haemophilia patients was not conducted in the same way as a look-back for transfusion patients. Haemophilia Centres would usually do the testing. However, Dr Lawlor agreed that the issue should have been looked at, and it was somewhat unsatisfactory that this had not been done.

Mr Trainor asked Dr Lawlor, was part of the difficulty the absence of despatch records in the BTSB? Dr Lawlor said the problem was in the hospitals; they had no records. Dr Lawlor said factor IX records were held by the BTSB. She also agreed that some factor IX was issued to the Mater Hospital, Dublin, in 1985. The Mater Hospital is not a haemophilia centre. Dr Lawlor agreed that this was the case and that the factor IX had been issued in respect of a person who was undergoing a liver transplant, one of the first liver transplants conducted in this country. The patient did not survive for more than a few days after the operation, so the issue of factor IX did not arise, she said.

Mr Trainor asked Dr Lawlor, was there a possibility that an eighth person had been infected with HIV from BTSB factor IX? Dr Lawlor said, as far as she was aware there were seven, and seven only, infected from BTSB factor IX. Dr Lawlor said there may have been a case of false positive results but she did not have the document. It was agreed the document would be produced to Dr Lawlor over the lunch hour.

Mr Trainor asked Dr Lawlor, was it the practice of the Scientific Committee of the BTSB to meet every Friday? Dr Lawlor agreed that this was the case. She said the Future Development Committee may have sat as the Scientific Committee Meetings on some occasions. However, she agreed that there was nothing in writing to suggest that this was the case. Mr Trainor asked Dr Lawlor, had she been able to locate in her search for documents, the Minutes of the Scientific Committee from 14th December 1983 until 19th December 1985? Dr Lawlor said she had made inquiries at the BTSB, but no-one remembered what had gone on at the meetings during this time. Mr Trainor asked Dr Lawlor, had she asked those who participated in the meetings, had they taken place during the period? Dr Lawlor said she had not put this question to the people concerned, but had looked for the documents. Numerous sets of documents existed. No person who had a set of documents from the Scientific

Committee Meetings had the documents for the period in question, nor was there a master set of documents or minutes kept from the Scientific Committee Meeting.

Mr Trainor asked, was it the case, therefore, that the Board had no documents for this period? Dr Lawlor agreed, and she said things had become more informal at this time.

Mr Trainor then directed Dr Lawlor to a chart she had prepared illustrating the administration of batches 90753 and 90633. Of the people whose cases were recorded on the chart, five were deceased. Dr Lawlor agreed that if a product recall had taken place in August of 1985, then five of the seven people infected would not have become so infected. Dr Lawlor said however, that there was no question of a product recall in August of 1985.

Mr Trainor put it to Dr Lawlor that, as far as the BTSB was concerned, there was no question as to the consequences of HIV infection for those who became infected in 1985 and 1986.? Dr Lawlor said it was not apparent in August 1985 that HIV would inevitably lead to AIDS; it was thought at the time that a certain percentage of HIV positive patients would go on to get AIDS.

Mr Trainor then directed Dr Lawlor to the evidence of Mary, who gave evidence on behalf of her husband on Day 8 of the personal testimony hearings. Mary described the death her husband endured. Mr Trainor asked, was it known to the Board that those infected with AIDS exposed to such a death? Dr Lawlor said caring doctors continued to use factor IX in the best interest of their patients. There was no suggestion that the product should be pulled at the time, she said. Dr Lawlor said that all medical treatment carried a risk to those using it. Mr Trainor asked Dr Lawlor, did the Board take a conscious decision to produce factor IX knowing that it exposed the users to the risk of HIV infection? Dr Lawlor said there was a balance of risk, and decisions to use concentrates were taken in light of that balance.

Mr Trainor put it to Dr Lawlor that the decision not to have a recall at the end of August 1985 was unsupportable and wrong.

Mr Finlay, for the Tribunal, intervened at point, he said that different standards prevailed in 1985, and the witness could not be expected to make a judgement based on the state of knowledge in the year 2000 about circumstances which prevailed in 1985. Mr Trainor said that the witness could give a judgement on the standards that prevailed at the time. Mr Trainor asked Dr Lawlor, as a medical professional, what was her view of what should have happened in August 1985? Dr Lawlor said AIDS was not on the map at this stage.

Mr Trainor put it to Dr Lawlor that if she didn't wish to answer the question, he would pass from it. Dr Lawlor said she did not wish to answer the question.

Following the lunch break, the Tribunal returned to the issue of a possible eighth infection with BTSB factor IX. Mr Trainor asked Dr Lawlor, had she been able to ascertain whether or not this could be the case? Dr Lawlor said, no, there were only seven infections. When asked how she could be so sure, Dr Lawlor said she had telephoned Prof. Temperley and discussed the matter with him, and he confirmed that only seven infections accrued from BTSB factor IX.

Mr Trainor then returned to the table prepared by Dr Lawlor concerning the seven HIV factor IX patients. Mr Trainor asked Dr Lawlor, had she access to patient records to construct this chart? Dr Lawlor confirmed that she had obtained copies of patient records in Drogheda.

At this point Mr Finlay, for the Tribunal, intervened, and asked was the I.H.S. questioning the factual content of the table. Mr Trainor said the factual content was not in dispute, but he wished to know if Dr Lawlor had obtained permission from the various patients to use their medical records for the construction of the chart. When asked what the relevance of this question was, Mr Trainor referred back to an observation earlier in the week when Dr Lawlor could not answer questions concerning a particular patient without sight of the medical records. Mr Trainor wanted to know if Dr Trainor had had these medical records and if she had the authority of the persons concerned to use the records. Counsel for the BTSB said that if this line of questioning persisted, he would have serious things to say about the conduct of the representatives of the I.H.S.

Mr Trainor then indicated to the Tribunal that, as the remainder of the documents dealt with the post 1986 period and, in checking against the transcript he noted that there were witnesses available to answer questions arising in this period, he proposed to deal with the area of viral inactivation and testing by cross examining those witnesses who were there at the time. As this area had already been comprehensively dealt with by the Tribunal, and any questions which the I.H.S. may have could be directed to the persons concerned, Mr Trainor said he proposed to question the persons concerned and reserved his position as to whether or not Dr Lawlor may be required to answer questions on any outstanding issues.

PROCEEDINGS: FRIDAY 14th JULY, 2000 – DAY 28

Mr John Trainor S.C. continued his cross-examination of Dr Emer Lawlor of the BTSB.

Mr Trainor directed Dr Lawlor to a booklet of correspondence concerning Armour batch A28306. Among the documents examined was a communication from Armour dated 12th March 1986. In this document, to Prof Temperley among others, Armour makes a positive assertion for its factor VIII. The company says: "Each donation is now specifically screened for HTLV-III antibody, and all products being supplied are donor tested." The letter also stated that the lyophilised solution was dry heated to 60 degrees Centigrade for 30 hours.

Mr Trainor then directed Dr Lawlor to an article by Prof. Prince, contained in *The Lancet* of May 1986. Dr Lawlor said she was familiar with the article and knew that it contained research which had previously been done for Armour Pharmaceutical, and which the company had refused to clear for publication. Dr Lawlor said Prof. Prince had to do the work again and publish the article in *The Lancet*. The article expressed concern about the efficacy of dry heat treatment, and pointed to seroconversions among people using the product. Dr Lawlor said the 60 degrees for 30 hours heat treatment protocol resulted in a lot of residual virus. However, she said all heat treated products would be looked at with a certain caution at this time.

Mr Trainor asked Dr Lawlor, was she familiar with the adverse conclusions about the Armour product drawn in the Krever Report. Mr Trainor said it would not be appropriate at this stage to do more than advert to the conclusions drawn in the Krever Report, but if those comments were correct then clearly a question would arise as to Armour's state of knowledge in relation to its heat treatment process when it wrote to Prof. Temperley in March of 1986. Dr Lawlor agreed with this observation.

Mr Trainor then drew Dr Lawlor's attention to the sequence of events which led to the recall of Armour Factorate in September of 1986. In particular, he directed Dr Lawlor to an indication from Mr Dunbar of Armour which was contained in a memo of 11th July 1986, entitled Armour House Message. This letter to Mr Hanratty stated that only donor tested material had been used in Ireland since 1st January 1986. A list of batch numbers was appended to the memo, however A28306 was not on the list. The appended list contained non-donor screened batches. The company asked that these should be returned, whereupon they would be exchanged for donor screened product. However, A28306 was not on this list. Dr Lawlor said the absence of A28306 from the list must be of some significance, or else it is a simple mistake. But it was certainly unfortunate.

Dr Lawlor said the BTSB did not issue any Armour product after the end of 1985. A list entitled Issues to NCH 1985/1986 was not a list prepared by the BTSB, said Dr Lawlor. However, it contained information relating to issues from the BTSB which was correct.

Mr Trainor referred to a line on the chart recording an issue on 22nd January 1986 of 30 vials of Armour A28306. Dr Lawlor said it was not an issue from the BTSB. She assumed it was an issue from the company to the hospital; the hospital in this case being St. James' Hospital. Dr Lawlor said the BTSB returned 350 vials of Armour A28306 in December 1985. Prior to this, in November of 1985, the BTSB had taken delivery of 100 vials of a batch with the same unit number, ie. 230 units were contained in batch A28306. In these circumstances, 100 vials may have come from the same batch. However, since there are no despatch records in BTSB for the period before 1st January 1986, Dr Lawlor said she couldn't be sure if this was the

case. Dr Lawlor said she could not out rule the fact that some of those 100 vials had been issued prior to 1st January 1986. Dr Lawlor did not agree that the batch Armour A28306 was necessarily a non-donor screened batch. She said Armour A28306 was not on the list of non-donor screened batches sent to Mr Hanratty, and she had not been able to find a record of the batch on any list. She also said that the whole issue of donor screening was irrelevant, as donors in the window period would test negative. Therefore, any products obtained from donations derived from a multi-donor pool were high risk.

Mr Trainor put it to Dr Lawlor that the only other possibility was that the person who seroconverted on using the Armour A28306, in fact seroconverted from an infected batch of BTSB cryo. Dr Lawlor said this was much less likely, and the Armour batch was the more likely cause of infection. Dr Lawlor noted that Prof. Temperley had written to Armour in 1986, inquiring as to the donor screening status of the batch, and got no reply from the company. Dr Lawlor wrote to the company in September 1999, whereupon Armour replied to the effect that the batch had not been donor screened. In correspondence with Dr Lawlor, Armour said that the batch had not been recalled and re-issued. The batch was made and issued but was not donor tested. It had not therefore been sent back and forward.

Mr Trainor directed Dr Lawlor to the series of correspondence surrounding the recall of Armour product in late 1986. Armour responded to adverse publicity in newspapers by issuing a press release. The press release noted that two boys with haemophilia had tested positive for the AIDS virus. The press release stated: "These patients have not died, nor have they been diagnosed with AIDS." Dr Lawlor said this was an extraordinary statement for Armour to make at the time, as it was then known HIV would lead to AIDS.

Dr Lawlor said she would view statements from Armour at this time with scepticism, and this scepticism was based on what emerged from the Krever Report. Dr Lawlor said the chapter in the Krever Report on the Armour product indicated the company was economical with the truth. A serious question mark was placed over the veracity of Armour products at this time.

The book of documents continued with application by Armour for a renewal of its product licence. The application to Dr Smith of the NDAB indicated that the product would now be heat treated at 68 degrees for 72 hours. Armour 's plan o heat treat its product to this heat treatment protocol, was almost two years after Prof. Prince had carried out his experiments on behalf of Armour, which stated that the heat treatment protocol of 60 degrees for 30 hours was ineffective with respect to the HIV virus.

Mr Trainor then turned to a list which had been drawn up with respect to patients treated with A28306. Number nine on the list received one vial of A28306 and became HIV positive, therefrom. 86 vials remain unaccounted for. Dr Lawlor said that you must go into the list being drawn up. A further 32 vials were accounted for, so in the end 54 vials remained unaccounted for. Mr Trainor said that unaccounted for in this context, meant that the vials had been used. Dr Lawlor agreed that this was the case.

A total of 12 patients were treated with A28306. Seven of the patients were already HIV positive and were therefore not newly infected with this batch. Two of the patients appeared to be immune to HIV, having already been exposed to numerous batches, and remained negative. Two patients appeared to have received A28306 which did not contain virus. One patient seroconverted having used only one vial of A28306 on one occasion only.

Mr Trainor said that, therefore, in addition to the 100 vials of A28306 which could not be accounted for which was issued, or appeared to have been issued sometime in 1985, a total of between 154 and 186 vials of A28306 were unaccounted for, and all may have been administered at some stage. Dr Lawlor said greater access to hospital records would allow her to determine where the 54 vials may have gone. However, part of the problem was also the absence of despatch records in the BTSB, and in respect of the 100 vials this was true.

From Dr Lawlor's investigations it would appear that a batch of A28306 was issued in January 1986, from Armour directly to James' Hospital. This batch was heat treated to 60 degrees for 30 hours and was drawn from the donations of untested donors. Dr Lawlor said she did not know how the product found its way back into St. James' Hospital, but she was assuming that it was returned to the distributors in Ireland, and that the distributors re-issued it to St. James'. The product was heat treated but it was not donor tested.

Mr Trainor then referred Dr Lawlor to various issues which remained outstanding in her evidence, the first issue being Dr Lawlor's assertion that by the start of 1983, 95 per cent of those infected by HIV were so infected. Mr Trainor noted that, from Prof. Temperley's evidence, a report would show 58 per cent of persons with severe haemophilia A were HIV positive at the start of 1983. Dr Lawlor continued to dispute these figures. Mr Finlay, for the Tribunal, said Prof. Temperley's evidence should not be given at this stage. It was therefore decided that the Tribunal will return to this issue with Dr Lawlor.

Also noted were the Gunson report; the MMWR report of July 1982 which reported three cases of PCP in haemophilia A patients in the U.S.; the destruction of documents was also mentioned. Dr Lawlor said Mr Hanratty said the documents were destroyed, but not that he destroyed them. On the payments for the heparin project, no assistance was forthcoming from the BTSB, no light could be shed on who paid for the project. The Bass letter could not be located. The I.H.S. indicated that a reply letter from the UK Haemophilia Society was under investigation.

Mr Trainor then turned to the matter of the transcripts of two television programmes broadcast in 1975 in the World in Action series. The programmes were broadcast on 1st December and 8th December 1975. A third programme was broadcast in 1985. Dr Lawlor said that, overall, the programmes show, and it was not disputed, that it was known that paid U.S. donors were not good donors. It was also known that hepatitis was a risk in using blood concentrates, but it was considered to be an acceptable risk. It was also accepted that HIV and AIDS got into the blood supply via the same route as hepatitis. Dr Lawlor said that, if at the time she had had a child with haemophilia, she would have had her own child on the concentrate. Dr Lawlor also said that the information contained in the programme was not news to the BTSB.