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: WEDNESDAY 11th OCTOBER, 2000 – DAY 53

Mr John Finlay S.C. for the Tribunal examined Mr Brian O'Mahony, Chairman of the Irish Haemophilia Society.

Mr O'Mahony described to the Tribunal how he joined the Irish Haemophilia Society in 1982 after a brief spell on the Committee in 1978. Mr O'Mahony has been Chairman of the Irish Haemophilia Society from 1987 until the present. Mr O'Mahony has also been President of the World Federation of Hemophilia since 1992. He was re-elected to this position in 1996 and commenced his final term as President earlier this year.

Mr Finlay said that it seemed from the documentation that the Irish Haemophilia Society was founded by a number of parents and other persons interested in haemophilia, who first of all got in contact on an informal basis, and then combined with a number of medical people to form the Society. Mr O'Mahony said that in 1968, when the Society was formed, he was 10 years old. Mr O'Mahony said he was aware that Dr O'Riordan, Prof. Temperley and Mr Sean Hanratty were involved in getting the organisation started in 1968.

Mr O'Mahony said he became actively involved with the I.H.S. committee from 1982 onwards. In 1984 he attended his first meeting of the NHSCC as a substitute for Mr Scallan. In preparation for the meeting Mr O'Mahony reviewed the minutes of the NHSCC with particular reference to the issue of home production of factor VIII. Mr O'Mahony said his review of the minutes did not include reading the policy documents of the NHSCC, particularly those relating to the purchase of concentrate. This policy had been adopted by the NHSCC in January 1980. However, Mr O'Mahony said that he was now aware that the policy document allowed the directors of the treatment centre to select products. The document envisaged that the directors would get together with the BTSB and decide on which product to purchase. This decision would then be remitted to the NHSCC meeting.

Mr O'Mahony said that the minutes of the NHSCC meetings seemed to indicate that progress was being made by the BTSB in the home production of concentrate. Mr O'Mahony attended the NHSCC in February. The minutes of January 1982 indicate that Mr Hanratty expected that trials for the new product would be completed in three months time, and the introduction of home produced concentrates would occur six months hence.

It was noted in October 1982 by Dr O'Riordan that clinical trials of the new product were imminent. Mr O'Mahony said he understood by this that a more convenient concentrated

product would be made available, manufactured from the plasma of Irish donors, and it would be something similar to commercial product. The product was expected to be on a par with commercial concentrate and would replace imported commercial products.

Mr O'Mahony said he knew Mr Hanratty from his role in the BTSB and on the NHSCC. He had a chance meeting with Mr Hanratty in May 1983 following a seminar attended by him and Mr Hanratty. Mr O'Mahony said his conversation with Mr Hanratty on the subject of AIDS followed the publication in May of 1983 of a newspaper article concerning AIDS and blood products. The article published in *The Mail on Sunday* raised concerns and gave rise to the conversation with Mr Hanratty.

Mr O'Mahony noted the conversation. Mr Hanratty's view of the BTSB home production of factor VIII at this stage was that the project was viable, and he asked Mr O'Mahony if the IHS discussed the matter with Prof. Temperley. Mr O'Mahony's note states that he informed Mr Hanratty of the I.H.S. Committee's concern over AIDS and the use of imported American blood products which could lead to cases of AIDS in Ireland. Mr Hanratty agreed that American blood products, because of the payment system and nature of the donor panel, were of inferior quality to BTSB products.

Mr Hanratty informed Mr O'Mahony that the BTSB was developing a new factor VIII product which would be an improvement on cryoprecipitate. However, the work was proceeding slowly and he felt that any pressure the I.H.S. could bring to bear would be useful in accelerating the project. Mr Hanratty said he saw no reason why Irish haemophiliacs' needs could not be met totally by BTSB products, and noted that this would decrease the risk of AIDS, hepatitis and other blood-borne diseases which may surface.

Mr O'Mahony said he took his handwritten note and gave it to the I.H.S. May 1983 meeting. The I.H.S. contacted their British counterparts and were supplied with a reply containing advice from Prof. Bloom. The thrust of Prof. Bloom's advice was that reports of AIDS among people with haemophilia were alarmist, and that people with haemophilia should keep taking treatment for their condition.

On 31st May 1983 the I.H.S. wrote to Prof. Temperley expressing concern over the risk of AIDS contained in blood products. Prof. Temperley eventually replied in August of 1983 seeking to allay the fears of I.H.S. members of the risk of AIDS from blood concentrates. Prof. Temperley advised that the policy of the directors of the Regional Haemophilia Centres in the UK was to allay fears and to continue using all concentrate products, both national and commercial, until more evidence regarding the incidence in haemophilic subjects of the nature of the condition, became available.

Prof. Temperley included an article to be inserted into the I.H.S. newsletter. In summary, the article offered the following advice:

1) Haemophiliacs had faced the problems of jaundice and hepatitis with courage and understanding. The possible problems of AIDS must be encountered with the same fortitude.

2) Present information suggested that AIDS was rare in people with haemophilia. The benefits of the usual intravenous therapy were too well known to be enumerated. The balance, therefore, fell decisively on the side of continuing treatment as before.

3) Do not hesitate to visit the national and regional centres for advice, and

4) Keep attending the clinic.

Prof. Temperley said special assessments would be undertaken throughout 1983 and 1984.

On 11th November 1983 the I.H.S. called a special meeting with Mr Hanratty to discuss the current situation with respect to factor replacement therapy in the BTSB. Mr Hanratty stated that the BTSB was at present testing a new factor VIII and was hopeful for its future success. Following the meeting, Mr O'Mahony was deputed to write to Dr O'Riordan seeking information on the treatment of haemophilia with concentrates. Mr O'Mahony said Dr O'Riordan was of the view that the I.H.S. was not entitled to information regarding the cost of concentrates, quantities imported and quantities supplied by the BTSB. Dr O'Riordan was of the view that this was a matter for the BTSB and hospitals, and was not information to be given to patients.

Mr O'Mahony's letter sought to establish from Dr O'Riordan the number of units of factor VIII used in the last year, the numbers of units of factor VIII imported, the cost of imported factor VIII, the number of units of factor IX used in the last year, the number of units of factor IX imported, and the cost of imported factor IX.

Mr Finlay then referred Mr O'Mahony to his record of the NHSCC meeting he attended on 3rd February 1984. Mr O'Mahony's record is at odds with the official minutes of the meeting. Mr O'Mahony noted that two alternatives were before the meeting:

1) To go ahead with the production of BTSB factor VIII, and

2) To get factor VIII produced on a contract basis.

Mr O'Mahony noted it was decided to go ahead and do detailed costings on both alternatives. The official minute notes that it would now be necessary to prepare costings on the procurement of plasma. The official minute thus neglects the decision to do a detailed costing on the production of BTSB factor VIII. Mr O'Mahony said that the official minute did not tally with his recollection. He also pointed out that his note was written on the same day as the meeting.

Mr Finlay said that moving into 1984, the whole area of heat treatment started to come into general view. Mr O'Mahony said his recollection was that heat treatment became an issue in the second half of 1984, when reports from companies indicated that heat treating concentrates might kill the causative agent of AIDS.

Mr O'Mahony said that in August of 1984, when he attended the World Federation of Hemophilia congress in Rio de Janeiro there was still no definite information on heat treatment. Heat treatment was initially considered in relation to viral inactivation with respect to hepatitis.

The development of heat treatment with respect to HIV was assisted by the discovery of the HIV virus in 1984. It was then discovered that heat treatment could kill the HIV virus, in addition to hepatitis.

In the November/December 1984 period the first Irish case of a person with haemophilia infected with AIDS was treated at St. James' Hospital by Prof. Temperley. Prof. Temperley contacted the Society and informed it that a young man with haemophilia was being treated in St. James' for AIDS. Following this case Dr Cotter and Prof. Temperley decided that from 1985 onwards all product should be heat treated. The I.H.S., with the assistance of Prof. Temperley, issued information to its members concerning the heat treatment of all factor concentrates. No information on heat treating the products was forthcoming from the BTSB at this time.

With respect to freeze-dried cryo and factor IX there was no indication that these products could not be heat treated.

The early part of 1985 was dominated by the production of home products and the details of the contract fractionation programme. The BTSB and Prof. Temperley appeared to be in dispute concerning the freedom of choice and the issue of the BTSB developing a monopoly on the selection of contract fractionators.

In April of 1985 an I.H.S. delegation met Prof. Temperley to discuss their concerns. Prof. Temperley informed the delegation that 80 per cent of the HTLV-III blood tests were positive with respect to people with haemophilia. He also informed the delegation that he was leaving the country for six months on a sabbatical. Mr Finlay put it to Mr O'Mahony that the issue between Prof. Temperley and the BTSB was one of medical politics. Mr O'Mahony agreed that this was a good way of putting it, and it was not on the issue of the quality of the product.

Mr O'Mahony said alarm within the I.H.S. intensified on 25th July 1985 with the broadcast of the World in Action programme on AIDS, which forecast that 50 per cent of people infected with AIDS would die.

From 1st January 1986 factor VIII from Irish plasma was available. This factor VIII was heat treated. Factor IX from Irish plasma was also produced, but there was no discussion about heat treating BTSB factor IX. The I.H.S. was not aware that factor IX was not heat

treated at this time. The I.H.S. assumed that all product was heat treated in compliance with Prof. Temperley's directions issued in January of 1985. Mr O'Mahony said those using the product assumed that the safest product was made available by the experts in the BTSB. People with haemophilia had to take the product which was prescribed for them.

Mr O'Mahony described attending a seminar at UCD on 6th and 7th June 1986 concerning HTLV-III infections. Prof. Temperley gave a lecture on infection of haemophiliacs, the lecture was attended by Mr O'Mahony. Mr O'Mahony said he was not at the lecture in his capacity as a representative of the I.H.S., but was there in a personal capacity. Mr O'Mahony said he was expecting a lecture on statistics concerning HTLV-III. However, he received an awful shock when Prof. Temperley projected the initials of four factor IX deficient people with haemophilia onto a screen. Prof. Temperley stated that, while no proof was available, he estimated that these people had been infected with HIV by Pelican House product. Mr O'Mahony said that he was totally stunned. This was one and a half years after viral inactivation had become available. He was looking at the screen and saw there the initials of people he knew. He said thankfully, he was not one of those people. This was the first time it came to the notice of any member of the I.H.S. that there were late HIV infections of people with haemophilia B. Mr O'Mahony said the BTSB had not communicated this information to him or to anybody else, and it was a total shock.

In cross-examination Mr Brian McGovern S.C. for Prof. Temperley, said the last issue may be for the next phase of the Inquiry and he would reserve his position on this.

Mr Meenan S.C. for Prof. Egan cross-examined Mr O'Mahony, however Mr Meenan's questions were deemed to be more relevant to the knowledge of the I.H.S. and were ruled out by the Chairperson.

The NDAB had no questions for Mr O'Mahony.

Mr O'Mahony was then cross-examined by Mr Michael McGrath for the BTSB. Mr McGrath asked Mr O'Mahony if the trip taken by Dr O'Riordan to Las Vegas was a junket, and were similar trips, undertaken by members of the I.H.S., considered to be junkets? Mr O'Mahony said that the I.H.S. did not send its members on junkets.

PROCEEDINGS: THURSDAY 12th OCTOBER, 2000 – DAY 54

Mr John Finlay S.C. for the Tribunal cross-examined Prof. Ian Temperley. Prof. Temperley is former director of the National Haemophilia Treatment Centre, Dean of Medicine at Trinity College, Dublin, and a member of the board of the BTSB from May 1987 until 1999.

Prof. Temperley told Mr Finlay that he commenced his career as a junior pathologist at TCD in 1958. In 1968 he was appointed consultant haematologist at the Federated Dublin Voluntary Hospitals. In 1976 he was appointed medical director at St. James' Hospital. He retired from his medical posts in 1995. In 1968 Prof. Temperley was a founder member of the Irish Haemophilia Society. Prof. Temperley said that the Society resulted from the joint efforts of parents, people with haemophilia and concerned medical professionals coming together to found the Society.

Mr Finlay pointed out that this section of the Tribunal would examine the BTSB and its role, and would seek to concentrate on that aspect of the investigation. The treatment of persons with haemophilia would be dealt with in the third division of the Tribunal's work.

Prof. Temperley said that in 1968 the regime of treatment for haemophilia consisted of individual doctors giving treatment around the country. Factor IX deficiency was treated with plasma and factor VIII deficiency was treated with frozen cryo. With respect to factor IX deficiency there was always a worry about heart overload, said Prof. Temperley.

The treatment of factor VIII deficiency consisted of the administration of 5-10 donations of plasma at a time in the form of cryoprecipitate. Prof. Temperley said these treatments were effective in controlling routine bleeding. Serious bleeding was, however, a great danger due to the uncertainty surrounding the number of units of factor being administered with each treatment. Surgical operations were hazardous for people with haemophilia. Prof. Temperley said people with haemophilia in those days encountered serious joint bleeding and could suffer enormously.

Prof. Temperley said that the first successful treatment with cryo was carried out in June 1967, and from then until freeze-dried cryo became available in 1976/1977 cryo was used for the treatment of haemophilia.

The National Haemophilia Treatment Centre was established in 1971 at the Meath and at the National Children's Hospital. In 1976 the National Haemophilia Treatment Centre moved to St. James' Hospital. Prof. Temperley said that in 1974 home therapy was commenced in some instances, using cryo. There were one or two children treated at home with cryo, but it presented problems due to the volume required for successful treatment. Prof. Temperley said allergic reactions were a serious danger, especially for

home therapy. He also said that he was not covered for persons who fell ill while on home therapy.

Prof. Temperley said that in 1974 the BTSB produced its own factor IX with a dedicated giving set. A fixed amount of factor IX was contained in each ampoule. This was usually around 150 units of factor IX. Prof. Temperley said that in 1974 concentrated factor VIII was available in Ireland. The advent of factor concentrates meant that surgical operations could be performed on persons with haemophilia, including elective surgery. The number of units was indicated on each ampoule. The concentrate was thus preferable to cryo. Prof. Temperley said the level of cryo could not be assessed with respect to the units contained in each bag of cryo.

Prof. Temperley agreed with Mr Finlay that it appeared to be Dr O'Riordan's view that he was opposed to the use of commercial concentrate. Prof. Temperley said that this objection was based on humanitarian grounds. Mr Finlay asked Prof Temperley was Dr O'Riordan concerned about the nature of the donors. Prof. Temperley agreed that Dr O'Riordan appeared to have concerns that unsuitable people were being used as donors, however the debate on paid and unpaid donors continued to be a characteristic of blood donation.

Mr Finlay referred Prof. Temperley to a telephone memo of a call made by Dr O'Riordan to the Department of Health in the early 1970s. Dr O'Riordan expressed concerns that concentrates were being imported into the country and such concentrates were being made from plasma derived from skid row donors in the U.S.

Mr Finlay asked Dr O'Riordan was he concerned about the product being imported, namely Hemofil from Travenol. Prof. Temperley said he was not as concerned as Dr O'Riordan. He had different views. Prof. Temperley said he did not have the same degree of responsibility for these products as had Dr O'Riordan. Prof. Temperley said as far as he was concerned the least troublesome product was the best product.

Prof. Temperley said one of the difficulties presented by Hemofil was the fact that it could be administered on an individual basis. This was unsatisfactory as the level of factor VIII and factor IX could not be monitored. Prof. Temperley said he had no difficulty with Hemofil itself, and when a National Haemophilia Treatment Centre was established this problem was overcome.

In order to facilitate correct usage of factor concentrates Prof. Temperley said Dr O'Riordan took over the distribution of Travenol through the BTSB. Prof. Temperley said he had no difficulty with Dr O'Riordan acting as distributor for the Travenol product. Prof. Temperley said self sufficiency was an important aspiration, but it was never actually achieved.

The next advance in the treatment of haemophilia was the arrival of freeze-dried cryo. Prof. Temperley said this was a considerable advance. Freeze-dried cryo was used in hospital for a considerable time, said Prof. Temperley. With respect to home treatment,

freeze-dried cryo could be used for home therapy but it presented difficulties, and only one or two people on home therapy were using freeze-dried cryo. Prof. Temperley said certain individuals would be selected for home therapy, he said that those who could cope with home therapy would be selected. The criteria for selection was the ability to self administer the freeze-dried cryo.

Prof. Temperley noted that in June 1975 Dr O'Riordan attended the Council of Europe conference in Helsinki. Prof. Temperley said this conference appeared to equate self sufficiency with self reliance. Prof. Temperley agreed that commercial product was used in Ireland at this time. However, Dr O'Riordan was of the view that commercial concentrates should not be used, and he favoured the use of cryo. Prof. Temperley said Dr O'Riordan held these views in a positive way, however he pushed the view that the best possible treatment for hemophilia should be employed, and in this he was in conflict with Dr O'Riordan's view concerning freeze-dried cryo.

Prof. Temperley said Dr O'Riordan was a strong member of the Council of Europe. As a member of the Council of Europe he would have strong views on commercial product. Furthermore, blood banks such as the BTSB were in competition with commercial companies in that some Council members were producing product which was in direct competition with the commercial concentrates produced by commercial companies.

With respect to hepatitis Prof. Temperley said that by August of 1975 hepatitis testing was introduced. As a result, hepatitis was practically eliminated from the blood supply. However, hepatitis B continued to appear in the blood supply, but not as frequently as in the past.

In 1975 Travenol withdrew Hemofil following an outbreak of hepatitis.

Prof. Temperley contacted the BTSB and expressed concern on behalf of people with haemophilia that Hemofil was no longer available. Prof. Temperley said that Dr O'Riordan was responsible for information on the products. Mr Finlay asked who had advised Dr O'Riordan. Prof. Temperley said that Dr O'Riordan would be advised by Mr Hanratty or maybe his colleagues in Europe.

Prof. Temperley said that he would pass the results back to Dr O'Riordan and would pass on UK information. Prof. Temperley said his patients on Hemofil would sometimes get hepatitis B. Prof. Temperley said if this happened he would sometimes complain to the manufacturers that his patients were contracting hepatitis B. He would start a row if his patients got hepatitis B from blood concentrates. Mr Finlay asked Prof. Temperley was there any evidence to substantiate this, and Prof. Temperley said that he could not present any evidence until in and around 1985. Prof. Temperley said that drug companies may have evidence. He made his complaints in 1975 and 1976.

Prof. Temperley said that by the late 1970's freeze-dried cryo was considered to be inferior to the commercial products. Prof. Temperley said the BTSB always seemed to

be one step behind requirements at this time. However, freeze-dried cryo continued to be used up until 1985.

On 1st September 1978 Prof. Temperley attended a BTSB scientific committee meeting. The question raised was would the BTSB produce an intermediate product, ie. a more concentrated product than freeze-dried cryo. Prof. Temperley said this would have been the ideal at the time as many of the available commercial products were intermediate products. The discussions concerning the production of a BTSB intermediate product continued between 1978 and 1981. Prof. Temperley said some thought was put into this project but technical problems prevented it from going ahead.

In November 1978 Prof. Temperley wrote to Dr O'Riordan concerning the BTSB's practice of adding a 3p mark-up on Hemofil. Dr O'Riordan replied indicating that he had doubts whether or not these products should be purchased at all. Prof. Temperley said Dr O'Riordan appeared to be opposed to commercial products and naturally lent his support to BTSB products. Prof. Temperley said the BTSB was a competitor to commercial products in some respects. It was a producer and had to compete. Dr O'Riordan had two aims, said Prof. Temperley. One was the aspiration to self sufficiency and BTSB products, and the other was the business reality of supplying imported concentrates. While he may have been of the opinion that Irish derived products were safer, and would have said this to Prof. Temperley, the business reality meant that the BTSB imported and distributed commercial concentrates.

Mr Finlay referred Prof. Temperley to a Council of Europe document in 1979. Prof. Temperley's name is on the draft document, along with authors from Belgium and Finland. Prof. Temperley said that hepatitis risks arose from all products, both paid and voluntary. However, it was recognised that the paid donor risk was higher.

Mr Finlay also referred Prof. Temperley to Dr Daly's 1979 study of hepatitis in persons with haemophilia and the role of the NHSCC with respect to its policy on concentrate purchase. It was noted at the NHSCC that if the Heparin project was successful it would decrease the risk in hepatitis. The Tribunal examined Prof. Temperley's role in assisting Mr Hanratty with the BTSB's home production of factor VIII.

Mr Finlay directed Prof. Temperley to the February 1983 period and the results of the BTSB's factor VIII production. Prof. Temperley said, as best he could remember, these trials did not report favourable levels of factor VIII. There were difficulties with the half life of the BTSB's own factor VIII, and it was difficult to assay the amount of factor VIII due to the presence of heparin in the product.

PROCEEDINGS: FRIDAY 13th OCTOBER, 2000 – DAY 55

Mr John Finlay S.C. continued his examination of Prof. Ian Temperley.

Mr Finlay referred Prof. Temperley to the results of tests carried out on the BTSB's factor VIII produced by Mr Hanratty's project. The trial took place between February and October 1983. The report of the clinical trials suggested that the BTSB factor VIII was a very good product. Seven out of eight rises were greater than expected. The difficulty with the product arose because it did not have a sufficient half life.

Mr Finlay referred Prof. Temperley to a draft letter to *The Lancet*. Prof.Temperley said the letter was prepared in response to the BTSB's factor VIII project, but he was not completely happy with the methodology used, and was not absolutely sure about the results obtained in the trials. In the event, the letter to *The Lancet* was not published.

Mr Finlay and Prof. Temperley tracked the BTSB's project through various NHSCC meetings, at which positive reports were offered on behalf of the scheme. However, Prof. Temperley said that this project was not the only thing that concerned him. He said he had his own life to live and a lot of other work to do. He also said that what was recorded in the minutes at various meetings was not necessarily what had been said. With respect to the viability of the project Prof. Temperley said he didn't feel it was a wasted effort. The BTSB could have gone on. The project could have continued. The only problem was the assay of the product.

At a BTSB board meeting of December 8th 1983, the Board heard that 15 patients had been treated with BTSB factor VIII product. Prof. Temperley said, while 15 patients may have received this factor VIII product, he did not think that this was their treatment programme. However, as far as he was concerned at this stage, the heparin project was going ahead. At the BTSB board meeting of 18th January 1984 a change of policy concerning the production of home product was noted. Mr Finlay said that within a month it appeared that home production had given way to the concept of contract fractionation. Prof. Temperley said he didn't know why there was a sudden change of policy.

Mr Finlay referred Prof. Temperley to a handwritten note of the NHSCC meeting of 3rd February 1984. The issue of home production and contract fractionation was discussed. The handwritten note, by Mr Brian O'Mahony of the I.H.S., recorded that detailed costings of both these options would be obtained for the next NHSCC meeting. In the official note of the meeting it was recorded that a costing would be obtained for contract fractionation only. Prof. Temperley said he was not aware of any contract fractionation at this time. He was not aware of any change-over in policy, and it came as a surprise to him that contract fractionation was the way to go.

Mr Finlay asked Prof. Temperley could the BTSB have produced sufficient quantities of heparin factor VIII? Prof. Temperley said he didn't know, but there was a considerable difference between bringing a product to trial and bringing it into production. Prof. Temperley said in late 1984 he had doubts that the BTSB would have the capacity to produce its own factor VIII, however, in 1983 he had been sure they could achieve this. Prof. Temperley said he did not recall any further discussions with Mr Hanratty concerning the product, however he did note that a major change had taken place in BTSB policy.

With respect to heat treatment of factor concentrates, Prof. Temperley said the first heat treatment information he received was from Travenol and not from the BTSB. He received this information in late 1984. Mr Finlay referred Prof. Temperley to a letter to the NDAB of 9th October 1984. Prof. Temperley told the NDAB at this stage that he was not convinced about the effectiveness of heat treatment of factor concentrates. He said this was the view of the UK centre directors at the time.

Prof. Temperley said he changed this opinion after the UK Centre Directors meeting of December 1984. At this stage the HTLV-III virus had been identified by Gallo, and it had been determined that viral inactivation could be achieved through heat treatment. This information had come from the CDC.

Prof. Temperley said in December 1984 he met the Department of Health in the company of Dr Cotter, and they decided that heat treated products only would be used for 1985. Prof. Temperley informed the NDAB and withdrew his advice concerning heat treatment. He now said it was essential that heat treatment be applied to factor concentrates. The BTSB was not represented at this meeting. Prof. Temperley said he could not think why the BTSB was not invited. Prof. Temperley said he was anxious to take some action in late 1984 and heat treatment offered him a means of doing something.

Prof. Temperley agreed that in 1984 the first Irish haemophilia patient with AIDS had been treated in St. James' Hospital. On December 17th 1984, Prof. Temperley wrote to Dr O'Riordan concerning the heat treatment of factor concentrates and the selection of products for the forthcoming year. Prof. Temperley estimated that the cost of heat treatment would be an extra £100,000 per annum.

The BTSB informed Prof. Temperley that it may not be possible to heat treat factor IX until 1985. Prof. Temperley said he was under the illusion that early heat treated product would be available from the BTSB. Dr O'Riordan wrote to Prof. Temperley telling him that heat treatment was being given urgent attention, and on the subject of contract fractionation the treaters would be consulted in due course.

Prof. Temperley said he was very disappointed to be told that heat treatment would not be made available immediately. At an open discussion on heat treatment at the Federated Dublin Voluntary Hospitals conference in early 1985, the BTSB made the case that Irish plasma, without heat treatment, was safer than U.S. plasma with heat treatment. Prof. Temperley said Mr Cann of the BTSB led the argument that Irish plasma unheat-treated

was safer than heat-treated U.S. factor VIII. The BTSB's view point seemed to be there was no question of HIV in Ireland at this time.

Mr Finlay put it to Prof. Temperley that, as he was charged with making the treating decision, he could have decided not to use BTSB product. Prof. Temperley agreed, but if he had decided to take this course of action he would have had to say no further factor IX from the BTSB.

Prof. Temperley said the BTSB made it clear it would not heat-treat the product at this time. Prof. Temperley said the BTSB was adamant that it would not heat treat its product. He said he had discussions with Dr O'Riordan and Mr Hanratty, and that they insisted they knew better. However, they also hinted that BTSB factor IX heat-treated might be made available in April of 1984. Prof. Temperley said he was insistent but they were reluctant to heat treat. He got the impression they would provide heat-treated material by April 1985. In May of 1985 Prof. Temperley commenced his six month sabbatical leave.

Upon his departure Prof. Temperley said he had the impression that heat-treated product might be made available by September of 1985. Prof. Temperley agreed with Mr Finlay that from the 17th January 1985 heat-treated factor IX from Cutter was available to St. James' Hospital. A communication from the BTSB points out that Pelican House factor IX would be heat treated shortly. Mr Finlay said it did not appear from this that the BTSB was refusing to heat treat its factor IX. In fact, said Mr Finlay, it said the opposite.

In February of 1985 Prof. Temperley and Dr Cotter voted against the BTSB plans for contract fractionation at the National Haemophilia Services Co-ordinating Committee. Prof. Temperley's opposition to the plan came about as a result of not being consulted on the BTSB's strategy for contract fractionation. Prof. Temperley said he and Dr Cotter felt left out of things. He felt they should have been informed about the product and involved in the choice of fractionator by the BTSB. He was also concerned that the BTSB was establishing a monopoly over factor VIII and factor IX sales in this state. Prof. Temperley said he was getting into a position where he had no alternative to BTSB product, and as the BTSB was not getting on well in relation to heat treating his products he felt that the treaters should have more say in the product bought by the BTSB.

Prof. Temperley said he had no objection in principle to contract fractionation. He wanted products from the BTSB but he would want to know what the product was, and did not want to continually rely on U.S. concentrates.

On 9th April 1985 Prof. Temperley received a letter from Dr O'Riordan offering him a chance to meet the contract fractionators. Prof. Temperley agreed that this was a conciliatory letter. However, when Travenol was selected as the contract fractionator, Prof. Temperley wrote to Dr McCann expressing his concern over the choice of Travenol as the company chosen to produce BTSB factor VIII. Prof. Temperley said he thought Travenol had been in trouble in the past, and the company had a poor reputation in the United Kingdom at that time.

In August 1985 Prof. Temperley, while on sabbatical, received a call from Dr Daly who was his locum in Dublin. Dr Daly informed him that the BTSB was supplying unheat treated factor IX. Dr Daly's contact with Prof. Temperley resulted in his letter to Dr O'Riordan, where Prof. Temperley pointed out to Dr O'Riordan that they would be failing in their duty, knowing what they then knew, to continue to supply unheat treated factor IX. Prof. Temperley said, in hindsight, he should have instructed Dr O'Riordan to stop using non-heat treated factor IX.

Prof. Temperley noted that in October 1985 BTSB heat-treated factor IX was available in St. James' Hospital. St. James' was the first institution to obtain BTSB heat-treated factor IX. It was used there first in order to cater for any case of thrombogenicity which may result from its use.

With respect to later HIV infections of people with Haemophilia B, Prof. Temperley said he first became aware of these seroconversions between January and April of 1986. On 22nd April 1986 Prof. Temperley contacted Dr Walsh and presented him with the information he had to date. Prof. Temperley agreed that his letter to Dr Walsh was the first contact he made with anyone in the BTSB concerning the late infections of people with Haemophilia B with HIV.

On 6th and 7th June 1986, Prof. Temperley attended a seminar in UCD. At this stage he had more information concerning late infections with HIV of people with Haemophilia B. Prof. Temperley did not contact the BTSB. Instead he put the information on public display by way of using it to illustrate his lecture at the seminar. Prof. Temperley said he thought it needed to be put into the public domain at this point, and he felt that the issue should be pushed. He said a newspaper report in the *Irish Times* of the seminar was broadly accurate and carried his viewpoint quite well. He said it was a big decision for him to take at the time and he worried on reading in the newspaper. He said he did not take the decision to put this information on display light heartedly. He said it was very worrying at this time that native factor IX may have been causing HIV infections.

Mr Finlay referred Prof. Temperley to Dr Walsh's memo concerning the recall of un-heat treated and unscreened BTSB factor IX. Prof. Temperley said at this stage he had received an anonymous telephone call concerning non-screened plasma being used for production of BTSB factor IX, and that took up a major part of his discussion with Dr Walsh.

At this stage Prof. Temperley said he was concerned that even heat treated product may be carrying HIV infection. Prof. Temperley said he insisted that not only should product be heat treated, but derived from HIV-screened donors. Prof. Temperley said he may have agreed to use re-heat treated product, but once he discovered it was not screened he refused to use it. He agreed with Mr Finlay that there was no evidence that HIV infection was caused by heat-treated BTSB factor IX.