IRISH HAEMOPHILIA SOCIETY

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CONTENTS:

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TRIBUNAL OF INQUIRY

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

PROCEEDINGS: Monday 28th June 2001 - Day 137

Mr. McGuinn, Chief Pharmacist for the Department of Health, had given evidence on Friday 25th May. Mr. Aston, for the National Drugs Advisory Board, began his examination of Mr. McGuinn.

Mr. McGuinn confirmed that the National Drugs Advisory Board had no role under the Therapeutic Substances Act. Mr. McGuinn said that, although other European countries did not use European regulations to control blood or blood products within their states, those countries had other mechanisms in order to ensure the safety of blood products. When asked by Mr. Aston, was that the case in the United Kingdom. Mr Mc.Guinn said it was. Mr. Aston asked Mr. McGuinn whether it was really within the realistic ability of the NDAB to draw up standards equivalent to those in the United States for the control of blood substances within the State. Mr. McGuinn said emphatically that it was, and that the NDAB was capable of doing so. Mr. McGuinn went on to say that there were international standards available, such as the UK pharmacopoeia, which the NDAB could apply in order to assess the quality and safety of blood products.

Ms. Rafter then gave evidence, examined by Mr. Finlay for the Tribunal. Ms. Rafter was an Assistant Pharmacist in the National Drugs Advisory Board from 1983 to 1987. She explained that her role was to assess the pharmaceutical side of applications for product authorisations under the 1984 regulations. She said she worked under, and reported to, Dr. Scott. Ms. Rafter said that she had been responsible during her time in the NDAB for the pharmaceutical side of applications relating to factor VIII. However, she said that she had no formal training in the analysis of blood products. Ms. Rafter explained that, when applications for product authorisations were made to the NDAB, she would examine the products on the pharmaceutical side. Ms. Rafter explained that she would receive data from the Pharmaceutical companies in relation to the product which set out how the products were tested and what the constituent parts of the products were. She would then examine this data in relation to international standards, and if she was satisfied that the data was in order, she would give approval for a product authorisation in relation to the pharmaceutical tests.

Mr. Finlay asked Ms. Rafter specifically about two products which she dealt with while employed by the NDAB. The first was product authorisation for heat-treated factor VIII produced by Armour Pharmaceuticals. The product authorisation in relation to this product had been surrendered in 1986, and all stock of the product had been recalled by Armour when it was discovered that the product was not safe. This factor VIII product had been heat treated by Armour at 60 degrees for 30 hours. Armour had claimed in 1986 that this was sufficient to kill the HIV virus that may be carried in the product. However, when it emerged that this was not the case, the product had been withdrawn. In 1987, Armour proposed a new heat treatment which they claimed would render the product safe. This treatment involved heating the product for 72 hours at 68 degrees Celsius. The National Drugs Advisory Board agreed to renew this product authorisation on the grounds that no product would be issued in the State until the heat treatment test was varied by the NDAB. On receipt of data to the effect that the heat treatment proposed by Armour was in fact sufficient, the NDAB renewed these product authorisations.

Mr. Finlay asked Ms. Rafter about production authorisation applications that she made for a non-heat treated product manufactured by Miles Laboratories. The product application was made in February 1984 for a product called Koate.

In September 1984, Ms. Rafter wrote to Miles Laboratories stating that no non-heat treated product would be given a product authorisation, because no non-heat treated products were currently on the market in Ireland. However, she admitted that this was not the case, and that the product authorisation application by Miles for Koate was processed.

Ms. Rafter told the Tribunal that the NDAB granted product authorisation for the non-heat treated Koate product following consultation with Prof. Temperley. Prof. Temperley advised the NDAB that he still wished to use non-heat treated factor VIII products. However, in December 1984 Prof. Temperley informed the NDAB that one of his patients, who had been using non-heat treated factor VIII, had developed AIDS. Ms. Rafter told the Tribunal that the product authorisation for non-heat treated Koate had nonetheless been approved by the NDAB. She said that this must have been an administrative error and she could not explain how this came about.

The Tribunal then adjourned to the 29th May 2001.

PROCEEDINGS: Tuesday 29th May 2001 - Day 138

Ms. Rafter, Pharmaceutical Assessor with the National Drugs Advisory Board, continued her evidence. Ms. Rafter told the Tribunal how in 1985, the NDAB became aware that Alpha Therapeutics Corporation distributed contaminated factor VIII and factor IX products in the USA. People with haemophilia who had used these products had subsequently become HIV positive. Dr. Scott of the NDAB requested that Ms. Rafter write to all pharmaceutical companies with whom the NDAB dealt, to ensure that they had no connection with Alpha Therapeutics Corporation and neither plasma nor concentrate of any kind from Alpha was being processed or distributed in Ireland. Ms. Rafter dealt with a third pharmaceutical company, Travenol, who produced a factor IX concentrate product. Ms. Rafter explained how in early 1985, she had been directed by Dr. Scott to request that Travenol heat treat not only their factor VIII product but their factor IX product, for which they intended to seek a product authorisation in this country.

Mr. Giblin for the I.H.S. cross-examined Ms. Rafter. He directed her to the issue of a product authorisation for the Armour Pharmaceutical factor VIII. Mr. Giblin asked Ms. Rafter whether a licence which had been surrendered could be reinstated. Ms. Rafter said that it was a matter for the Medical Director, that she had no input into that decision. Mr. Giblin asked Ms. Rafter whether it would have been preferable to require Armour to apply for a new product authorisation for the factor VIII product. Ms. Rafter said she could not answer that. She said that in any event, the only difference between renewing a product authorisation and applying for a new product authorisation, was that a fee would have to be charged for a new product authorisation.

Mr. Giblin then asked her, was it not a requirement that a new product authorisation be put before the Committee of the NDAB, and that this requirement didn't exist for a renewal of a product authorisation. Ms. Rafter agreed. Mr. Giblin said, was it not the case that the NDAB should have been more circumspect about renewing this product authorisation. Ms. Rafter said she couldn't comment on that.

Mr. Giblin asked Ms. Rafter about the Koate product authorisation application. Mr. Giblin asked whether it was NDAB policy at that time to require that all products seeking a product authorisation be heat-treated. Ms. Rafter said she could not comment on whether it was NDAB policy or not. She said that in September 1984 opinions differed in relation to that. Mr. Giblin then asked, how was it that on the 13th September she wrote to Miles Laboratories in relation to the Koate product authorisation application, stating that only heat-treated products were on the Irish market. Ms. Rafter said that she could not really explain how this had happened, but that this was a consultative letter which would have been drafted in consultation with Dr. Scott.

Mr. Giblin then asked Ms. Rafter how it was possible that a product authorisation could have been issued for Koate non-heat treated in March 1985, when it was clearly NDAB policy at that stage not to give product authorisation for non-heat treated product. Ms. Rafter said that it was an administrative error, but she could not explain how it had happened and that it was not within the remit of her responsibility. Ms. Rafter said it was very unfortunate that this had happened.

Mr. Aston then examined Ms. Rafter on behalf of the NDAB. In response to Mr. Aston's questions, Ms. Rafter stated that product authorisation for heat-treated Koate was processed much more quickly, largely because of the earlier product authorisation application for non-heat treated Koate.

Mr. Frank Bird of the Irish Haemophilia Society was examined by Ms. Grainne Clohessy for the Tribunal. Mr. Bird was a member of the I.H.S. Executive Committee during the 1970s and Chairman of the Society in 1979 and1980.

Mr. Bird described the early days of the Irish Haemophilia Society and said the Society came together to give people with haemophilia a better life, to disseminate information on haemophilia and to raise funds for items such as telephones for people with haemophilia. He said the Society was totally voluntary at the time with no full time employees, no premises and no secretarial services of any kind. He said that the establishment of the National Haemophilia Services Co-ordinating Committee represented an important event for the Society. Mr. Bird said he himself was not directly involved with the NHSCC and never sat on the co-ordinating committee.

Mr. Bird said that in 1979 going into 1980, the Society made contact with the Haemophilia Society in Britain. The I.H.S. was on the mailing list of the British Society and was a member of the World Federation of Hemophilia. Mr. Bird said at this stage the Irish Haemophilia Society was still a roving band. The Society was a voluntary group, organised on an informal basis. However, some information was coming through to it from the international haemophilia community. Mr. Bird described the organisation of the Information Clearinghouse of the World Federation of Hemophilia to Ms. Clohessy. He told her that certain publications would be listed by the Clearinghouse, and if a particular person or group of members of the WFH wanted a copy of any particular information, the Clearinghouse would provide it. However, the Irish Haemophilia Society was not in receipt of all the titles and information documents listed by the Clearinghouse.

Ms. Clohessy referred Mr. Bird to a report on his visit to the World Federation conference in Bonn on 2nd – 8th October 1980. The Mr. Bird said the conference from his point of view was very successful. He made contact with delegates from Canada, Israel and New Zealand, and these proved to be long-lasting contacts. Mr. Bird said he was involved in the youth group at the time. He met young representatives from countries who were of like mind. He said the detailed medical aspects of haemophilia were not uppermost in the minds of the young delegates. He said various treatment regimes in different countries would be compared, however this would not be based on any detailed medical knowledge. Mr. Bird said this was the first conference of its type organised by the international haemophilia community. Mr. Bird said he kept in touch with some of the people after the conference. Mr. Bird said that, while there were medical presentations at the conference, the Irish Haemophilia Society did not have the expertise to assess these contributions. Mr. Bird said he and members of the Society were reliant on the treaters to advise on the appropriate treatment. The Irish Haemophilia Society in 1980 and 1981 was still very much a voluntary organisation, with very little expertise, and was still organising bring and buy sales just to raise funds for the Society.

Mr. Bird said the introduction of cryoprecipitate to him was a wonderful development, and the introduction of concentrates were likewise viewed AS being of great benefit to people with haemophilia. Mr. Bird said he did not recollect seeing any originating documents of the National Haemophilia Services Co-ordinating Committee or recommendations to Ministers that these documents may have contained.

Mr. Bird was examined by Mr. Michael McGrath FOR the BTSB.

Mr. Bird was examined by Mr. Raymond Bradley for the Irish Haemophilia Society. Mr. Bird told Mr. Bradley that the Irish Haemophilia Society in 1979 and 1980 had no permanent premises. It did not own a filing cabinet, and correspondence was sent either to the address of the secretary or the chairman.

Mr. Shay Farrelly of the Irish Haemophilia Society was examined by Mr. Gerry Durcan of the Tribunal. Mr. Farrelly described his early involvement with the Society. He said in 1981 he was in his early 20's.

He joined the Committee in October that year and continued his involvement on the Committee until October 1985. He came back as a member of the Committee in the 1990s.

Mr. Farrelly said that, on joining the Committee, he would spend about two to three hours a week meeting fellow committee members. He said the organisation was totally voluntary at the time. Mr. Farrelly said that by the time he joined the Committee, many of the difficulties facing people with haemophilia had been addressed, in that concentrate was available and people with haemophilia were able to lead a normal life. However, among the general public there was widespread ignorance about haemophilia, said Mr Farrelly. The Condition was seen by many as something of a social disease and many people with haemophilia didn't really like to have it known that they suffered from the condition.

Mr. Farrelly said that the Society was more of a social and welfare organisation. Mr. Farrelly said that the Society did not have access to medical expertise and characterised the organisation as a consumer group. Mr. Farrelly said he did not feel that the Irish Haemophilia Society had any influence on the activities of the National Haemophilia Services Co-ordinating Committee at this time. They had no influence over what product would be used for the treatment of haemophilia, and had no medical expertise available to the Society. Mr. Farrelly said that in 1982 he did not consider the risks of hepatitis arising from the use of factor concentrates. Mr. Farrelly said that Haemophilia Exchange information documents were before the Tribunal, but such documentation would not have been available to the Irish Haemophilia Society in the 1980s. Mr. Farrelly said he first became aware of the issue of AIDS in 1983 when he visited the UK for the purposes of putting together a proposal for a National Haemophilia Treatment Centre. He said he was informed by Mr. Watters of the UK Haemophilia Society in February 1983 of a risk of AIDS. However, he said he did not understand the implications of the information at the time.

In May 1983 the issue of AIDS resurfaced. Mr. Farrelly said that the Haemophilia Society wrote to both Mr. Watters of the UK Haemophilia Society and to Prof. Temperley, to get more information on the issue of AIDS. Mr. Farrelly said he believed that the UK Society replied but the reply from Mr. Watters could not be located at this time. Prof. Temperley replied in August 1983. Mr. Farrelly said that the combination of the reply from Mr. Watters and the eventual reply from Prof. Temperley together would have allayed fears with respect to AIDS at that time. The Society was told in 1983 that AIDS in haemophilia was very rare. Mr Farrelly said the impression he formed was that Professor Temperley was on top of the situation. Mr. Farrelly said that the responses of Prof. Temperley and Mr. Watters allayed fears and concerns of Society members. Prof. Temperley's article was reproduced in the I.H.S. Newsletter of September 1983. Mr. Farrelly agreed that the newsletter containing this article was the first formal written communication between the I.H.S. and its members on the issue of AIDS.

PROCEEDINGS: Wednesday 30th May 2001 - Day 139

Mr. Gerry Durcan for the Tribunal continued his examination of Mr. Shay Farrelly of the Irish Haemophilia Society.

Mr. Durcan referred Mr. Farrelly to the National Hemophilia Federation Newsletter of August 1983. A hand written notation on the newsletter notes, "Give this to Prof. Temperley". Mr. Farrelly said that the most likely time that this documentation would have come into the possession of the Irish Haemophilia Society was in 1985, when an information pack was put together by the Irish Haemophilia Society and Prof. Temperley following the first HIV AIDS case in St. James's Hospital. Mr. Farrelly said that this document was not in the possession of the Irish Haemophilia Society in 1983.

Mr. Durcan referred Mr. Farrelly to the 1983 I.H.S. AGM. The issue of AIDS was not raised at the meeting. Mr. Farrelly said the main issue on the agenda was Report 1983 which contained the proposals for the establishment of a National Haemophilia Treatment Centre. Mr. Farrelly said that information on AIDS, prepared by Prof Temperley, was contained in the September newsletter. Mr. Farrelly said that at this time fears as regards AIDS had been allayed, so it was not a big topic during the remainder of 1983.

Mr. Durcan referred Mr. Farrelly to a meeting between the Irish Haemophilia Society and Mr. Hanratty, which was scheduled to discuss the AIDS problem. Mr. Hanratty discussed the home production of factor VIII at the meeting and a plan of campaign was drawn up in order to facilitate and further this project.

Mr. Farrelly was further directed to a document where the Irish Haemophilia Society Committee decided to provide £8,000 to Prof. Temperley for research into the immune system of people with haemophilia. Mr. Farrelly said the Committee agreed to provide funding for the research proposed by Prof. Temperley.

It would appear that during 1984, said Mr. Durcan, that things got quieter with respect to AIDS in that there were no documents recording discussions at the Committee on the subject. However, the Irish Haemophilia Society Newsletter of July 1984 describes the proposed research funded by the Irish Haemophilia Society into immune system dysfunction.

At the end of 1984 it was reported that a person with haemophilia had developed AIDS. He was being treated at St. James's Hospital. In order to pre-empt the effects of the publicity which would attend this development, Prof. Temperley contacted the I.H.S. and together members of the Society and Prof. Temperley compiled an information pack for Society members. This occurred in January 1985. The information pack consisted of a covering letter from the Society, a leaflet entitled "Information on AIDS and Haemophilia", and a letter from Prof. Temperley. Mr. Farrelly said the bulk of the information contained in this pack was taken from information contained in the National Hemophilia Foundation information leaflets published in 1983. Mr. Farrelly said Prof. Temperley would have seen the finished product before it was dispatched to members. In the information leaflet distributed to members in 1985, it is noted that it is thought that HTLV-III virus is heat sensitive, therefore from early January 1985 all factor concentrates used in Ireland would be heat treated. It was hoped that this would inactivate the virus.

It was noted in the document that the NHTC and the Cork Regional Centre would be recalling all factor VIII concentrate from early January 1985 and replacing them with new heat treated products. The NHTC also advised that all home produced product should be heat treated.

Mr. Durcan asked Mr. Farrelly what was the understanding of the Irish Haemophilia Society with respect to heat treatment of Irish products? Mr. Farrelly said he thought it was clear from the second paragraph of the situation in Ireland section of the document, that from early 1985 all factor concentrates used in Ireland would be heat treated. He said the document did not differentiate between where the concentrate was produced, it just says used. Mr. Farrelly said to him factor concentrates included both factor VIII and factor IX. It was his understanding that all factor concentrate would be heat treated including factor IX.

Mr. Duran referred Mr. Farrelly to his meeting with Prof. Temperley in May of 1985, prior to Prof. Temperley's departure for London to take up his sabbatical post. An Irish Haemophilia Society Committee minute recorded what occurred at the meeting. Prof. Temperley said that 80 per cent of the HTLV-III blood tests showed positive. He expected that there may be one more case in the country according to U.S. findings. Mr. Durcan asked Mr. Farrelly, what was the response of the three people from the I.H.S. to Prof. Temperley's news? Mr. Farrelly said he took reassurance from the idea that, while while those testing positive may have the antibodies to the virus, they would be very unlucky to have more than one case. He understood that exposure to the virus did not necessarily mean exposure to the risk of AIDS. However, he said that they were concerned that people had been exposed to risk, but this was tempered by what appeared to be the fact that it was very unlikely that people would go on to develop AIDS. Mr. Farrelly said he may have been surprised that Prof. Temperley was going on sabbatical, but he was not too sure about his reactions. Mr. Farrelly said he agreed that he was anxious that people who had been tested should be given their test results as soon as possible, and should be informed of what the risks were and the risks to their partners and families and so forth.

Mr. Farrelly said that in August 1985, after viewing the World in Action documentary on AIDS which was discussed at the I.H.S. Committee meeting of that month, percentages of possible infection with AIDS were revised upwards to the range of 1-5 per cent. Also, the blood donor population or panels that were being used to produce U.S. concentrates were a source of concern.

Mr. Farrelly was cross-examined by Counsel for Prof. Temperley, the Southern Health Board, the BTSB and the Department of Health, and by the Irish Haemophilia Society.

Ms. Pamela Aldrich of the Irish Haemophilia Society was then examined by Ms. Grainne Clohessy for the Tribunal. Ms. Aldrich described preparing the booklet "Haemophilia: The Basic Facts". Ms. Aldrich said that the chapter on AIDS and haemophilia included in the booklet was drafted by Dr. Helena Daly and was approved by Prof. Temperley. She said there was a big demand for the book, which went into two editions.

In 1985 Ms Aldrich was involved in organising counselling insofar as it was possible for the members. Ms. Aldrich attended the World Federation of Hemophilia conference in Milan in June 1986. She said she did her best to attend to both the medical and social aspects of the conference. Many of the medical matters under discussion were of a highly technical nature, she said. Ms. Aldrich was also involved in drawing up fact sheets for the Society.

Ms. Aldrich was cross-examined by Mr. Ian Brennan for the Department of Health, and by Mr. Raymond Bradley for the Irish Haemophilia Society.

PROCEEDINGS: Thursday 31st May 2001 - Day 140

Mr. Brian O'Mahony, Chairman of the Irish Haemophilia Society and President of the World Federation of Hemophilia, gave evidence. Mr. O'Mahony said that the first time he became aware of difficulties in regard to AIDS in persons with haemophilia was in May 1983. This followed an article in *The Mail on Sunday* and a meeting with Mr. Sean Hanratty on 10th May 1983. Following these events the Society wrote to Prof. Temperley and the British Haemophilia Society to get information on the issue of AIDS and haemophilia. Mr. O'Mahony said that the British Haemophilia Society replied, and he believed that the statement of Prof. Bloom, as contained in a letter from the Reverend Tanner of the British Haemophilia Society, was the reply or the reply was in similar terms. The contents of the reply from the British Haemophilia Society served to reassure members of the Society in Ireland as to the dangers posed by AIDS to those with haemophilia. Prof. Temperley's reply in August was in similar vein.

At the AGM of the Irish Haemophilia Society in October 1983, no mention of AIDS is recorded. Mr. O'Mahony said, as far as he could recollect it didn't come up, and in any event the issue had been dealt with in the newsletter of September 1983 which contained Prof. Temperley's advice on the subject.

During 1983 the major work of the Society was Report 1983, which set out the Society's plans and proposals for a National Haemophilia Treatment Centre. Mr. O'Mahony said that members of the Society followed the medical advice they were being given, and Prof. Bloom and Temperley seemed to be on a broadly similar track.

With respect to funding research at the request of Prof. Temperley, Mr. O'Mahony said he came to the view that the research should be supported. The research would investigate the effects of therapy on the immune system of people with haemophilia.

Mr. O'Mahony said that the Society met with Mr. Hanratty on 10th November 1983. Mr. Hanratty was pushing the idea of blood products from Irish donors and wanted the Society to promote this case at the National Haemophilia Services Co-ordinating Committee. Mr. O'Mahony wrote to Dr. O'Riordan to obtain certain information. No reply was forthcoming in writing. He received a telephone call. Dr. O'Riordan explained he would meet with Prof. Temperley and the information might be forthcoming later. Mr. O'Mahony said the views of the Society in November 1983 was that the BTSB's self sufficiency project had the potential for success. He said his memory of the time was a sense of frustration coming from Mr. Hanratty that self sufficiency was not being achieved, and there was a feeling that it should be pushed harder. Mr. Hanratty said the needs of persons with haemophilia could be supplied with Irish product.

With respect to access to National Hemophilia Foundation publications, Mr. O'Mahony said that the Society did not usually have such access. His information in terms of AIDS in haemophilia was mostly domestic. Mr. O'Mahony said Prof. Temperley was the medical advisor and treater of people with haemophilia, and the Society and its members relied on his advice. Mr. O'Mahony said that at the NHSCC meeting of February 1984 he expressed his dissatisfaction at progress in relation to the achievement of self sufficiency. He said the meeting was told that of concentrate to be used for 1984. Two companies Cutter and Armour would be employed.

In June and July of 1984, the newsletter containing a report on the research to be funded and carried out by Ms Eagleton was put together.

Mr. O'Mahony said he attended the World Federation of Hemophilia conference at Rio in August 1984 and put together a comprehensive report of the conference for the Society. Mr. O'Mahony said he had a reasonable degree of scientific knowledge but attended the conference as a voting delegate and persons with haemophilia from Ireland. Mr. O'Mahony said that with his background some of the medical presentations made sense, but others went over his head. Viral inactivation was mentioned at the conference but it was a new concept to him at this time. He was aware that this was a possible area for the prevention of infection.

Mr. Durcan asked Mr. O'Mahony did he come back from the conference with the knowledge that AIDS was a greater threat than previously thought? Mr. O'Mahony said that this wasn't the case. There had been a symposium on AIDS at the conference, but his assessment of the symposium was that the risk was slight and the feeling of reassurance which had previously existed, continued. Mr. O'Mahony said AIDS was a minor subject at the conference. It was discussed and was contained in the abstract which he brought back from the conference.

In December 1984 Mr. O'Mahony said a significant meeting took place. Prof. Temperley contacted the Society and had discussions with them. A person with haemophilia was in St. James's Hospital and had developed AIDS from his HIV infection. Media sensationalism was anticipated. Mr. O'Mahony said in this circumstance, it was important to get information out to the members in advance of the story breaking in the media. While Prof. Temperley said that this was very likely to be the only case of AIDS, Mr. O'Mahony said he was quite shocked at this development.

With the assistance of Mr. Farrelly and Mr. Sheridan and Prof. Temperley, Mr. O'Mahony co-ordinated the compilation of an information pack. Mr. O'Mahony described this as a collaborative effort. Mr. O'Mahony said that the information contained in the leaflet put together was drawn from the National Hemophilia Federation document of August 1984, not August 1983. The Society believed that this was accurate and good advice at the time. Mr. O'Mahony said it was almost an exact lift from the U.S. document. He acknowledged that this information had been available to persons in the Unitd States for a number of years previously and was now available in Ireland. Mr. O'Mahony said the same information was also being disseminated in England.

The situation as it was understood by the Irish Haemophilia Society, was that from early 1985, all factor concentrate would be heat treated. Mr. O'Mahony said this was the information given to the Society by Prof. Temperley. Mr. O'Mahony said that when Prof. Temperley said that all products would be heat treated from the start of 1985, he expected it would be done. The Society had no information that what had been advised was not being done.

Mr. O'Mahony said at the time many of the media reports were sensationalistic and lurid. He said this approach heightened the guilt associated with AIDS infection for people with haemophilia, and affected the self-confidence of people with haemophilia. Mr. O'Mahony said ignorance led to incidences such as a person with haemophilia who was HIV positive being dispatched from a rural destination to Dublin in a sealed ambulance. And where children were being boycotted at school because haemophilia had become publicly associated with AIDS.

Mr. O'Mahony said secrecy and fear surrounded the entire AIDS scene at this time. Employment problems were encountered by some people and parents felt guilty about treating their children with products which had been contaminated with HIV.

Mr. O'Mahony explained the dilemma that the Society found itself in, whereby its members needed information regarding AIDS but at the same time, they had to play down the association between haemophilia and AIDS. Mr. O'Mahony said that the health education booklet was designed to counterbalance the lack of knowledge among the general public concerning AIDS. He said fact sheets were compiled and the periodical *Positive News* was launched. Mr. O'Mahony said the Society organised workshops and meetings for people with AIDS. At the time, said Mr. O'Mahony, the only people who could discuss AIDS were those who had been infected.

Mr. O'Mahony said that by 1987 the real effects of the AIDS epidemic among people with haemophilia was becoming apparent. Members were becoming unwell, with many unable to work. Members who became ill were falling into poverty. Those with AIDS were instructed to maintain a good diet and a healthy lifestyle but on disabled persons maintenance allowance of £47.00 per week this was not possible. Mr. O'Mahony said that where possible, the Society subsidised its members.

Mr. O'Mahony said that the efforts of Dr. Daly in 1985 in informing members of their results of HTLV-III tests and the distribution of condoms and advice as to how to minimise the risk of sexual transmission, was crucial in reducing infection among spouses of people with haemophilia and HIV.

Mr. O'Mahony described the recompense campaign of 1988 and 1989. Mr. O'Mahony said a positive reaction was experienced from the Department of Health in the first instance. This continued up to the submission of the Society's document "AIDS, Haemophilia and the Government" in 1988. Mr. O'Mahony said that the initial positive reaction to the Society's submissions created an expectation of a positive response to the recompense request for life insurance, mortgage insurance, *ex-gracia* payments, or a trust fund.

By November 1988 the attitude of the Department had changed. It was explained by Department officials that the budgetary situation had deteriorated. Mr. O'Mahony said at this time the Society had lost yet another three members. Many other members were in dire circumstances and were attempting to cope on inadequate State supports. Mr. O'Mahony said the Society had no choice but to go public in its demands, and did so at the end of 1988. Mr. O'Mahony said that the dilemma for the Society was that the publicity campaign sacrificed confidentiality of persons with HIV. He said members had to come out and say they were HIV positive. Some very brave individuals did so.

By February 1989 Mr. O'Mahony said the Society met a group of TDs who voiced support for them. On meeting the Minister during that month the Society was offered £50,000.00 for counselling and offered a place on a review committee. Mr. O'Mahony said that this was not acceptable. This had been the Society's first meeting with the Minister for Health. He had expected detailed discussions on the submissions. Mr. O'Mahony said that the atmosphere at the meeting was cold. At this point Mr. Brennan for the Department of Health objected, and said that the emotional atmosphere had not been put to the Minister in his evidence.

Mr. O'Mahony continued that moral and legal liability was denied by the Department of Health. They were offered money for counselling and very little else, and this was not what he had expected the meeting to be about. In the event the Government was defeated on the Labour Party motion to increase the funding to the Society. Following the General Election, the Trust Fund was set up. This had been promised during the course of the election campaign. Mr. O'Mahony said the fund did a remarkable job, and put on record his appreciation of the work carried out by members of the Trust.

With respect to Hepatitis C, Mr. O'Mahony said he would be surprised if people with haemophilia were aware of the dangers of Hepatitis C during 1980s. The seriousness of the condition only became apparent in the 1990s.

Mr. O'Mahony said he first became aware of BTSB factor IX infections following the UCD seminar in 1986. Mr. O'Mahony said he had assumed that heat treated factor IX was in use in 1985. He was shocked to learn that HIV infections had taken place among people with Haemophilia B.

Mr. Durcan asked Mr. O'Mahony had there been any follow-up to the UCD meeting. Mr. O'Mahony said the I.H.S. had no role to play in following up the information. He did not ask Prof. Temperley about these infections as he was unsure whether it was Irish or commercial concentrates had been the cause. Mr. O'Mahony said he was very upset by the whole episode and the way the results were imparted. However, he knew there was a difficulty with BTSB factor IX when it was withdrawn from use shortly after the meeting. Mr. O'Mahony said he did not become fully aware of the factor IX situation until the Tribunal sat in public hearings. He said he had suspicions, but the Tribunal had confirmed that BTSB factor IX was the source of infection.

Mr. Durcan referred Mr. O'Mahony to a hand written note of an NHSCC meeting on 30th January 1987. Mr. O'Mahony's note records observations by Prof. Temperley. The note records that out of 16 people tested, five were positive in factor IX cases. Mr. O'Mahony said this was mentioned by Prof. Temperley. He had noted it as the meeting was going on and there was no discussion as to the source of this

information. Mr. Durcan asked Mr. O'Mahony had he, with this information, pieced it together with the previous information available from the 1986 meeting and come to any conclusions? Mr. O'Mahony said he had not connected the information at the time. A further piece of information later became available, where it was indicated that eight persons with haemophilia B were positive for HIV. Mr. Durcan said that pulling the three pieces of information together, would it not be clear to the Society that the seroconversions had occurred after 1986? Mr. O'Mahony said there were suspicions but no cause was shown.

Mr. O'Mahony said the likelihood was that BTSB product had caused infection. This was a suspicion but he could not know for sure. He did not know whether it was heat treated or un-heat treated and could not rule out commercial product.

Mr. O'Mahony was cross-examined by Ms. Deirdre Murphy for St. James's Hospital. Ms. Murphy put it to Mr. O'Mahony that between the Irish Haemophilia Society and Prof. Temperley, a team-based approach to the treatment of haemophilia developed at the NHTC. Mr. O'Mahony said that when the Irish Haemophilia Society started in 1968 he was ten years old. The Irish Haemophilia Society did not give treatment. It supported its members and families and he was not aware it was a member of any team as regards the treatment of haemophilia.

Mr. O'Mahony was cross-examined by Mr. Michael McGrath for the BTSB. Mr. McGrath asked Mr. O'Mahony if he understood the AIDS part of the Rio conference? Mr. O'Mahony said he was a delegate from the I.H.S. The treaters were in attendance. They understood the AIDS part of the conference.

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Mr. Brian O'Mahony of the Irish Haemophilia Society was examined by Mr. Ian Brennan of the Department of Health.

He was then examined by Mr. Martin Hayden of the Irish Haemophilia Society. Mr. Hayden directed Mr. O'Mahony to the information pack of January 1985. Mr. O'Mahony said this booklet was dispatched to all members on the mailing list. Included in this was Dr. O'Riordan of the BTSB. On 10th January 1985 Dr. O'Riordan acknowledged receipt of the document. Mr. O'Mahony said he expected any inaccuracies in the document would have been pointed out by Dr. O'Riordan. In December 1985 Mr. O'Mahony said the Society was informed by Prof. Temperley that heat treated product was on hand and there would be only a short delay in the provision of heat treated factor IX. It was clear that Prof. Temperley thought that factor VIII and factor IX heat treated product was available.

Mr. O'Mahony said that with respect to the document "AIDS, Haemophilia and the Government" in April 1988, the Society got a positive response up until November of that year from the Department of Health. In November and December the Department appeared to change its attitude. Mr. O'Mahony said that at meetings with the Society and the Department, the Department was represented by Mr. Collins. At the meeting in February 1989, Mr. O'Mahony said that the Society was looking for assistance for its members. He said he outlined the case for the Society and the response of the Minister was to set out a legal position and offer the Society £50,000 for counselling.