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: Tuesday 27th February 2001 - Day 94

Mr John Finlay S.C. referred Prof. Temperley to the evidence of Mr Raymond Kelly, the father of John Kelly. Mr Kelly gave evidence to the Tribunal as a personal testimony witness on behalf of his son, John.

After examining the medical record of John Kelly, who died as a result of HIV and hepatitis C infection in 1994, aged 13 years, Mr Finlay referred Prof. Temperley to a number of specific complaints made by Mr Kelly about Prof. Temperley in his evidence.

With regards to discussing the boy's HIV condition in the hallway of the National Children's Hospital when other persons were in the proximity, Prof. Temperley said that in the course of the ward rounds he may well have discussed with his team the boy's condition in the corridor of the National Children's Hospital, however he was not aware of other people being around and he could not really remember the details of the incident. But he said it was possible that it had taken place, and it was conceivable in the course of discussion that people may have overheard the conversation. However, he said a very serious matter was under consideration, he was deeply concerned for the patient's illness, and this may have caused him to have the conversation with his team.

Prof. Temperley said he would not have knowingly hurt a person's feelings, including the boy's mother. Prof. Temperley's remark arose from his observations concerning John in 1994, where he said to Mrs Kelly that John may recover from this, and then again he may not, referring to a particular infection from which he was then suffering. Prof. Temperley said it was an on-going problem at the time, and he was in and out of the boy's room. Prof. Temperley said he may have been "upping the ante" as the boy was terribly ill at the time. Prof. Temperley said John was being treated for avian tuberculosis, which was associated with his HIV infection. He realised that difficulties were encountered in the administration of the tubercular therapy as had been mentioned by Mr Kelly. However, Prof. Temperley said he was not conducting any experiment. He was treating the boy for what he thought was avian TB and he had discussed this decision with the microbiologist.

Prof. Temperley agreed that there were strains and tensions between himself and Mr Kelly. He said it was very distressing for him. He was ploughing through difficulties and was under tremendous pressure. He said he felt he needed help and support from the parents. Prof. Temperley said he was trying to help the situation and that was all he was trying to do.

Prof. Temperley was referred to the medical records of Mr John Berry; the witness who appeared under the pseudonym of "Dominic"; the witness who appeared under the pseudonym of "Vincent"; the witness who appeared under the pseudonym of "Edward"; Mr Bernard Smullen; "Albert"; "Donal"; "Brendan"; "Cecil"; "Sharon"; "Luke"; "Roy" and "Herbert". Prof. Temperley was also referred to the case of "Cyril", the witness "Francis"; "Shirley" and her son "Hugh"; Ms Linda Dowling; the witness known as "Una"; the witness "Jackie" with respect to her son "Rory"; and "Declan" the husband of "Deirdre".

Prof. Temperley was referred to a retrospective study conducted in 1986 by Dr Shattock on stored serum samples, which showed that by the end of 1983 approximately 75% of those who would become HIV positive from the selection of samples available, were positive for HIV.

Mr Finlay concluded his direct examination of Prof. Temperley.

Mr Martin Hayden for the Irish Haemophilia Society, cross-examined Prof. Temperley.

Mr Hayden directed Prof. Temperley to a retrospective study of a group of 43 severe haemophilia A patients, upon whom a retrospective study of stored serum samples was conducted. Prof. Temperley agreed that by the end of 1983 the majority were infected, but not the vast majority. He also agreed that this study of severe haemophilia A patients would contain a selected group, the members of which had been exposed to continuous therapy for haemophilia over a number of years, and therefore exposed to the greatest danger of infection with HIV. Prof. Temperley agreed that mild and moderate haemophilia patients would have been exposed to a lesser degree of infection by virtue of the fact that they would have been subject to less therapy.

Mr Hayden directed Prof. Temperley to the testimony of Dr Emer Lawlor given on July 5th 2000, where Dr Lawlor stated that by the start of 1983 95 per cent of those who would be infected with HIV were in fact infected. Prof. Temperley said that this was Dr Lawlor's view and it was not a view he could support, but neither did he want to be drawn on the issue. He could say that he vaguely and intellectually understood why she had this view, but he still had to work it out with her whether or not it was in fact correct.

With respect to Dr Lawlor's view that the issue of thrombogenicity delayed the introduction of heat treated factor IX by the BTSB, Prof. Temperley said he was never deeply impressed by this theory.

Mr Hayden referred Prof. Temperley to the medical record of the late Mr John Berry. In relation to his medical record it is noted that, when being treated for a nose bleed in 1979, Mr Berry was originally to be treated with cryoprecipitate. It would appear from his medical record that when treatment with cryoprecipitate was anticipated, such treatment was not given as there was insufficient water to reconstitute the cryoprecipitate available on the day. Prof. Temperley agreed that the only reason Mr Berry appeared to have been treated with concentrate was that no water was available. Prof. Temperley agreed that it would appear from the record that the junior doctor administering the treatment referred to the Registrar on duty before changing the instruction that cryoprecipitate should be administered. The Registrar in question is identified as Dr Lawlor. Mr Hayden asked Prof. Temperley which Dr Lawlor would that be? Prof. Temperley replied: "that's Dr Emer Lawlor as far as I am aware".

Mr Hayden they referred Prof. Temperley to early correspondence between himself and Dr O'Riordan concerning the importation of Hemofil and the cost of Hemofil. This correspondence commenced in 1975 and continued through to 1979.
By 1979 with the establishment of the NHSCC, Prof. Temperley eventually became the person who selected the product to be imported by the BTSB. Mr Hayden asked Prof. Temperley, would he agree that Dr Lawlor was correct in her assertion before the Tribunal that the BTSB's function was to act as a warehouse for the products, while the treaters were responsible for the administration of concentrates to patients. Prof. Temperley said he did not agree that the BTSB acted solely as a warehouse. He said the BTSB was a medical centre with a medical director, and had an input into the product itself. Prof. Temperley said that the BTSB was akin to any reputable company which would stand over the product it supplied. Prof. Temperley said all those involved were responsible for ascertaining the safety of the product with respect to its manufacture. Prof. Temperley said information was forthcoming from the drug companies. He did not agree that the BTSB had an overriding responsibility for safety, but he did think that they had a responsibility.

Prof. Temperley said he was extremely busy at the time and was not sure who would be absolutely responsible for the safety of imported blood concentrates. He said it could have been the BTSB. However, he said a large number of issues were never dealt with.

Prof. Temperley said contact between himself as a treater and product selector, and commercial companies, was a fact of life. Prof. Temperley said that representatives from the drug companies would call into the hospital in order to obtain support for their products. He said they were also in touch with the BTSB.

Under the auspices of the National Haemophilia Services Co-ordinating Committee,.Prof. Temperley and the Regional Directors selected products which would be supplied by the BTSB to the hospitals. Prof. Temperley said that, while various rules and regulations were laid down in product selection documents of the National Haemophilia Services Co-ordinating Committee, he did not feel bound by these arranements. He said in real life he did not think this was the job he had to do, and he did not know whether or not the NHSCC was aware of this view.

Prof. Temperley said that he was in favour of the policy of promoting home therapy, and even in 1983 and 1984 when it became apparent that concentrates were a source of infection, the policy of advocating home therapy was never revisited. Prof. Temperley said he took his advice from the UK Haemophilia Centre Directors. If they said to stop using concentrate in 1983 he would have stopped.

Mr Hayden referred Prof. Temperley to a document from the UK Haemophilia Centre Directors, of May 1983. Amongst other things the document recommends the following. "For treatment of children and mildly affected patients or patients unexposed to imported concentrates, many directors already reserve supplies of NHS concentrate, cryoprecipitate or freeze-dried, and it would be circumspect to continue this policy." Prof. Temperley agreed that he had received a copy of this document. Prof. Temperley issued a treatment guideline in December 1983. Prof. Temperley said he did not recall any move on the part of the Haemophilia Directors themselves in relation to cryoprecipitate. He said this may well have coloured his opinion at the time.

Prof. Temperley said the UK Haemophilia Centre Directors did not carry out their own recommendation. Prior to this Prof. Temperley had stated that, if the UK Directors issued a recommendation he would follow it. Prof. Temperley said he did not suppose that every piece of a recommendation was put into practice. Prof. Temperley said he would have discussed the recommendation with his colleagues in the UK at the time. Prof. Temperley agreed that he did not sent a copy of his recommendations when they finally emerged to Prof. Egan in Galway or Dr Basheer in Limerick. He did however send a copy to Dr Cotter in Cork.

Prof. Temperley maintained that, despite having drafted and dispatched the Centre Director's recommendations in June 1983, neither Drs Rizza or Bloom in fact implemented these recommendations. Prof. Temperley said he did not recall any sort of move on the part of Haemophilia Directors themselves in relation to cryoprecipitate. This issue was re-visited the following day.

Prof. Temperley sought and was granted permission by the Tribunal to clarify evidence given the previous day. Prof. Temperley told the Tribunal he had considered overnight the evidence he had given, and wanted to comment on the climate of opinion which prevailed in May 1983 when the UK Haemophilia Centre Directors issued their directions, particularly with respect to the use of cryoprecipitate.

Prof. Temperley said this document was not followed, even by the Centre Directors themselves. He had taken the opportunity, upon giving evidence to the Tribunal before Mr Finlay, to talk to colleagues in the UK, in particular Dr Christine Lee of Great Ormond Street Children's Hospital and Prof. Hann. Prof. Temperley said he had not alluded to this particular matter on the previous day, as he had tired towards the end of the day and it had not occurred to him. He said these colleagues affirmed that the British Directors had never at any stage adopted the procedure of administering cryoprecipitate only.

Mr Martin Hayden for the Irish Haemophilia Society, objected to the evidence of the professor being given at this stage. A debate ensued between Mr Hayden and the Chair as to the relevance of whether or not cryoprecipitate only had been administered in 1983. The Chair instructed Mr Hayden to provide a list of centres which he [Mr Hayden] said had provided cryoprecipitate only. He was instructed to make such a list available to the Tribunal by 2.00pm that day.

The cross-examination of Prof. Temperley they re-commenced.

Prof. Temperley agreed that in 1983 hepatitis B was under discussion at the BTSB Scientific Meeting in the context of being a surrogate marker for AIDS. Prof. Temperley agreed that a discussion on heat-treated factor VIII at this time, and the agreement to administer DDAVP for dental treatment, was directed at minimising exposure to concentrates. Prof. Temperley said this issue was discussed and was a matter of concern at the time.

With respect to selecting products and drug companies involved, Prof. Temperley agreed that the NHTC procedure involved himself and Dr Cotter. He also said Mr Hanratty was involved. He said Mr Hanratty was a person who specialised in product selection, and would have been involved in product selection in previous years. He would not agree that Mr Hanratty played a significant part in product selection, but he said Hanratty was always interested and he was a very important man in relation to product selection.

Prof. Temperley said the policy followed in 1983 with respect to children was covered by the fact that young children would be treated only in hospital, and the standing instruction that cryoprecipitate only be used for hospital treatment. In this way Prof. Temperley said children would be unexposed to any risks emerging from concentrate. However, Prof. Temperley said it may have been the case that some children were treated with concentrate. Prof. Temperley agreed that he proposed home therapy, and that home therapy relied on the use of concentrate.

Prof. Temperley said the protocol in place covered children because any child under the age of four would have to go to hospital for treatment; such a child would not therefore get concentrate. Persons with mild haemophilia and previous unexposed patients also fell into this category. Prof. Temperley said the proof of the pudding was that only four people with mild haemophilia had become HIV positive, and they got concentrate in and around the years 1980 – 1982. Prof. Temperley said, while these infections were most unfortunate for those concerned, it was a small number. He also said that no-one with von Willebrand's disease contracted HIV. He did not agree with Mr Hayden's suggestion that this was as much a matter of chance as a matter of observing the protocol put in place.

Mr Hayden referred Prof. Temperley to a letter from Mr O'Donnell of Accu-Science dated 6th November 1983, setting out the details of Accu-Science provision of Cutter product to the BTSB. Prof. Temperley agreed that he had contact with Accu-Science and Mr O'Donnell prior to the NHTC meeting which agreed the product selection for the year 1984.

Mr Hayden asked Prof. Temperley, had he any knowledge at this time of Mr Hanratty's role, and interest in Accu-Science. Prof. Temperley said he could not recall details of any specific knowledge of Mr Hanratty's connections with Accu-Science. He learned of this some time later.

With respect to the first infection of a person with haemophilia with AIDS in November 1984, Prof. Temperley said it came as a terrible shock. He did not expect this to happen in one of his own patients.

Mr Hayden referred Prof. Temperley to various documentation which outlined the steps to be taken in light of the outbreak of AIDS among people with haemophilia. However, while various steps to be taken concerning informing people with haemophilia as to the threat from AIDS and testing, and informing people of the results of tests, were outlined in this correspondence, nothing was set in train to actually tell people the results of tests until June of 1985.

Prof. Temperley said it was decided as of November 1984, that only heat-treated products should be used. He expected heat-treated product to be available with respect to factor VIII, in January 1985 and for factor IX, heat treated product to be available in February 1985. Prof. Temperley said the use of the word "forthwith" in the various correspondence open to him, was an indication of his expectation that this would happen. Prof. Temperley agreed that he had not informed the regional centres at either Galway or Limerick about the outbreak of AIDS among people with haemophilia, which was in front of him at St. James' Hospital.

After resuming for lunch, Mr Hayden asked Prof. Temperley, was it in fact the case that he had remembered overnight the evidence he had forgotten to give the previous day, and had he talked to the various people he mentioned after he had given evidence in direct examination by Mr Finlay? Prof. Temperley said that he had in fact spoken to Prof. Lee on the previous night by telephone. Mr Hayden put it to Prof. Temperley, if that was the case, he could not then have had it in his mind to mention any evidence based on her views on the previous afternoon. With respect to Prof. Hann, Prof. Temperley, who in the morning had said that he had spoken to Prof. Hann on the telephone, agreed that he had not in fact spoken to Prof. Hann at all. Someone had spoken to Prof. Hann on his behalf.

With respect to the substantive matter as to whether or not the directors followed the UK Centre Directors Guidelines in 1983, Mr Hayden listed a number of centres which in fact confirmed they had followed the guidelines. With respect to whether or not only cryoprecipitate was used, it was clarified that the centre directors used both NHS concentrate and cryoprecipitate. This direction when offered to Prof. Temperley, meant that only cryoprecipitate could be used if the directive was to be followed by the National Haemophilia Treatment Centre. This is because the National Haemophilia Treatment Centre did not have NHS concentrate at its disposal. To observe the Centre Directors' Guidelines therefore, the National Haemophilia Treatment Centre would have to only use cryo. Prof. Temperley said with respect to the product, the directors always selected the product.

Mr Hayden then turned to the issue of Prof. Temperley's sabbatical. Prof. Temperley agreed that arrangements for his sabbatical were first mooted in 1984 with TCD. Prof. Temperley said to the best of his recollection, such arrangements were put in place in mid-1984, and there was some documentation to support this.

Prof. Temperley said that at the time of his sabbatical he had established the Bone Marrow Transplant Unit and this had required a major effort. He said only about 30 per cent of his time was devoted to haemophilia in and around 1984. He agreed that this was not sufficient, and he also agreed that he did not voice any concern as to this issue at the time. Prof. Temperley agreed that there were too many demands on his time during this period and this had become apparent to him during the course of the 1980's.

Prof. Temperley said he relinquished his post as head of the bone marrow transplant unit. Prof. Temperley agreed that by late 1984 and into 1985, very serious difficulties had arisen. However, Prof. Temperley said that even though he was the main treater of haemophilia, he had to go away at this time. Prof. Temperley said sometime one has to go away.

Prof. Temperley also agreed that he expected at least 50% of the tests to be returned as HTLV-III positive. These tests were taken in December and January of 1984 and 1985. By March 1985 the results had been returned from Middlesex Hospital. Yet he continued with his plans to take a sabbatical. Prof. Temperley's Counsel, Mr Brian McGovern S.C., then interjected and said it should not be suggested that Prof. Temperley was not entitled to take a sabbatical or to take a break, and it should not be suggested in evidence that he had run away from his responsibilities, as this would be unfair. However, the Chairperson said that the I.H.S. was entitled to put the question in order to find out why Prof. Temperley had chosen this particular time to take his sabbatical. Prof. Temperley pointed out that his position was to be covered by a number of locums. They were all competent and could deal with the situation they found themselves in.

Mr Hayden put it to Prof. Temperley, was it not the case that he should have taken the responsibility of telling his own patients whether or not they were HIV positive. Prof. Temperley said that ideally this should have been so, but he had been in hospital with a stress-type illness and was all the better for going away. He was able to work much more efficiently when he returned. Prof. Temperley agreed that he had exercised his own choice to take his sabbatical at this time. Prof. Temperley agreed that he had seen the Middlesex results, but he said these results were not sufficient or adequate for him to tell patients that they were either positive or negative for HTLV-III. Prof. Temperley said he had instructed that repeat tests be carried out.

Mr Hayden referred Prof. Temperley to a minute of the Irish Haemophilia Society committee of 7th May 1985. At the meeting a delegation reported that they had met with Prof. Temperley before he left for London, and Prof. Temperley had told them that up to 80 per cent of tests coming back from Middlesex were positive for HTLV-III. Prof. Temperley said that happily this was an over-estimation on his part, and he said he had informed the delegation of his view as he was of the opinion that they were concerned members of the Society, and as senior members of the Society they would be able to cope with the information.

PROCEEDINGS: Friday 2nd March 2001 - Day 97

Mr. Brian McGovern, Counsel for Prof. Temperley made a Submission to the Tribunal. Mr. McGovern made reference to a radio programme broadcast on the previous day on Today FM. Mr. McGovern referred to the Last Word and an interview carried out by Eamon Dunphy with Mr. Raymond Kelly. Mr. McGovern said that he was satisfied that when the Chairperson read the transcript of the interview, that some of the remarks made were both scandalous and outrageous and quite unfair to the witness, [Prof. Temperley] and particularly scandalous of the Tribunal. Mr. McGovern said he would be making a transcript of the radio interview available to the Tribunal Chairperson. The Tribunal Chairperson indicated that she would read the transcript over the weekend and Mr. McGovern would be free to make an Application on the matter on the following Tuesday.

Mr. Martin Hayden then resumed his cross-examination of Prof. Temperley on behalf of the Irish Haemophilia Society.

Mr. Hayden referred Prof. Temperley to the list of results, which had been available in early 1985 from Middlesex Hospital. Mr. Hayden asked Prof. Temperley, that given he had told the delegation from the Irish Haemophilia Society that 80 per cent of the patients tested were proving positive, was he not then in a position to tell individuals of their test results. Prof. Temperley said that before telling individuals he needed to be absolutely sure of the facts.

Prof. Temperley said that the system envisaged for telling people of their results was reflected in a letter to the Hospital from Ms. Kennedy in the Social Work Department. Prof. Temperley said he had also advised his Locums that individuals were to be informed of their results and this was reflected in the instruction to Dr. Peter Daly to inform two persons per week. Prof. Temperley said he understood a system was being set up whereby patients would be told. Prof. Temperley said he had an idea at the time that there were going to be repeat tests on the original results and this would take some time. Prof. Temperley said that this system apparently didn't work out but that was his idea. Prof. Temperley said that patients could have been informed if the repeat test had been done quickly.

Prof. Temperley said at this time he was only sizing up the problem. He said Dr Shattock was to carry out repeat tests and he presumed that he had left instructions that once the repeat test results were available, individual patients were to be told. Prof. Temperley said however, he could not be sure of what he had said about the repeat test list.

Prof. Temperley agreed that he did not hear from his staff at the National Haemophilia Treatment Centre until he was contacted by Dr. Helena Daly on the 20th of August 1985 concerning the continued use by the BTSB of unheat treated Factor IX. Prof. Temperley said he accepted the position that BTSB unheat treated Factor IX would be in use during his sabbatical. Prof. Temperley said that he was not aware of any medical reason which would prevent a direction from him that only heat-treated Factor IX should be used. Prof. Temperley said however, he thought it would take a relatively long time to heat-treat Factor IX. Prof. Temperley said that until the introduction of heat-treated Factor IX in November 1985, both non heat-treated and heat treated Factor IX were in use by the National Haemophilia Treatment Centre.

Prof. Temperley said that by the time he got the letter of Dr. Helena Daly in August 1985, she had been in the position for seven weeks. If she was going to be surprised at the use of unheat treated BTSB Factor IX, he would have expected she would have contacted him before this. As a result of Dr. Daly's representations to Prof. Temperley, it was agreed that BTSB would provide heat-treated Factor IX by November 1st 1985. With respect to product issued before November the 1st 1985, Prof. Temperley said he was happy to get the supply of heat treated Factor IX and heat treated Factor IX was used exclusively

from early November. He was not aware of any recall of BTSB unheat treated Factor IX issued prior to November 1st.

Prof. Temperley said that the present stock of unheat treated Factor IX was exhausted. This was done on the basis that the non heat-treated BTSB Factor IX was made from safe Irish Plasma. Prof. Temperley agreed that this was despite Dr. Daly's warning in August that unheat treated product was unsafe. Prof. Temperley said that a psychological state of accepting unheat treated BTSB Factor IX was in place at this time.

Mr. Hayden referred Prof. Temperley to a letter from Dr. Daly in October 1985 to the Social Work Department at St. James's Hospital relating her experiences in telling patients they were HIV positive. Dr. Daly noted the need for a second consultation with most patients after receiving the bad news that they were in fact HIV positive and also pointed out that only a quarter of the patients who requried counselling had been counselled by her.

Mr. Hayden then referred Prof. Temperley to the issue of HIV infection by BTSB Factor IX. Prof. Temperley was also referred to the late HIV Factor VIII infection by the Armour product A28306.