

IRISH HAEMOPHILIA SOCIETY

TRIBUNAL NEWSLETTER

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23rd March 2001

TRIBUNAL OF INQUIRY

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

PROCEEDINGS: Tuesday 6th March 2001 - Day 98

Mr Brian McGovern SC for Professor Temperley addressed the Tribunal on the matter of the Radio Programme “The Last Word” which contained an interview between Eamonn Dunphy and Mr Raymond Kelly. The substance of Mr McGovern’s submission was that the radio Interview was unfair to his client who was in the process of giving evidence. Mr McGovern also reminded the Tribunal that it had powers under the Tribunals of Inquiry Acts to bring the matter before the High Court and, while he was not asking the Tribunal to do so in this instance, he nevertheless invited the Tribunal to make some observations on the matter.

Mr Martin Giblin replied to Mr McGovern’s submission and informed the Tribunal that while Mr Kelly was an honoured and respected member of the Irish Haemophilia Society, he was speaking in a personal capacity in his interview with Mr Dunphy. Mr Giblin said that the Irish Haemophilia Society was not on notice of the content of Mr McGovern’s submission and consequently could not be sure as to the full nature of the application made by Mr McGovern.

The Chairperson in reply said that her guidelines to the media on reportage of the Tribunal was that it should be fair and accurate. She said that the interview with Mr Kelly over-stepped the boundaries of these guidelines. The Chairperson said that Mr Kelly was represented by the Irish Haemophilia Society and, in this instance by Mr Hayden, who could put Mr Kelly’s position to Professor Temperley in evidence. She said that Mr Kelly should make his case through his counsel.

Mr Martin Hayden then resumed his cross-examination of Professor Temperley. Mr Hayden referred Professor Temperley to a BTSB Board minute of February 1989. Professor Temperley agreed that at this time he was pretty certain that BTSB Factor IX had caused infection among people with Haemophilia B. Mr Hayden directed Professor Temperley to the minutes of the meeting where it is noted that the Board was of the opinion that only imported factor concentrates were responsible for infection.

Professor Temperley said that this was the opinion of the Board because the majority of the infections were Factor VIII. Professor Temperley said 97 infections were caused to people with Factor VIII deficiency and seven to people with Factor IX deficiency. Mr Hayden asked Professor Temperley did the minute address the BTSB Factor IX situation and was it accurate to state that only imported products caused the infections? Professor Temperley said that he did not wish to defend the Minute and he said he was sure he reminded the Board about the infection of seven patients with the Board’s products. Professor Temperley said he could recall himself being a bore about the subject. He did not recollect mentioning any contribution to be made to any settlement of litigation on behalf of people with Haemophilia who had been infected with HIV.

Mr Hayden directed Professor Temperley to the attendance at the meeting and noted that in addition to Professor Temperley both Dr Walsh and Mr Keyes were present. Professor Temperley agreed that both of these would have known that B T S B Factor IX was responsible for the Haemophilia B infections. Professor Temperley also agreed that he is noted as having advised the Board of the present position, a position of which the Minister had also been advised and his officials had been briefed.

Professor Temperley said he did not think he ever tried to disguise the B T S B's involvement in the infection of people with Haemophilia B with HIV. Mr Hayden asked Professor Temperley did he think he should have told the Factor IX Patients that their infection had been caused by B T S B Product. Professor Temperley said he would not be bound to do this in relation to the Factor IX either in 1986 or 1989.

Mr Hayden directed Professor Temperley to a series of documents which seemed to indicate that he was involved in an investigation of the different products used for the treatment of Haemophilia during the 1985/6 period. This investigation was conducted in July and August of 1990. Professor Temperley said he was trying to confirm at this stage which products had been heat treated in 1985. He said this investigation may well have been conducted in light of the impending litigation then in train. Among the batches queried by Professor Temperley, was batch 90753 which was a nonheat-treated B T S B Factor IX product. Professor Temperley agreed that in the course of this investigation he identified the batch number of a product implicated in the infection of people with Factor IX deficiency with B T S B product.

Professor Temperley agreed that during the course of 1990/91 he re-confirmed that B T S B Factor IX was a source of HIV infection. Professor Temperley did not agree that it would have benefited the individuals to know that the B T S B product had caused their infection. Professor Temperley said there were different ways of relating to patients in a medical manner and in relation to litigation. Professor Temperley added that it was known that the vast majority of infections were caused by imported products.

Mr Hayden then directed Professor Temperley to another investigation conducted by him into the HIV infection of a person with Haemophilia A. During the course of this 1987 investigation Professor Temperley established that the patient had been treated with Armour batch A28306.

In relation to batch A28306 Mr Hayden directed Professor Temperley to documents from Armour recalling batches heat-treated to 60⁰ for 30 hours. In the course of Professor Temperley's investigations, Dr Walsh of the B T S B suggested that the Armour batch was the most likely source of the infection for the Factor VIII person involved. However, Professor Temperley said that during 1986 it was uncertain that the Armour batch had in fact caused the sero-conversion.

In the course of his investigations of the Armour product, Professor Temperley wrote to Mr Christie of Armour on the 16th January 1987, however no reply on the impugned product was forthcoming from Mr Christie. Professor Temperley said as time went by he was always concerned about not getting a reply to his queries at this time.

Mr Hayden asked Professor Temperley for his view of Armour in and around January 1987. Professor Temperley said Armour was a most supportive company and had been to the forefront of providing heat-treated product at the end of 1984 and the start of 1985. Professor Temperley said he had no reason to query Armour in any respect until 1986 and was particularly impressed by their attitude in replacing non-heat-treated Factor VIII with heat treated Factor VIII in 1984 and 1985. Professor Temperley said his faith in Armour was somewhat shaken by their failure to respond to his queries on A28306 in 1987.

On the 3rd June 1987 Professor Temperley agreed that he attended a meeting with Armour to discuss the forthcoming contract for the BtSB's own Factor VIII. Professor Temperley agreed he would be somewhat concerned by Armour's failure to answer his queries on A28306 but, by June of that year he was faced with the task of assisting the BtSB to select a contract fractionator. Professor Temperley said Armour was considered to be a reputable Company at this stage. He said they may have heat-treated their product at 60⁰ for 30 hours in all good faith and they did not bargain for the infection of people using their product.

Mr Hayden asked Professor Temperley had he subsequently become aware of the issues raised in the Krever Report and the research of Dr Prince. Professor Temperley said he was unfamiliar with the Krever Report.

With respect to the meeting in June 1987 with Armour it was agreed that the BtSB's Factor VIII would be heat-treated to the British standard. Professor Temperley said he understood this standard to be 68⁰ for 72 hours. Mr Hayden pointed out to Professor Temperley that the British standard prevailing at BPL was 80⁰ for 72 hours which was a different heat treating protocol to that accepted by him during 1987. Professor Temperley said he was concerned with the prevention of transmission of HIV and he understood 68⁰ for 72 hours to be effective for HIV.

With respect to Factor IX on the contract fractionation, Professor Temperley said he accepted that the BtSB would use a Travenol protocol of 60⁰ for 144 hours and as this was the protocol applied to Proplex T he could see no reason why it should not be accepted.

Professor Temperley agreed that the result of the contract with Armour was that Armour went on to contract fractionate the BtSB's plasma into Factor VIII with the BtSB producing Factor IX from raw material supplied by Armour. Shortly after the contract arrangements were concluded at the end of 1987, the BtSB received a request for an indemnity from Armour concerning the the BtSB contract. Professor Temperley said he was amazed that Armour had asked for an indemnity at this stage. Professor Temperley said he thought that Armour was demanding a high price for producing the BtSB's Factor VIII and that the request for an indemnity was a way of promoting its own Monoclate P product.

Professor Temperley agreed that the main thrust of the Armour contract was to provide Factor VIII. A year later Professor Temperley wrote a letter to the Board of the BtSB advising the Board that it should continue to seek Armour's co-operation in producing Factor VIII for the following year, 1989. Professor Temperley said this letter set out the position with respect to Factor VIII only. He was not thinking about Factor IX. Mr Hayden put it to Professor

Temperley that the same risks attaching to Factor VIII also attached to Factor IX. Professor Temperley said he was thinking of Factor VIII and that was the size of it.

Mr Hayden referred Professor Temperley to his letter to Mr Lynam where Professor Temperley says that “no more dry-heat Factor VIII should be ordered. Professor Temperley said this letter was directed at Factor VIII but, Factor VIII was common parlance for both Factor VIII and Factor IX and he understood the letter directed Mr Lynam not to order dry heat treated Factor VIII and Factor IX.

PROCEEDINGS: Wednesday 7th March 2001 - Day 99

Martin Hayden continued his cross-examination of Professor Temperley.

Mr. Hayden referred Professor Temperley to the cases of “Gordon”, “Ian” and Henry and the case of “Joseph” each of these children was treated with BTSB Factor IX in and around the summer of 1989. Prior to this the children had been treated with solvent detergent products.

In being treated with the BTSB Factor IX each child was infected with Hepatitis C.

With regard to Ian, Gordon and Henry, Professor Temperley agreed that the children’s mother was a regular attendee with the children at the National Children’s Hospital and would be frequently dealt with at the inpatients. Professor Temperley said the reason why she was not told the children were Hepatitis C positive from the time of their diagnosis in 1991 until she found out by her own efforts in 1996 was that they attended the inpatients rather than the outpatients. Professor Temperley said inpatient treatment did not lend itself to a discussion on the matter of test results as the children would often be in the course of acute treatment.

Professor Temperley said that the children were called for testing and were tested, however when the results were available they were not communicated to the children and their mother. Professor Temperley said that the system failed at this point and it was terribly unfortunate that she was not told.

Mr Hayden then referred Professor Temperley to the issue of informing the wives and partners of people who were positive for HIV of the dangers of sexual transmission of the condition and the issue of counselling made available to those persons suffering from HIV infection.

Professor Temperley said that in 1984 he could not really remember a social work input into the Haemophilia Service. It is recorded that the social worker who was available to deal with Professor Temperley’s haemophilia patients could spend approximately 15 per cent of his time on Haemophilia issues.

Professor Temperley agreed that Ms Maeve Foreman recorded that anxiety and anger was abroad among those infected with HIV and this emotion was exaggerated by the lack of counselling services. Sister O’Shea also highlighted these inadequacies. Professor Temperley said there were often difficulties with the patients themselves in that they did not want social work services.

During 1987, Government cut backs put the lack of social services on a collision course with the manifestation of AIDS. Professor Temperley said the Haemophilia service was faced with a threat with regard to cut backs. At this time it was acknowledged there was a low but real risk of HIV transmission by sexual partners. Professor Temperley said that testing facilities were available to partners and they did in fact test partners. However this was done on request and there was no systematic testing of partners.

Professor Temperley said that in 1987 they had to buckle under it at the time and provide the service they could in the circumstances. Eventually lottery money was made available to provide the social workers and counsellors with respect to Haemophilia patients suffering from

AIDS. Approximately £15,000 was made available. Two temporary social workers were appointed. Professor Temperley also said there was an antipathy to social workers and it was not altogether the fault of the social workers.

Professor Temperley said that the fact was that not everyone was tested for HIV. Not all partners were tested for HIV but this not simply down to a lack of testing facilities. A systematic attempt was made to test wives and partners prior to the compromise of HIV litigation in August 1991.

With respect to a letter to the hospital authorities asking who had ownership of social workers' notes, Professor Temperley said this was written viz a viz litigation pending in 1989.

Professor Temperley said he was sure that Mary the wife of Norman who had given evidence before the Tribunal could have been tested had Norman brought her along to be tested. Professor Temperley said if they asked they would have been screened. Mr. Hayden put it to Professor Temperley that he should have advised that testing take place. Professor Temperley said that he could remember talking to the couple on a number of occasions but did not know if a test had been suggested to Mary.

With respect to Dr Tobin's trial for Interferon, Professor Temperley said that it was quite common for a research program to be harnessed in this way and that the research program conducted by Dr Tobin was very useful to the Haemophilia Service.

PROCEEDINGS: Thursday 8th March 2001 - Day 100

Mr. Martin Hayden continued his cross-examination of Professor Temperley.

Mr. Hayden referred Professor Temperley to the case of John Kelly. Professor Temperley said if he had uttered any words in the hearing of John Kelly and John's mother which could have been hurtful he regretted it, he said he did not remember stating in the hearing of John Kelly that "he may survive and then again he may not." Professor Temperley said it was not his practice to say such things, but if he did say it, he regretted it.

Professor Temperley said he had difficulties and disagreements with Mr. Kelly, John's father. Mr. Hayden said that the issue for Mr. Kelly was that his thirteen-year-old son was in a room when a conversation centring around the fact that the child may or may not recover took place. Mr. Hayden said the only thing he was putting to the Professor was, was it medically acceptable to say such a thing in front of a thirteen year old boy who hadn't been told of his HIV status.

At this point Professor Temperley's Counsel, Mr. McGovern, intervened and asked do we know if the child was asleep, if the child was awake, if the child was sedated? Mr. McGovern said there were many imponderables and they were dealing with a situation where Mr. Kelly was not in the room at the time. Mr. McGovern said he did not think it was fair that this matter might go beyond this room on the basis that this is what happened. Mr. McGovern said it may or may not have happened.

Mr. Finlay for the Tribunal suggested that if Mr. Hayden's instructions were to the effect that the Professor said the particular words in the hearing of John Kelly while he was awake and conscious so that he could hear it, he could put that to the Professor. Mr. Hayden agreed with this course of action.

The Tribunal Chairperson said if these were his instructions he could have put that to the Professor five minutes previously.

Mr. Hayden said his instructions were that John was conscious and was there, within earshot, and may have heard this. Mr. Hayden said that as the boy was dead he could not take instructions from him.

The Chairperson demanded an apology from Mr Hayden and then adjourned the Tribunal.

The Tribunal resumed half an hour later. The Chairperson said she thought that Mr. Hayden should put his instructions to Professor Temperley. She said she did not think the manner in which Mr. Hayden's words were uttered were helpful to the Tribunal nor were they called for.

Mr. Hayden proceeded to cross-examine Professor Temperley on the issue of John Kelly. Professor Temperley said if he said anything, which was hurtful to any member of the family, he regretted that. Professor Temperley said he did not remember exactly the words spoken. He said he was deeply concerned about how best to manage the boy and that's the best he could say about it. Professor Temperley said it was never his practice to say such things and if it happened he did regret it.

Professor Temperley said he understood the terrible problems that existed with John and with his parents. In response to what Mr. Kelly has said, he said he was deeply distressed. Professor Temperley said he had his heart and soul in the treatment of the boy and that must be taken into consideration, he said it was not a matter of indifference for him. Professor Temperley said in his treatment of the child he had to defend himself and said he did what he felt was right at the time. " I may have made mistakes in relation to individual bits and pieces. I just don't know. These are things that have been said about me but by and large my interest was to help John", Professor Temperley said.

Mr. Hayden then referred Professor Temperley to the medical records of "Bernard" with respect to the Factor VIII protocol. Professor Temperley agreed it was not followed but he was satisfied that all the staff were advised.

Mr. Hayden then referred Professor Temperley to the medical records of "Stephen" and the evidence given on behalf of Stephen by his father Martin.

PROCEEDINGS: Friday 9th March 2001 - Day 101

Mr. Martin Hayden continued his cross-examination of Professor Temperley.

Mr. Hayden referred Professor Temperley to the medical records of “Vincent”. On the 24th July 1987 it is noted in Vincent’s medical record that he was recalled to discuss his HIV status on that date. Vincent’s HIV test serum sample was drawn on the 14th September 1985 a result was available on the 16th October 1985 and Vincent was not told until the 24th July 1987 by Dr. Jackson.

Professor Temperley said Vincent’s test result was somewhat late and he did not know whether during the intervening time he had received an outpatient appointment. Professor Temperley said that the most likely reason Vincent wasn’t told during the intervening period was for one reason or another he didn’t attend the outpatients. Mr. Hayden said he had to put it to Professor Temperley that there should have been an actual policy in place by him to make sure somebody was told, be it by arrangement of a special meeting or some formula that people be told within a short space of time of the results of HIV tests.

Continuing with the case of Vincent Mr. Hayden directed Professor Temperley to the patient’s treatment record. Up until 1979 Vincent was treated with Cryoprecipitate, on the 15th March 1979 he was treated with concentrate. Mr. Hayden asked Professor Temperley why, given that Vincent was a mild Haemophilia A patient, would he have been treated with concentrate at this time. Professor Temperley said no distinction was made between mild, moderate and severe in relation to giving either concentrate or Cryoprecipitate at this time.

Mr. Hayden referred Professor Temperley to the case of “Albert”, who had severe Factor IX deficiency, and who testified he did not know he was Hepatitis C positive until 1999. An examination of Albert’s medical record shows that in March of 1993 he was counselled for Hepatitis C on the same date he was also vaccinated for Hepatitis A. Mr. Hayden put it to Professor Temperley would it not have been wiser to separate the two events i.e. the vaccination for Hepatitis A and informing Albert that he was Hepatitis C positive. Professor Temperley said he could not explain if confusion had arisen at this time.

Mr. Hayden referred Professor Temperley to the medical record of “John” who is the son of Arthur who gave evidence on behalf of John to the Tribunal. Mr. Hayden also referred Professor Temperley to the medical records of “Aongus” and “Kieran” two brothers. Professor Temperley agreed that he deferred telling Aongus of his HIV positive status on two occasions between 1985 and 1987. Aongus was eventually told he was HIV positive by Dr. Jackson in July 1987. Professor Temperley said he deferred telling Aongus of his HIV positivity as he may have thought he was not ready to receive such information.

Mr. Hayden referred Professor Temperley to a letter from Dr. Elizabeth Mayne, director of Haemophilia Services in Northern Ireland. Professor Temperley agreed that the rate of infectivity for HIV was much lower in Northern Ireland than in the Republic. Professor Temperley said that Dr. Mayne had access to Immuno product and agreed that she also had

access to Scottish Blood Transfusion Unit 80 degrees by 72 hours contract fractionated Factor VIII.

With this evidence Mr. Hayden completed his seven-day cross-examination of Professor Temperley.

Mr. John Finlay SC in re-examination of Professor Temperley referred him to the Middlesex results, which Mr. Finlay has identified as being copied from the daybook of the Virus Reference Laboratory at UCD.

Mr. Finlay identified a date pertinent to the test of “Donal” of the 16th January 1986. Professor Temperley agreed that the list could not therefore be the list that Dr. Daly had worked from given that this list was not available until sometime after the 16th January 1986.

Mr. Finlay put it to Professor Temperley that those tests indicated for repeat on the list could not be the source of any delay in telling individuals they were HIV positive given that some other list was in use and the fact that individuals were eventually told without having a repeat test. In these circumstances no delay was attributable to Dr. Shattock at the VRL, any retests noted on the list conducted by Dr. Shattock were in respect of testing the efficacy of a particular test rather than re-testing for the result itself.

Professor Temperley was cross-examined on this issue by Mr. Gleeson for Dr. Shattock. Mr. Gleeson put it to Professor Temperley that Dr. Shattock had no conversations with him about test repeats and that Dr. Shattock simply carried out random tests on new commercial tests. Professor Temperley said that his recollection may be fallacious but he understood that there would be repeat tests.