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TRIBUNAL OF INQUIRY

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

PROCEEDINGS: Tuesday 20th February 2001 - Day 90

Mr John Finlay continued his examination of Professor Temperely. Mr Finlay referred Professor Temperley to the early 1985 period, and discussions he may have had with Dr Cotter, concerning HTLV III infections. Professor Temperley said he probably discussed the Middlesex results with Dr Cotter but could not bring it specifically to mind. Professor Temperley said he did not inform the NDAB of the results at the time, but he imagined the NDAB would have learned of the positive results from information supplied to the Government.

Professor Temperley said that there was no all-embracing system of reporting HIV results but a good relationship existed between himself and Dr Cotter and in this way information was exchanged. Mr Finlay referred Professor Temperley to the infection of Haemophilia B patients with HIV. Mr Finlay directed Professor Temperley to the case of "Andrew". His first HIV test on the 1st February 1985 was reported as negative, in July 1985 "Andrew", who had severe Haemophilia B was reported as positive and again reported positive in November 1985. It is determined from "Andrew's" medical record that he seroconverted between the first of February 1985 and the 26th of October 1985. Professor Temperley said that this information was not communicated by Dr Cotter to him and he first became aware of the situation with this patient in April or May of 1986. Therefore in the lecture given by Professor Temperley in May of 1986 the Cork patient was not included.

Professor Temperley agreed with Mr Finlay that positive tests among patients with Haemophilia B were not brought to his attention immediately. Professor Temperley said he must of being pondering the results of some Haemophilia B patients for a number of months. Professor Temperley also said it was difficult to establish when Haemophilia B patients became positive. Professor Temperley said he thought about this issue and came to terms with it in April of 1986.

Professor Temperley said that it took him time to come to terms with the fact that Haemophilia B patients were seroconverting. Professor Temperley said that he eventually got in touch with Dr Cotter but he had to wait for a second or third test result. Professor Temperley said that the delay occurred as he had to wait for confirmatory results before he could say that the Haemophilia B patients were in fact seroconverting.

Mr Finlay also referred Professor Temperley to the cases of "Hugh and Norman" both Heamophilia B patients who seroconverted between the start of 1985 and mid-1986. During this time heat treated Factor IX was available.

Professor Temperley said BTSB non-heat-treated Factor IX continued to be used because it was the national product and he had agreed to use it for a period of time.

Mr Finlay referred Professor Temperley to the case of "Mark" who continued to use BTSB Factor IX until the 20th February 1986. Professor Temperley said that it would appear that Mark had been issued with home treatment BTSB Factor IX which was not recalled. Professor Temperley said he did not know if efforts had been made to recall it.

Mr Finlay asked Professor Temperley if he had been informed about the Cork Factor IX Haemophilia B infection in November 1985 would it have made a difference to the subsequent use of BTSB Factor IX during the period between November 1985 and February 1986 Professor Temperley said that it was difficult to say given that this was the first case. Professor Temperley said he had determined in November 1985 that no more non-heat-treated Factor IX would be used. He said it was implicit in this instructions that non-heat-treated Factor IX in circulation for home therapy should be recalled.

Professor Temperley said there were limits to his responsibility. The witness stated that those in senior positions in other departments including Blood Transfusion Unit had a responsibility to see that BTSB Factor IX in circulation for home therapy was recalled. Professor Temperley said he did not have the staff available to see that this was done. A gap existed in controlling the situation and the patient should not have been given the concentrate up until the 20th February 1986.

Mr Finlay referred Professor Temperley to the efforts to recall BTSB Factor IX in the summer of 1986. Professor Temperley said that during this time he was so concerned about BTSB Factor IX that he directed that it should not be used either heat treated or otherwise. He eventually communicated this information to Professor Egan in August of 1986. In the meantime Professor Temperley had addressed the meeting at UCD where it was noted that four Haemophilia B patients had sero-converted. Professor Temperley said that he had decided to make this information public the night before the meeting. At this stage Professor Temperley said he was unsure of his ground with respect of the source of infection.

Mr Finlay then referred Professor Temperley to the importation by St James Hospital of Factor VIII from Armour, specifically batch A28306 which caused the infection of a person with Haemophilia A with HIV in 1986. Professor Temperley said that he had no reasons to have any misgivings about Armour prior to ordering half a million units of Factor VIII from the company in January 1986. Professor Temperley said that he was not aware of the article published by Professor Prince in *The Lancet* on May 31st 1986. However he was aware that at around this time queries began to emerge concerning the Armour produce. Professor Temperley said that discussions about problems concerning Armour product were vague at this stage and it was difficult to know how much weight to give the reports. The Armour product was withdrawn from circulation in October 1986.

Professor Temperley said that in response to HIV infection, problems existed in telling people of their infection. HIV infection was dealt with in the centre itself which was inadequate for the purpose in that it was too small.

Mr. Finlay continuing his examination of Professor Temperley referred the Professor to services available for the treatment of Haemophilia during the period after which HIV infections had occurred. Professor Temperley said that in coping with the HIV infections his efforts and advocacy for increased services underestimated the staffing required. Professor Temperley said that he should have pushed harder in relation to getting services but at the time, during 1987, a threat appeared to exist over the very existence of the National Haemophilia Treatment Centre. While the Haemophilia service was not dispensed with, cuts across the board in the health services meant that an improvement in the service was very unlikely. Professor Temperley said that requests for improvements in the service and for the provision of counselling and social work services came at a very bad time. Just as people who had been infected with HIV were beginning to show the clinical signs of infection the health service cutbacks were beginning to take effect.

Mr. Finlay referred Professor Temperley to letters between himself and Dr. James Walsh of the Department of Health. In briefing Dr Walsh on the AIDS situation, Mr Finlay noted that the document does not clarify that BTSB Factor IX caused HIV infection to people with Haemophilia B. Professor Temperley said that he did not try to withhold information from Dr. Walsh and he did not know why he did not mention that BTSB Factor IX caused infections.

Professor Temperley said that in and around 1988 attempts were made to screen the wives and partners of people with HIV but this did not work out. Prof. Temperley said that tests could be done but it was difficult to follow up as counselling staff were not available. A further attempt to introduce a comprehensive scheme for the testing of wives and partners was introduced in 1991 in advance of the settlement of Haemophilia HIV litigation. Prof. Temperley said that the scheme never really got off the ground. In December 1988 a full time social worker was appointed to work with people with Haemophilia and also to work in conjunction with the Irish Haemophilia Society.

Mr. Finlay referred Prof. Temperley to the subject of body bags and the requirement that they be used. Prof. Temperley said that to him it did not seem necessary and he understood that the issue of body bags was at the insistence of mortuary attendants in that they did not want to be exposed to infection. Prof. Temperley said that this reaction was part of the hysteria which attended the problem of HIV infection.

Mr. Finlay referred Prof. Temperley to the issue of Hepatitis C infections. In the first instance the Tribunal examined the case of Neil, whose son-in-law Larry gave evidence concerning the circumstances surrounding the death of Neil. Prof. Temperley said that at the time it appeared that the cause of death may have been Non A Non B Hepatitis complicated by the fact that Neil was suffering from a form of Leukemia. Prof. Temperley said that up to this time in 1984 Non A Non B Hepatitis was considered to be a relatively benign condition. Non A Non B Hepatitis appeared to implicated in the patient's death but the situation was complicated by Leukemia. Prof. Temperley said that the fact that Non A Non B was implicated in the death of this patient was a cause of concern.

Mr. Finlay referred Prof. Temperley to the case of Edward, a Haemophilia B patient, who was infected with Hepatitis C. Edward was diagnosed with Non A Non B of a long incubation type leading to active chronic liver disease. Prof. Temperley said that the significance of this was that no one was sure at this time of the rapidity of the disease. However, he agreed with Mr. Finlay that it could not be considered a benign prognosis. With respect to research carried out by Preston and others published in late 1985, Prof. Temperley said that Non A Non B was still a slow moving infection. Prof. Temperley said it was regarded as a condition that a patient could live with and attitudes to Non A Non B changed slowly. Prof. Temperley said that liver changes under this condition could take place over a period of 20 years.

Prof. Temperley agreed that by 1986 BPL 8Y and 9A were both receiving favorable comments as regard their properties for inactivating Non A Non B Hepatitis. With respect to selecting Armour product in 1989 and writing to the BTSB Board to this effect, Prof. Temperley said that the letter written to the BTSB concerned only Factor VIII and his concern at this stage was to ensure viral inactivation against HIV. In this regard he selected the 68 degrees x 72 hours as a suitable viral inactivation technique. His letter, directed to the Board of the BTSB, did not purport to contain a policy for Factor IX. Prof. Temperley said that the policy adopted in 1988 for Factor VIII previously untreated patients was not applicable to Factor IX.

Mr. John Finlay continued his examination of Prof. Temperley. Prof. Temperley agreed as a result of the negotiations with Armour BTSB Factor IX became available in 1988. This material was fractionated from Irish Plasma, drawn from non-remunerated Irish donors, was HIV screened and was not subject to either AST or ALT testing. The raw material for BTSB FIX was returned in the form of a paste from Armour and subjected to heat treatment by the BTSB to a proported Travenol heat treatment protocol of 60 degrees for 144 hours or 60 degrees for 150 hours. This heat treatment protocol was not directed at virally inactivating the product for Hepatitis Non A Non B.

Prof. Temperley said the BTSB Factor IX followed the Proplex T heat treatment protocol. Professor Temperley said he was quite happy to use the 60 degrees by 144 hours. He agreed that first generation dry heat treated product was still capable of transmitting Non A Non B Hepatitis and was aware that 80 degrees by 72 hours as provided by BPL indicated in studies that it did not result in Non a Non B Hepatitis. It was clear in 1988 that NHS Factor IX was safe for Non A Non B. Prof. Temperley said that he did not think of using it at the time and that he would generally wait for the UK Directors to make a recommendation.

Prof. Temperley said that the NHS product was not for sale at the time, however, he agreed to Mr. Finlay that the amount required for previously untreated patients would be relatively small and that no difficulties would be encountered in getting these relatively small quantities of product. Prof. Temperley said that this was true but the difference was in the mindset of those using the product.

Prof. Temperley said that at this time he was only coming to terms with the idea of solvent detergent product. In October 1988 Prof. Temperley visited Octapharma, however, he had doubts about the capacity of Octapharma to meet the contract and Octapharma was the only solvent detergent source in Europe at that time. Prof. Temperley agreed that he could have perhaps got solvent detergent product for previously untreated patients at this time. However Prof. Temperley said that this was difficult as the product was not licensed and was not made from Irish Plasma.

With respect to the use of Koate HS on a named patient basis Prof. Temperley said the product came into the St James's Hospital on a named patient basis. While Koate HS was used the named patient basis list was not adhered to and the product was provided to previously untreated patients who were not on the list. Prof. Temperley said he did not observe the NDAB formalities at the time.

Prof. Temperley said that the level of concern for the Factor VIII previously untreated patients was such that NDAB requirement was bypassed. No similar scheme was instituted for patients with Haemophilia B. Prof. Temperley said he did not have a suitable treatment for Factor IX but agreed, in retrospect, that he could have gone to the UK and got suitable Factor IX product. Mr. Finlay suggested to Prof. Temperley that this was not retrospective, he could have obtained suitable Factor IX at the time.

In March 1990 the Octapharma Contract provided both Factor VIII and Factor IX solvent detergent product. In May of 1989 Prof. Temperley wrote to Mr. Lynam of the Blood Transfusion Unit in St. James's Hospital inquiring as to why the hospital was no longer using BTSB Factor IX. Professor Temperley agreed that his note encouraged Mr. Lynam to use this product. Prof. Temperley said the motivation for his letter to Mr Lynam came from the Board of the BTSB. He said the BTSB material was home product and was within the terms of national self sufficiency and, according to Mr Keyes, the Department of Health wanted it to be used. In these circumstances, said Professor Temperley, there was no reason why he should not use it. Prof. Temperley agreed that in the autumn of 1989 Octapharma Factor IX was available.

Mr. Finlay referred Prof. Temperley to the medical record of Gordon who is the brother of Ian and Henry and the son of Felicity. In March 1988 to July 1989 he was treated with Konyne a commercial heat treated Factor IX product by Cutter. In July 1989 to May 1990 Gordon was treated with BTSB Factor IX and as a result was infected with Hepatitis C from the BTSB product. Prof. Temperley said that he would prefer not to comment on this case. Likewise Henry, brother of Gordon, was infected with BTSB Factor IX in the summer of 1989. Prof. Temperley agreed that Cutter Factor IX appeared to be safe against the risk of Hepatitis C and in general was quite satisfactory. It was known that Cutter Konyne presented a reduced risk of Non A Non B Hepatitis and that no specific evidence existed that Konyne was associated with Hepatitis C.

Prof. Temperley was also referred to the Hepatitis C infection of Joseph, via BTSB Factor IX and the infection of Luke. Luke is a person with mild Haemophilia B and was treated with solvent detergent product on 19th September 1990 to cover a dental extraction. On 25th October 1990 Luke was treated with Pelican House BTSB Factor IX.

Prof. Temperley said that he thought by this time no more heat treated BTSB Factor IX would be in use. It would appear that BTSB Factor IX was returned to St. James's Hospital in August of 1990 and was kept by the laboratory and given to the patient. Prof. Temperley said he only learned of this in 1992. At the time the BTSB Factor IX was given to Luke Prof. Temperley said that there was a shortage of Octapharma product and this may have led to the BTSB Factor IX being used. However, he agreed with Mr. Finlay that there was no absolute lack of Factor IX and that dental treatment did not constitute a life threatening emergency and that the amount required to cover dental treatment would be very small. Mr. Finlay put it to Prof. Temperley that this should not have happened and it was his job to ensure that it did not happen. Prof. Temperley said that he agreed with the proposition that it should not have happened but did not agree with the observation that it was his job to ensure that it did not happen.

Prof. Temperley said that other senior persons in the ward, the stores or the Blood Transfusion Unit should have ensured that his instructions were carried out. Mr. Finlay put it to Prof. Temperley that it was his responsibility to see that doctors carried out his instructions. Prof. Temperley said that he could not be in a position to supervise the day to day management of all the doctors and all the units. However, he said while he accepted overall responsibility he did not accept responsibility in every detail.

Mr. Finlay put it to Prof. Temperley that this was a matter of no little consequence. Prof. Temperley said he agreed but he did not think that he should take the responsibility. Prof. Temperley agreed that there was no protocol in place to ensure that the BTSB Factor IX would not be used. Prof. Temperley agreed that a written instruction should have been in place.

Mr Finlay referred Prof. Temperley to the medical record of Cyril, son of Herbert. Cyril has mild Haemophilia A and was born in October 1985. In June 1986 he received his three-in-one vaccination. Concentrate was administered to cover the vaccination. The administration of Haemofil resulted in Cyril seroconverting for Hepatitis C. Prof. Temperley said it was settled policy at this time to cover three-in-one vaccination with concentrate. However, in June 1986 Cyril had been exposed to no previous treatment. Prof. Temperley said at the time the concern was to prevent the transmission of HIV. Mr. Finlay put it to Prof. Temperley that he should have considered using the pasteurised product. Professor Temperley said he did not think of that at the time.

Mr. Finlay referred Prof. Temperley to the medical records of Roy, Gerard and Samuel and the issue of testing for Hepatitis C.

PROCEEDINGS: Friday 23rd February 2001 - Day 93

Mr. John Finlay S.C. continued his examination of Prof. Temperley. Mr. Finlay referred Prof. Temperley to the case of Felicity and her children. Felicity's children were tested in September 1991for Hepatitis C, in 1995 Felicity discovered her children were Hepatitis C positive. The positive diagnosis was confirmed Dr. Owen Smith. Prof. Temperley agreed that these infections were late Hepatitis C infections, but he said this aspect of their infection had nothing to do with not telling Felicity of the positive test concerning her children. Prof. Temperley said it was possible that Felicity did not attend the outpatients very often.

Mr. Finlay noted that the medical records indicated that Felicity was asked to bring two of her three sons for repeat Hepatitis C antibody tests. The tests were carried out on the two boys, but no follow up advice as to the results of the tests was contained in the Medical Records. Prof. Temperley said he could only say he was sorry that it happened. He accepted responsibility on behalf of the team that she wasn't told.

Prof. Temperley agreed with Mr. Finlay that the Hepatitis C infection of these young children was of particular significance as was the lateness of their infection and it was extremely unfortunate that they were not told for such a long period of time, that they were in fact infected. Prof. Temperley said that he did not think there was a delay in telling Felicity the test results because the infections were so late. Prof. Temperley said he was not sure of the system that was in place for informing patients of Hepatitis C positive status at the National Children's Hospital.

Mr. Finlay referred Prof. Temperley to the medical record of Kevin. Kevin was first tested for Hepatitis C in September 1991. He had a further test in October of 1992, but was not told of his Hepatitis C positive status until January 1993. Kevin was informed by post of his Hepatitis C positive status.

Mr. Finlay referred Prof. Temperley to the medical record of Kieran. Kieran lives in a remote part of Ireland and had difficulty getting to the outpatients department of St. James's Hospital. Kieran was tested for HIV in 1985 and was not informed until 1987 of his HIV positive status. Prof. Temperley said there may have been medical reasons for his not attending the outpatients clinic. When he eventually attended the outpatients clinic in July 1987, he was told by Dr. Jackson of his HIV positive status.

Mr. Finlay referred Prof. Temperley to the medical record of Angus. Angus is the brother of Kieran and had similar difficulties attending the outpatients clinic said Prof. Temperley. He was not diagnosed Hepatitis C positive until 1996. Prof. Temperley said strenuous efforts were made to get him to attend the outpatients clinic.

Mr. Finlay referred Prof. Temperley to the medical record of Patrick. Patrick was reported Hepatitis C positive on the 23rd of October 1992 and was informed of his Hepatitis C positive status by letter on the 14th of October 1994. Prof. Temperley said that Patrick may not have attended the outpatients at the appropriate time and would not therefore have received his results in person. The non-attendance of patients at the clinic was a reason why Dr. Tobin had taken it upon herself to inform those with mild Haemophilia as to their Hepatitis C status. Prof. Temperley said that Dr. Tobin volunteered to do this. He said that Dr. Tobin had been funded by

a pharmaceutical company to conduct research into the treatment of Hepatitis C with Interferon. This research came on stream in mid-1994, said Professor Temperley. Prior to this Hepatitis C patients were dealt with by Prof. Weir but, said Prof. Temperley, he had been overwhelmed by the amount of work involved. Prof. Temperley said he was referring patients to Dr. Tobin at this time.

Mr. Finlay referred Prof. Temperley to the medical record of Liam. Liam is HIV positive. By September 1992 he was positive for both HIV and Hepatitis C. Liam was not diagnosed as HIV positive until September 1992. He has mild Haemophilia. Liam was tested for both HIV and Hepatitis C in September 1992. Liam's general practitioner was informed of his HIV status in 1992; however, he was not informed of his Hepatitis C status until July of 1995. With regard to Liam, Prof. Temperley said he decided to tell him only about his HIV status. He thought it would be too much of a burden to inform him of both HIV and Hepatitis C positivity at this late stage. However, Prof. Temperley agreed that he should have informed Liam of his Hepatitis C status shortly after imparting the news that the was positive for HIV.

Mr. Finlay also referred Prof. Temperley to the cases of Albert and Gerard.

Mr. Finlay then referred Prof. Temperley to his statements in response to the evidence given by persons with Haemophilia to the Tribunal. Prof. Temperley said the purpose of his response was to convey most sincerely his feelings that when he saw some of the patients he had known for a long time, in bed, ill with HIV, it was like watching his own sons. In a lot of cases, Prof. Temperley said he was emotionally involved. He said his relationship with some of the patients was like that he enjoyed with his own sons. He said that this did not apply to all patients, but it did apply to some and he was very, very unhappy about the whole situation. He said that while he may not have shown his emotions, he wanted the parents and relatives to know that he had a fellow feeling with them. He said that it was difficult to show emotions when he was doing his ward rounds. He said that he was very upset on a personal basis as to what happened.

Prof. Temperley also recorded his total admiration for the nursing staff who attended patients at the National Haemophilia Treatment Centre and the National Children's Hospital. Prof. Temperley said they didn't bat an eyelid when the rest of the medical community might have run away from Haemophilia and from HIV. Prof. Temperley said they stood by the patients and kept treating them and didn't run away. They just treated them as they came. Prof. Temperley said the nurses looked after patients with tremendous dedication and he would like to pay tribute to them. Prof. Temperley said up to the time of HIV infections, the National Haemophilia Treatment Centre was just about managing to cope with the treatment of Haemophilia. The thin thread of coping broke when HIV came along. Prof. Temperley said there was not enough staff to deal with the difficulties, nor was there time available for doctors to explain about HIV and Hepatitis C. Prof. Temperley said the most that could be offered at this stage was practical advice, which did not purport to be emotional or psychological support for the difficulties arising from HIV.

With respect to Hepatitis C, Prof. Temperley said that the amount of knowledge available in the early 1980's was limited. Prof. Temperley said the concept of liver failure was only formulated as time went on. Also with respect to HIV, it was expected in 1985 that only a small number of

those infected would actively develop HIV related illnesses. They had now learned by experience that this was not the case.

Prof. Temperley responded to the evidence of Karen Stevens on behalf of her father, Jerome; Damien; Arthur; Gary; Nuala; Daniel; Martin with respect of his son Stephen; Dermot; Larry; Ronald; Trevor; Charles and Mary.