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TRIBUNAL OF INQUIRY

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

PROCEEDINGS: Tuesday 24th April 2001 - Day 117

Mr Gerry Durcan for the Tribunal examined Dr Emer Lawlor of the BTSB. Dr Lawlor conducted investigations into the treatment of haemophilia at Waterford, Galway, Castlebar and Drogheda.

With regards to Waterford, Dr Lawlor said the hospital at Ardkeen did not have central records of issues, so it was difficult to work out what was going on. The information provided by Dr Lawlor had been gleaned from treatment charts. Dr Lawlor said Ardkeen did not appear to use cryo during the time in question. If they had haemophilia problems they were dealt with by the administration of concentrates. Waterford ordered blood products from the BTSB. Dr Lawlor said she encountered difficulties getting a full list of who was being treated at Ardkeen during the period.

With respect to the patient known as Vincent, Dr Lawlor said there was no record of him having been treated at Ardkeen. Dr Lawlor said nothing turned up for Vincent in November 1981. There was no record of treatment for this patient at Ardkeen Hospital.

Dr Lawlor also examined the medical record of John, son of Arthur, and noted that he was treated mainly with concentrate from the time of his birth onward.

Dr Lawlor examined the medical record of Samuel. Samuel is a factor IX deficiency patient. However, Dr Lawlor said she didn't really go into his case in any great detail. Dr Lawlor said that Samuel was treated mainly with BTSB factor IX, but could also have been treated with commercial concentrate, and either of these products could have transmitted hepatitis C. Dr Lawlor said she did not think that information was transmitted from the regional hospital to the computer records at St. James' Hospital.

With regard to the treatment of haemophilia in Limerick, Dr Lawlor noted that up to 30 persons were treated for haemophilia and inherited coagulation disorders. Dr Lawlor said that Limerick never really functioned as a regional haemophilia treatment centre, and treatment decisions were taken in Dublin. Home therapy was also directed from Dublin. Dr Lawlor said there were 16 severe haemophilia A patients in the Limerick region, eight of whom were infected with HIV.

Dr Lawlor said that she had no reference in the charts at Limerick for the brothers of Una. She also said that two HIV positive patients' charts appear to have been destroyed. With respect to the patient Rory, Dr Lawlor had examined his chart. Dr Lawlor said that casual callers at the Limerick Centre were treated with cryo. However, it would appear that one person who had been passing through, a Cork patient, may have been treated with concentrate. Dr Lawlor said that those attending the hospital were generally treated with cryo. These were small issues of cryo.

With respect to the patient Rory, Dr Lawlor said it would appear from an examination of his medical record, that he got one vial of factor VIII early in 1980. Apart from this one shot of concentrate he was treated with cryo until he went onto home therapy in August 1983. He was also treated with concentrate at Limerick Regional Hospital in 1984. Dr Lawlor said that from around the end of January 1986, no cryo was administered at Limerick Regional Hospital.

Limerick went on to order Cutter products from the start of 1988. Dr Lawlor said that Limerick continued to use BTSB factor IX up until early 1987. She said that both recalls, i.e. those of January 1986 and June 1986, failed to operate in Limerick. In these circumstances, Limerick continued to use unheat-treated factor IX after the end of January 1986. Dr Lawlor said that unheat-treated factor IX may have been used at Limerick up until May of 1986.

With respect to Castlebar, Dr Lawlor said that the treating doctor of the period was deceased. It would appear that Castlebar had very little contact with Galway, said Dr Lawlor. The patients Angus and Kieron were sent to Dublin with very little reference back to the so-called regional treatment centre at Galway. There was no haematologist operating at Castlebar General Hospital. Dr Lawlor said that products were administered under a U.S. guideline. Dr Lawlor said Castlebar was isolated from the rest of the treatment world.

Dr Lawlor said she had examined the medical records of two brothers who were treated at Castlebar. One of the brothers, Liam, received Hemofil in September 1981 and June 1983, and was HIV positive. Dr Lawlor said neither Dublin nor Galway appeared to have been consulted about Liam. Mr Durcan asked Dr Lawlor, in June 1983, should some concern have existed about treating a person with concentrate for a tooth extraction, particularly when such a person was classified as having mild haemophilia. Dr Lawlor said DDAVP or cryo should have been used. She said there was no record of any reference to Dublin on this patient.

Dr Lawlor referred to a further patient who was unregistered at the NHTC. Dr Lawlor said this person with mild haemophilia A was treated on one occasion with a number of batches of Hemofil. Four different batches were used for the treatment of this person in the course of a surgical procedure. Mr Durcan asked Dr Lawlor, did the risk of infection increase when more than one batch was used? Dr Lawlor agreed that this was the case. She also agreed that a mix of batches was even more risky. Dr Lawlor noted that treatment was not recorded on the Dublin computer.

Dr Lawlor described the treatment of haemophilia at Galway under Prof. Egan. Mr Durcan referred Dr Lawlor to the case of Fionn. Fionn is a factor VIII deficient person with haemophilia. Dr Lawlor noted that no concentrate was stored in Galway until 1986, and she also noted that Fionn had not received concentrate elsewhere. Dr Lawlor said that Fionn had become infected with HIV using cryoprecipitate. Fionn would appear to have become infected with HIV in or around October 1984. Fionn tested positive in October 1985. Dr Lawlor said that by April 1986 the BTSB knew that a person using cryoprecipitate exclusively had seroconverted for HIV.

Mr Durcan asked Dr Lawlor, was any effort made to track the infected cryo supernatent, from which factor IX would have been manufactured. Mr Durcan pointed out that the cryo supernatent from the batch of infected cryo, if used in the manufacture of factor IX would itself

be infected. Dr Lawlor said that no effort was made to track this batch. Nor was any step taken to withdraw potentially infected factor IX. Dr Lawlor said that this was simply not thought of at the time.

It would therefore appear to be the case that the BTSB knew in August 1986 that a batch of cryo had infected a person with HIV, but no recall of either the cryo or the factor IX manufactured from the cryo supernatent of the infected batch, was effected. Dr Lawlor agreed with Mr Durcan that it was unusual for a centre such as Galway to be using cryo only in 1985.

With regard to the infection of the cryo pool with hepatitis C, Dr Lawlor said that her investigations revealed that 23 Anti-D donors had made blood donations, which subsequently were fractionated for the manufacture of cryoprecipitate. Dr Lawlor said 14 of these donors were high risk for hepatitis C and nine were medium risk. Every donation was hepatitis C infected. Dr Lawlor said the significance of high risk was that those donors had active virus in their system. Dr Lawlor agreed that this was a form of cross-infection.

Mr Durcan put it to Dr Lawlor that the 23 donors had made multiple donations, and also that each of the 23 had been initially infected by BTSB product – Anti-D. Mr Durcan said that these 23 infected transfusees would in turn donate blood, which in turn would infect yet more people.

Dr Lawlor was then cross-examined by Mr Martin Hayden SC on behalf of the Irish Haemophilia Society. With regards to Rory's treatment sheet from the Limerick Regional Hospital, and the administration of Hemofil on 21st January 1980, Mr Hayden asked Dr Lawlor, was it possible that the wrong designation had been recorded as the treatment received by Rory. Dr Lawlor said it was her view that the record indicated the patient received Hemofil, and she thought it unlikely that he would have received cryo, which was then described as Hemofil.

With respect to a recall from Limerick, Dr Lawlor said she could find no evidence of product being returned to the BTSB from Limerick, particularly heat-treated factor IX which was inadequately heat treated. Dr Lawlor said that the recall of product which allowed unheat-treated factor IX to continue in circulation up until April 1987, was a failure by the BTSB.

With respect to the patient Liam, Dr Lawlor said that if the treaters had been in touch with Dublin they would not have used concentrate for Liam. With respect to the patient Fionn who was treated in Galway with cryoprecipitate from which he contracted HIV, Dr Lawlor said she had approached the investigation from the viewpoint that Fionn must have received concentrate, but had come to the conclusion that he had received cryo.

With respect to the note of a meeting attended by Dr Hoppe, Dr Lawlor said that the conversation recorded at the meeting which mentioned the possibility of cryo infections among children, may have referred to Fionn and Vincent who were children at the time. Dr Lawlor said she could not speculate on this, but the meeting could have been discussing them. Dr Lawlor said that Fionn did not get cryo batch no. 21966. Dr Lawlor recorded that Vincent received infected cryo 21966, but said Vincent had been treated with a concentrate in November 1982. Dr Lawlor is of the view that Vincent was infected by this concentrate.

With regards to a list of 31 components that had not been traced from patients who were subsequently found to be HIV positive, Dr Lawlor said that two pooled cryos contained in the list, had been issued to St. James's.

With respect to cryo batch 21966, Dr Lawlor agreed that the supernatent from this batch became factor IX batch 90753. Mr Hayden pointed out that factor IX batch 90633 was also made from cryo supernatent. The cryo batch number had not been matched to 90633, but the cryo would nevertheless have been infected.

With respect to the cryo that infected Fionn, Mr Hayden said this would have made a total of three infected cryo batches. Dr Lawlor agreed that this as the case.

Dr Lawlor was also cross examined by Ms Anne Power for the Southern Health Board.

PROCEEDINGS: Wednesday 25th April 2001 - Day 118

Dr Lawlor was examined by Ms Anne Power for the Southern Health Board.

Ms Power put it to Dr Lawlor that Fionn's HIV positive result in October 1986, was the first indication to the BTSB that HIV was in the Irish blood pool. Ms Power's point was that it had been put it Dr Cotter that the BTSB could not have known of HIV infection in the Irish blood pool until she had the result of Andrew's test in November 1985. Ms Power put it to Dr Lawlor that Fionn's HIV positivity in October 1985 could have indicated to the BTSB that HIV was in the blood pool before the information on Andrew's case was available to Dr Cotter. However, Dr Lawlor said that positive donors also indicated that HIV was in the blood pool, or could be in the blood pool. Positive donors were turning up in October 1985, shortly after the introduction of testing.

Mr Gerry Durcan for the Tribunal examined Prof. Ernest Egan, Consultant Haematologist at Galway Regional Hospital.

Prof. Egan told the Tribunal that he cared for up to 12 people with haemophilia. He did not see himself as a regional centre direct. Prof. Egan said that his patients may have attended Dublin. He agreed with Mr Durcan that there was no communication between Galway and Dublin concerning the treatment of haemophilia patients, and he agreed that the situation was that two hospitals were treating the same patient, and neither knew what the other was doing.

Prof. Egan said that haemophilia was treated on a per incident basis, and he would not necessarily know what was being done elsewhere. Prof. Egan said he would provide advice to other hospitals in the area if necessary. While he did not regard himself as a haemophilia treater, he would provide advice to hospitals such as Castlebar.

With respect to the patient Fionn, Prof. Egan said he did not know whether Fionn had received treatment in Dublin. While he was being treated in Galway he received only cryoprecipitate. He was tested in October and December 1985 for HIV and a confirmatory result was available in Galway in January 1986. Prof. Egan said that a sample was drawn from Fion on 16th October 1985 which led to a request for a repeat sample, which was drawn on 29th November 1985. This sample confirmed positive and was reported positive on 6th January 1986. Prof. Egan said he did not know of Fionn's HIV positive status until January 1986.

With respect to a conversation that Prof. Egan may have had with Dr Terry Walsh of the BTSB on 14th January 1986, Dr Egan said that the subject matter of this conversation appeared to be BTSB cryoprecipitate. Prof. Egan said it was inconceivable that he did not tell Dr Walsh that he had an HIV positive patient who had been treated only with cryoprecipitate in the course of this conversation. Prof. Egan agreed that in light of the knowledge he now had about Fionn and the documentation available from the period, he was saying that he discussed the HIV positive case with Dr Walsh in 1986, and that he told the BTSB he had a HIV positive cryo user. Prof. Egan said he could not imagine not having told them. He said the coincidence of the date was too strong and he must have discussed it. He said he would also have been in telephone contact with Dr Walsh.

Prof. Egan said Fionn's family were informed by Dublin of his HIV positive status. On 15th January 1986 Prof. Egan had a discussion with Prof. Temperley about the cryo infection and Fionn's HIV positive status. Prof. Egan said he discussed Fionn with Prof. Temperley in and around 13th – 15th January 1986. Prof. Egan said Fionn was treated with cryoprecipitate only. Prof. Egan said that at this time Prof. Temperley appeared to confirm with him that Fionn had been treated only with cryo. Prof. Egan said it was likely that cryo was among the issues discussed at the time.

Prof. Egan said he used only cryo in the treatment of haemophilia A to reduce exposure to multi-donors. However, he said as time passed and viral inactivation and donor screening procedures were put in place, and factor VIII requirements changed, it was possible that he may have considered using concentrate. However, he was not aware that heat-treated concentrate became available in January 1985, and he was not aware other units ceased using cryo in and around this time. Prof. Egan said he did not consider using heat-treated product in 1985 or consider that it might be safer than cryo.

It would therefore appear that Prof. Egan used cryoprecipitate in the treatment of haemophilia in 1985 because he was not aware that heat treated factor VIII was available. By treating those with haemophilia A exclusively with cryo, Prof. Egan inadvertently protected his haemophilia A patients. By continuing to use cryoprecipitate in 1985 in the absence of a knowledge that heat treated factor VIII was available patients may have been exposed to infected cryo. Dr Lawlor stated previously that Fionn was probably exposed to the infected cryoprecipitate in October 1984.

Professor Egan was cross-examined by Mr Martin Hayden for the Irish Haemophilia Society.

Prof. Egan agreed with Mr Hayden that he chose cryoprecipitate over factor VIII concentrate, as it was less likely to cause infection to his patients. However, Prof. Egan said that from 1984 onwards the situation was fluid. With respect to a letter written by him to the NDAB, stating that he believed concentrates posed a significant risk, Prof. Egan said that he could not define what was meant in that letter by use of the phrase, "significant risk". However, he agreed that where special circumstances existed, he would choose cryo as he believed cryo reduced the risk across the board. Mr Hayden pointed to figures of infection among haemophilia A patients in Galway. Prof. Egan apparently had 11 haemophilia A patients and had 1 HIV infection, which was to the patient Fion who was exclusively on cryo. By contrast, 16 haemophilia A patients were treated in Limerick, 8 of whom developed HIV infection. Prof. Egan said that this was a simplistic presentation of the figures.
Prof. Egan said that if Prof. Temperley had told him to use concentrate he would have considered it, as Prof. Temperley had the expertise in the area. However, there was no communication between him and Dublin, and as such he did not discover that heated factor VIII concentrate was available in January 1985, and did not in fact discover the availability of such products until 1986.

With respect to HIV infection among factor IX patients in 1986, Prof. Egan said he was disappointed that Dr Walsh had not told him of this situation. With regards to participating in

the compilation of a national register of people with haemophilia, Prof. Egan said that this scheme was unworkable as far as he was concerned. He did not participate in it, nor did he participate in the compilation of a database for people with haemophilia. Prof. Egan said he did not refer his patients to Dublin as he wanted services developed in the Galway region.

With respect to being informed about the availability of heat treated product, Prof. Egan said it was up to the BTSB to inform him; he did not expect such information to emanate from Prof. Temperley. Prof. Egan said he had no recollection of receiving recalls of product from the BTSB in January and June of 1986, however he said the probability is that he did receive it but the record is no longer available.

Mr Hayden asked Prof. Egan, did he ever tell Fionn that he had in fact become infected from a BTSB product. Prof. Egan said he thought Fionn already knew this, and that in any event he lost contact with Fionn. In 1990 when he treated Fionn, he did not tell him about the BTSB product causing his infection. Prof. Egan said there was no reason why he didn't tell the patient of this.

Prof. Egan was cross examined by Mr Nicholas Butler for Prof. Temperley. Prof. Egan told Mr Butler that he never had any difficulty contacting Prof. Temperley should he need to do so. He then proffered a personal and professional testimonial for Prof. Temperley. Prof. Egan said that, while he may have differed with Prof. Temperley on structural issues, this did not affect patient care. He said Prof. Temperley did not have any formal relationship with Galway.

Prof. Egan was then cross examined by Mr Michael McGrath for the BTSB.

The Tribunal then examined Dr Anne Murphy, consultant paediatrician at Our Lady's Hospital, Drogheda. Dr Murphy said she had only one patient with haemophilia, the patient George who was factor IX deficient. Dr Murphy said she treated George from 1975. Dr Murphy said she carried out a HIV test on George at his mother's behest on 25th November 1985. Dr Murphy said this test was positive. She did not tell Prof. Temperley as it was agreed between her and George's mother that the patient's mother would inform Prof. Temperley of his HIV status. When Dr Murphy had George tested for HIV in November 1985, George had in fact been tested twice previously for HIV and had been found negative. Dr Murphy said she was unaware of previous negative tests. She did not know that there was no history of haemophilia B seroconversions at this time. She did not know which batch had infected George. It did not occur to her to tell the BTSB that her factor IX patient had seroconverted. It did not occur to her that other persons could have been infected with HIV by using the same batch of product as had infected George. Dr Murphy said she could not notify Prof. Temperley without the patient's mother's permission. Dr Murphy said she informed George's GP of his HIV status. She said George was the first HIV positive patient she had treated. She knew the infection had come from a blood product but did not know when it had happened.

In cross-examination by Mr Martin Giblin for the I.H.S., Dr Murphy said she did not know there were previous HIV negative tests until the Tribunal began. If she had been told, the significance of his HIV positivity would have been clearer, she said.

PROCEEDINGS: Thursday 26th April 2001 - Day 119

The Tribunal examined Dr Dermot Long. Dr Long is a physician at the Lady of Lourdes Hospital, Drogheda. He is a consultant physician with an interest in gastroenterology. Dr Long has no specialist interest in the treatment of persons with haemophilia.

In August 1985 Dr Long was involved in the treatment of the patient Hugh. He was also involved in the treatment of the patient Jason in 1988, but did not participate in his treatment in the mid-1980's.

Dr Long was cross examined by Mr Martin Giblin for the Irish Haemophilia Society. Dr Long said he was not aware of an investigation undertaken by Dr Daly into an outbreak of hepatitis A among persons with haemophilia in 1985. Dr Long said he did not report any cases of hepatitis A to the Dublin centre.

The Tribunal then examined Dr Sheik Mohammed Basheer, who is a retired consultant paediatrician previously engaged at the Regional Hospital, Limerick. Dr Basheer said he continues to perform his own locum at the hospital.

Dr Basheer told the Tribunal that the Limerick Regional Hospital did not operate as a regional haemophilia centre, although it had been described as such. Dr Basheer said his role on the National Haemophilia Services Co-ordinating Committee, was to liaise on behalf of patients with haemophilia in the Limerick region. Dr Basheer said there was no haematologist in Limerick and haemophilia treatment was directed from Dublin. There was no diagnosis or treatment of patients in Limerick other than on an emergency basis. Dr Basheer said as a paediatrician he had no dealings with adults; he dealt with children only and their treatment was usually directed from the national centre. Occasionally visitors may have required haemophilia treatment at the regional centre and they would be treated with cryoprecipitate. Dr Basheer said all blood products in Limerick came from the BTSB.

Dr Basheer said he was aware that the names of persons with haemophilia were contained on a national register at the centre in Dublin. The patient Rory was under the care of Dr Basheer from 1977 until he went onto home treatment in 1983. Dr Basheer said that Prof. Temperley would make the treatment decisions with respect to Rory.

Dr Basheer was then cross examined by Mr Jim McCullough on behalf of the Irish Haemophilia Society. Mr McCullough asked Dr Basheer, was he aware in his role as a member of the NHSCC that eight out of 16 persons with haemophilia A were infected with HIV in his region. Dr Basheer said he was not aware of this during his time on the NHSCC, and had only recently become aware of the extent of infections among people with haemophilia in Limerick.

PROCEEDINGS: Friday 27th April 2001 - Day 120

Mr John Finlay for the Tribunal, examined Dr Owen Smith, Director of the National Centre of Inherited Coagulation Disorders at St. James' Hospital.

Dr Smith is a consultant haematologist and paediatrician. Dr Smith took up his current post in 1995, having trained at the Royal Free Hospital in London. Dr Smith described the treatment of haemophilia at the National Centre. He said improvements in detecting haemophilia, and the growing numbers of those surviving HIV and hepatitis C, meant the national centre was picking up more patients as time went on.

Dr Smith said the major development in his time as director of the centre, was the introduction of recombinant factors in 1997. Dr Smith said his major goal was to obtain recombinant factor VIII and IX for the treatment of haemophilia, and he had achieved this. When he took up his post in 1985, children under 12 were on recombinant factor VIII and IX. Dr Smith said this led to a situation where in some households one child under 12 would be treated with recombinant factor, while another child over 12 would be on plasma derived products. Dr Smith described this as an unsatisfactory situation. He was motivated to write to the Minister for Health seeking to increase the numbers of those on recombinant factor VIII. Dr Smith said the Department responded positively to his request and suggested that all people with haemophilia should be put on recombinant factor. As a result, said Dr Smith, the cost of treating haemophilia had risen from £1.7 million in 1994, representing 2.5 per cent of St. James' Hospital budget, to £13 million currently, representing 12 per cent of the hospital's budget. Dr Smith said that in the US and UK there was no universal recombinant therapy available. He said that in certain areas of the US no recombinant therapy was available at all.

Dr Smith said the new centre opened in August 2000. He said this achieved the goal of bringing together the patients, the laboratory and the secretariat, and effectively providing a one-stop facility for the treatment of haemophilia and blood disorders. Dr Smith said the centre had been funded by contributions from the pharmaceutical companies. Dr Smith said he considered this to be an investment by the pharmaceutical companies. The funding was matched by the Department of Health. Dr Smith said no consideration was afforded to the drug companies for the investment made. Dr Smith said the company which funded the hospital, Bayer Pharmaceuticals, obtained the contract to supply recombinant factors in association with other companies. Dr Smith said the other companies contributed to the centre by way of providing equipment. Dr Smith said that between the operation of the centre and the operation of the on-call system, persons presenting at the hospital for the treatment of haemophilia could be assured of treatment. Dr Smith said recombinant factors were supplied by Bayer, Baxter, Immuno and Wyeth.

Dr Smith told the Tribunal that the in-patient haemophilia service for children will transfer from the National Children's Hospital at Tallaght to Our Lady's Hospital for Sick Children at Crumlin. Dr Smith said the out-patient element of treating children with haemophilia will transfer to St. James', and the National Children's Hospital in Tallaght will cease providing care for children with haemophilia.

With respect to relationships between St. James' Hospital and other treaters, Dr Smith said that protocols had issued to the regions. Two consultant haematololgists were engaged in the treatment of blood disorders in the Galway region, being Prof. Egan and Dr Murray. Dr Smith said his dealings were mostly with Dr Murray. Dr Smith said he also dealt with Dr Cahill in Limerick, Dr Jackson in Waterford and Drs Cotter and Madden in Cork, and Dr Crotty in Mullingar. Dr Smith said that Dr Hennessey was about to take up his post at Letterkenny, and Dr McMahon, who was an experienced haemophilia carer, was appointed to the North Eastern Health Board region at Drogheda. In these circumstances, said Dr Smith, there would be a consultant haematologist in each health board area within months.

Dr Smith said that all patients should be centrally registered and this was not the case at the moment. He said that more haematologists would rectify this difficulty. Dr Smith said difficulty was encountered in the administration of home treatment because a number of users did not complete the record forms for their product. Dr Smith said if the hospital didn't know what was being used, it was not in a position to issue more concentrate. Dr Smith said that with a world wide shortage of recombinant factor VIII, treaters had been forced to revert to plasma derived factor VIII for adults. This had arisen during the last two weeks. Dr Smith said the difficulty arose because he could not source Recombinate.

With respect to the management of patients outside Dublin, Dr Smith said if they attended him, their treatment was his responsibility. He would, however, advise local haematologists of their situation. An example of this was referrals taken from Dr Jackson in Waterford. Dr Smith said the situation was that the national centre would assess individuals for their haemophilia level and the local hospital would treat them in an emergency.

With regards to treatment afforded to patients, Dr Smith said he would recommend to the local treating doctor, the appropriate treatment for a patient. If the treating doctor demurred from this advice, then it would be a question of the local doctor taking responsibility. Dr Smith said in these circumstances he would also inform the patient as to the nature of his advice, and in a situation where a fundamental disagreement arose, such patient would return to his care. Dr Smith said that this situation had arisen once or twice during his "reign".

With respect to treatment protocols, Dr Smith said that all haematologists treating people with haemophilia must ask for protocols. He said they usually did ask for these protocols upon being appointed. Dr Smith said there was no formal meeting of haemophilia treaters in Ireland in their role as haematologists. He said the biggest meeting of the year was the Irish Haemophilia Society AGM. However, as more haematologists were appointed Dr Smith said he would like to see a system developing whereby meetings would take place along the lines employed by the UK Haemophilia Centre Directors. At present no such meeting took place in Ireland.

Dr Smith said that, with respect to information on people with haemophilia being available in a central register, the data manager in St. James' currently logged virology, haemovigilance and HIV status of people with haemophilia. Dr Smith said that most people with haemophilia had a record maintained at St. James's, but some of those treated in the regions did not. Dr Smith said that some patients did not want to register and may be looked after locally. With respect to an unregistered patient at Castlebar who had been referred to in earlier evidence, Dr Smith said this

situation was not unique and it was not desirable. He said all patients should be accounted for and treaters should send data to St. James's for use in constructing an accurate picture of the situation regarding people with haemophilia. Dr Smith agreed that failure to furnish him with a record of hospital based treatment was a weakness in the system.

With respect to people with haemophilia being tested for viral infection, there was no formal method of reporting back to St. James' Hospital. Dr Smith said that he believed all information should be held on a central register.

With respect to the future, Dr Smith said an increase in consultant manpower was required. Currently he was a sole consultant haematologist, a comparable situation at the Royal Free Hospital in London, where there were fewer patients with haemophilia, fewer children being treated and fewer with vonWillebrand's disease, was catered for by four consultants. Dr Smith said that haemophilia, being a complex area, required more than straight forward clinical care. Laboratory testing facilities were required. Dr Smith said the four consultants would have sub-specialties in such areas as the laboratory, the treatment of adult haemophilia and the treatment of thrombophilia.

With respect to the evidence of Peter, given on behalf of his son Dermot on day nine of the Tribunal, Mr Finlay asked Dr Smith, was he aware of the evidence as delivered which stated that Dr Smith had told Dermot of his impending death while no member of the family was available. This had been the subject of criticism from the witness Peter. Dr Smith said he remembered the situation well. He said Dermot was seriously ill in February 1996. Dr Smith said he had got to know Dermot while on a trip to the US Society of Haemophilia which Dermot had attended as an I.H.S. delegate. When Dermot had asked Dr Smith for his opinion as to whether or not he was going to die, Dr Smith said that he was confronted with a 42 year old man whose circumstances he was aware of in detail. He discussed the situation with him and was frank with him. He gave him his medical opinion and then arranged that he meet the family. Full counselling was provided and it was decided that it was in the best interests of Dermot that he return home. Dr Smith described escorting Dermot from the hospital. He said he shook Dermot's hand and had informed the family that Dermot's life expectancy at this stage amounted to no more than three months. Dermot died three weeks later. Dr Smith said he was very upset when Peter gave his evidence, at the criticism directed at his actions. However, given the full situation and the circumstances that prevailed, he would not change anything regarding his treatment of Dermot.

On the issue of liver biopsies, Dr Smith said that this was a safe procedure and he was aware of the debate concerning the hazards, which some contended for liver biopsy. Dr Smith said there was a split of opinion on this. Old treaters did not conduct invasive procedures on persons with haemophilia, said Dr Smith. However, younger treaters believed that in bringing up the factor levels to normal, a liver biopsy could be performed as a minor surgical procedure. Dr Smith said the liver biopsy was the only way of determining if interferon was working or not. In an article co-authored by Dr Smith, the procedure for conducting liver biopsy on persons with haemophilia is described. Dr Smith said this article was quoted all over the world. It was his opinion that a liver biopsy could be performed safely on persons with haemophilia.

Dr Smith said he did not believe that the Irish Blood Transfusion Service had any role in the provision of coagulation factors. He said it was his belief that centre directors should be buying the concentrate. This was particularly so with recombinant factor concentrate. He said the national centre should be in the front line. This had been Prof. Temperley's opinion, and it was also his opinion that doctors should be in the front line of selecting concentrate.

Dr Smith said he had spoken at length with the Irish Haemophilia Society on this issue, and the doctors, the Irish Haemophilia Society and the health authority should decide on which concentrate to use. Such concentrate should then be supplied from the national centre, said Dr Smith. Dr Smith said the benefit to be derived from this activity would be a more pro-active approach than that employed by the Irish Blood Transfusion Service in supplying these products.

With respect to the reintroduction of plasma derived concentrate, Dr Smith said he hoped it was a temporary return to plasma derived product. There was a world-wide shortage of Kogenate, and that Ireland was the last country in Europe to go back to plasma derived products.

Dr Smith was then cross-examined by Mr Raymond Bradley on behalf of the Irish Haemophilia Society. Mr Bradley asked Dr Smith that when the IBTS had entered into the supply contract with Bayer, was there any alternative supplier for recombinant products? Dr Smith said this was the case. He said that at this stage, 60 per cent of the factor VIII recombinant product procurement was from Wyeth. Upon request from the national centre, Wyeth increased its supply to around 72per cent of the requirement. Dr Smith said he did not think there was an emergency stock of recombinant factor VIII held by the Irish Blood Transfusion Service. Dr Smith said the plasma-derived product now in use was Mono-M. He said this product was safe. In determining which product to select Dr Smith said the issues to be taken into consideration were:

1) Safety
2) Supply
3) Efficacy

Dr Smith said that non-recombinant product by its nature being derived from human blood, contained viral and prion risk. However, he considered Mono-M to be a safe product. He said that he would insist on a monoclonal purified product treated with solvent detergent in selecting a plasma derived factor concentrate.

With respect to the withdrawal of Bayer products in the recombinant market, Dr Smith said that this withdrawal followed an FDA site visit. However, it was his understanding that Bayer itself had decided not to release its product. He said a quality control problem had arisen. Dr Smith commented that it was fortunate that the difficulty arose with factor VIII rather than factor IX, as there were three suppliers of factor VIII and only one supplier of factor IX. Dr Smith said that the policy at present was that children and other virally naïve patients would be kept on recombinant product, however the product was being rationed to about 50 per cent of its former use. In this way, children were being kept off plasma derived products. Dr Smith said in the worse case, Kogenate would be back on the market within six months. Dr Smith agreed with Mr Bradley that it would be desirable that a chemist be available to evaluate future products. Dr

Smith said that patients had been informed of the recombinant shortage through the Society via a mail shot.

With respect to the involvement of drug companies in the building of the national centre, Dr Smith said in an ideal world drug companies would not be involved. However, he said he operated in the real world and it was his opinion that drug companies had a responsibility for the treatment and diagnosis of haemophilia. Dr Smith said it was his dream that there would be a full delivery of service. He wanted a state-of-the-art facility put in place, and this is what had been achieved. He said upwards of 2,000 patients were treated at the centre, 300 of whom had haemophilia. He said there was a growing number of people with non-haemophilia blood disorders, and four consultants were needed to drive this programme.

With respect to the consequence anticipated as a result of hepatitis C infection, Mr Bradley asked Dr Smith was there any plan in place to deal with forthcoming illnesses. Dr Smith said that two consultant posts had been approved. However, there was no particular plan in place for dealing with HCV consequences. Dr Smith agreed that it would be a good idea to have such a plan, but said he would need manpower to put it into operation.

With regard to the issue of liver biopsy, Dr Smith said that liver biopsy was not the practice at the Royal Free when he was there, but he understood it was a procedure carried out at the Royal Free as of 2001. Dr Smith said that liver biopsies were performed at St. James' on people with haemophilia, with no significant bleeding following. However, there was some bleeding. Dr Smith agreed that this may be of more concern for a person with haemophilia than for a non-haemophilic person. Dr Smith acknowledged that there was a division of opinion on the issue of liver biopsy among those treating haemophilia. It was his opinion that it was the only way to tell the potential for drug therapy. However, Dr Smith said he was not a liver expert and one would need to speak to Prof. Kelleher on the matter. Dr Smith said he did not know if liver biopsies were performed at Sheffield as of 2001. Liver biopsy was the treatment choice, said Dr Smith.

With respect to the evidence of Felicity concerning her three children and their infection with hepatitis C, and the fact that she was not told until 1995 of their hepatitis C status, Dr Smith said he was surprised to know that three children had not been so informed at this time. Dr Smith said, with the appointment of a data manager at St. James' Hospital, it was hoped that such a situation could be avoided in the future.

With respect to the patient Albert, Dr Smith said he appeared to have slipped through the review and clearly did not understand he was hepatitis C positive until told by Dr Smith in 1999. Dr Smith said Albert was in clear denial of this fact when he was told he had hepatitis C. Dr Smith said he could not remember if any patient had been informed as late as 2000 that he had hepatitis C.

With respect to the care provided for persons with haemophilia at Waterford by Dr Jackson, Dr Smith said Dr Jackson was in close liaison with the centre, but had indicated he would prefer if the national haemophilia treatment centre would look after those with haemophilia until a second haematologist was appointed to Waterford.

Dr Smith was then cross examined by Mr Nicholas Butler for Prof. Temperley. Dr Smith agreed he inherited a situation where those under age 12 were on recombinant factor concentrates. He agreed that this was a very advantageous position to be in and was far in advance of the situation then prevailing in the UK. Dr Smith agreed that Prof. Temperley had pioneered the treatment of haemophilia in Ireland and he described Prof. Temperley as a "visionary".

Dr Smith was then cross examined by Ms Judy Blake for the Blood Transfusion Services Board. Ms Blake asked Dr Smith was he actively involved in the selection of blood products. Dr Smith agreed that this was the case and that he was employed in his consultant role for one session per week at the BTSB, with a view to assisting in the selection of such products. Dr Smith agreed that this was the case and said he had had co-operation in doing so by Mr Hynes and by his predecessor Mr Dunbar. He also agreed that it was a joint decision by those selecting product to appoint two suppliers and not one. Ms Blake put it to him that this was a prudent and responsible course to take, and that while no emergency stock was held by the BTSB, the appointment of two suppliers provided an alternative source of supply should one supplier default on delivery of recombinant product. The second supplier was effectively the fall-back position. Dr Smith agreed this was the case.

Dr Smith was also cross examined by Mr Ian Brennan for the Department of Health, and Ms Deidre Murphy for St. James' Hospital.