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TRIBUNAL OF INQUIRY

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

PROCEEDINGS: Monday 30th April 2001 - Day 121

Patrick McCann B.L. for the Tribunal examined Dr. Fiona Mulcahy. Dr. Mulcahy is a Consultant Genitourinary Physician at the Department of Genitourinary Medicine in St. James's Hospital. She took up this appointment in 1987. Dr. Mulcahy said one of the main purposes of her appointment was to develop the sexually transmitted disease service at St. James's Hospital.

Dr. Mulcahy said that in 1986, 3,000 persons attended the STD Clinic. In 1987 there were 9,000 attendances. Dr. Mulcahy said the service was planned as a sexually transmitted diseases service, it was not specifically directed at dealing with HIV.

The physical environment in which the service was delivered consisted of one room, said Dr Mulcahy. The service was staffed by a half time STD nurse and a senior house officer. Dr. Mulcahy said she conducted evening clinics for her first year of operation. She said that in the early stages of HIV the condition was mostly seen in gay men. Dr. Mulcahy said HIV among people with haemophilia was dealt with as a haematological problem by the haematology service. Dr. Mulcahy said at this stage those involved in delivering the service were learning about the condition, and each was developing his or her own expertise.

In 1988 special facilities to deal with HIV and AIDS were put in place. Dr. Mulcahy said that she availed of the facilities which had been vacated by the antenatal service. Dr. Mulcahy said that in 1988, St. James's Hospital was seen as the centre dealing with HIV. Other hospitals were not involved in the treatment of HIV patients. During 1988, more staff were recruited to the GUM Clinic. Dr. Mulcahy said that part of her task was lobbying for services, and lottery funding was used to put in place necessary services. She said the unit was spared the cut-backs in the late 1980's. A full time counsellor was appointed. Dr. Mulcahy said that this person was originally designated to be a HIV tracer, but the post developed into a counselling service.

Dr. Mulcahy said in 1988, HIV haemophilia patients and other patients were commenced on AZT. She said this treatment was made available as soon as it became possible to use it. The early version of AZT treatment consisted of 1,000mg per day and had serious side effects. Dr. Mulcahy said that the treatment had now been refined and the dosage was reduced to 300mg per day. Dr. Mulcahy said that in the early stages, some of those being treated with AZT came off the treatment due to its side effects.

Dr. Mulcahy said that post mortem was a routine policy with respect to those who died from HIV. She said the purpose of this was to determine if the correct diagnosis had been made. She said the rationale of this was explained to relatives.

Dr. Mulcahy explained that triple therapy became available in 1995. Triple therapy was available in Ireland from the beginning of 1995, said Dr. Mulcahy. She said those who met the criteria were put on the treatment. At this early stage the effectiveness of the treatment was gauged by examining T cells said Dr. Mulcahy. No viral load and copies of viral load were recorded at this point. Dr. Mulcahy said the policy with respect to HIV and the use of triple therapy, was to hit it hard and hit it early. In this way, a good response was expected. Dr. Mulcahy said that intravenous drug abusers did not participate in the use of triple therapy while still using drugs, because of the chaotic nature of their lifestyle. Dr. Mulcahy said that she had seen a significant number of patients from outside Dublin. She said many were self-referrals, and some were referrals from doctors.

With respect to the evidence of Dominic, which was heard by the Tribunal on Day 5, Dr. Mulcahy said there were no HIV referrals from Cork until 1996. She agreed that treatment was available in Dublin from the start of 1995. Dr. Mulcahy said that since 1996, no deaths had been recorded. Dr. Mulcahy said that Dr Smith ran a dedicated out-patient service for haemophilia HIV infected patients. She said the major problem attending triple therapy at this

stage was the development of diabetes and high cholesterol. She said different strategies may be required for different patients, but what was required was that HIV be treated at a one stop shop.

Dr. Mulcahy was cross-examined by Mr. Martin Giblin S.C. for the Irish Haemophilia Society. With respect to the evidence of Dominic, Mr. Giblin put it to Dr. Mulcahy that, when he was seen by her he had a CD4 count of 60. Dr. Mulcahy agreed that this was the case and said that Dominic was a self referral. She said that Dominic's case highlighted the need for an infectious diseases consultant in the Cork region. Dr. Mulcahy said that St. James's Hospital got significant additional resources to deal with HIV infections. Dr. Mulcahy agreed that those with haemophilia would prefer to be treated in their own unit, but she said that the primary aim in treating the patient was to ensure survival wherever that treatment was delivered.

PROCEEDINGS: Tuesday 1st May 2001 - Day 122

Prof. Sean McCann was scheduled to give evidence. However, due to the late arrival of his statement into the hands of the Department of Health, the Tribunal adjourned for the day to allow the Department to study Prof. McCann's statement.

PROCEEDINGS: Wednesday 2nd May 2001 - Day 123

Patrick McCann for the Tribunal examined Dr. Ann Tobin. Dr. Tobin described how in 1992 she was contacted by Prof. Weir of St. James's Hospital with respect to grant funding from Schering Plough, in the form of an unrestricted educational grant for research into the use of interferon. Dr. Tobin said testing the dosage was the first item to be considered in such research. She said she saw a copy of the database of haemophilia patients from Prof. Temperley. Dr. Tobin said funding from companies such as Schering Plough was not uncommon and applications were often made to pharmaceutical companies to provide funding for research.

Dr. Tobin said that by the late 1980's, it was realised that Hepatitis C was a more serious illness than had previously been considered to be the case. Dr. Tobin said a licence for Interferon Alpha became available in 1988. By the late 1980's, Interferon had become more available on the market due to advances in recombinant technology. Dr. Tobin distinguished between side effects which could arise from using Interferon, and contra-indications as to why it would not be administered. Dr. Tobin said the side effects were symptoms of such contra-indications in some cases.

With respect to using Interferon among people with haemophilia, Dr. Tobin said special considerations had to be put in place for haemophilia patients who were multi-transfused, were therefore multi-exposed to infection and may have more than one genotype of Hepatitis C in their system. Dr. Tobin said she contacted people who were attending Prof. Weir's clinic. She said she tried to recruit people with haemophilia for treatment with Interferon, and staff in the Haemophilia Centre assisted to this.

Letters were sent to selected patients who were potential candidates for treatment with Interferon. Dr. Tobin said that to evaluate the effectiveness of using Interferon, she would at that time use PCR rather than biopsy because, although people with haemophilia were a group at particular risk of liver disease, they had also been educated not to endure any invasive procedure unless it was absolutely necessary. However, the difficulty with using PCR is that it did not show liver status.

Dr. Tobin said she would counsel patients when they were selected for treatment with interferon. A patient information leaflet was prepared by Dr. Tobin and was distributed as the *ABC of Viral Hepatitis*. Dr. Tobin said this would be given to patients when they were being examined.

Dr. Tobin said that interferon treatment was effective in half the patients who were treated. However, when treatment stopped, the virus returned, again in about half of the cohort. Dr. Tobin said that a cure as such could be seen in between 20 per cent to 25 per cent of patients. Dr. Tobin said that pre-treatment counselling was part of the diagnostic process. Dr. Tobin said the cure rate for Hepatitis C was disappointingly low. Interferon improved the liver biochemistry and decreased the viral load, Dr. Tobin said such transient improvement was not without benefit.

Dr. Tobin said her appointment was terminated in May 1994. Dr. Tobin said that HIV itself was not *per se* a contra-indicator with respect to Interferon treatment. Dr. Tobin said that Hepatitis C Genotype 1B was the most common form of Hepatitis C found in Ireland, and was resistant to Interferon.

Dr. Tobin was cross-examined by Mr Martin Hayden for the Irish Haemophilia Society. With respect to the patient Albert, who gave evidence that he was not told he was Hepatitis C positive until 1999, but whose medical record reveals that he was counselled for Hepatitis C by Sr. O'Shea on 11th March 1993, it is also noted that he was Hepatitis C positive at the time. However, at the time he was also being treated for Hepatitis A, and received vaccination for Hepatitis A on that occasion. Subsequent entries on Albert's medical records show that he is Hepatitis C antibody positive. Mr. Hayden put it to Dr. Tobin that the most Albert could have been told on this occasion was about his Hepatitis C antibody status. He could not have been told, or may not have been told, he was Hepatitis C positive.

The Tribunal then examined Prof. Sean McCann. Prof. McCann told the Tribunal that he was upset and depressed at the reporting of the Tribunal and it has caused great difficulties for the practice of Haematology, and for the practice of medicine.

Prof. McCann was cross examined by Mr. Jim McCullough for the Irish Haemophilia Society.

Mr. John Finlay for the Tribunal examined Dr. Helena Daly. Dr. Daly told Mr. Finlay that, when she arrived at St. James's Hospital in 1985 to act as Locum for Prof. Temperley, cryoprecipitate and unheat-treated factor IX were in use. Dr. Daly said that she was aware of the risk attached to the use of blood products by people with haemophilia, as she had attended to a patient with haemophilia who contracted AIDS and died in Bristol in 1983. However, said Dr. Daly, the state of knowledge at the time would not have allowed her to say that all cases of HIV infection would progress to AIDS. Dr. Daly agreed that commercial heat treated factor IX was available to St. James's Hospital in 1985, however Dr. Daly said that she was unfamiliar with heat treated factor IX as she had not used it in her post in the UK.

With respect to the issue of thrombogenicity, Dr. Daly said that there was always a documented risk, but it was not to the forefront of her considerations. Dr. Daly said that this would be of concern where patients were already suffering from liver disease. She had never come across a case of thrombogenicity in her practice, and she said it was not an every day problem. But, she said she was aware that fractionators had concerns regarding thrombogenicity.

Dr. Daly said that she was under the impression that home therapy factor IX patients were receiving a heat-treated product. Dr. Daly said that she was concerned about all BTSB products in use at the time. She described a meeting with Mr. Hanratty and Dr. O'Riordan in August 1985. Dr. Daly said she attended the meeting with the intention of getting agreement from the BTSB that only heat treated product would be used. However, she left the meeting with them saying they were not going to heat treat their factor IX, and could not heat treat cryoprecipitate. However, she now understood that the heat treatment programme for factor IX was commenced the following day.

Dr. Daly said that when it came to a choice between BTSB factor IX and heat treated factor IX, she had no choice. Dr. Daly said she had been told that she would not receive heat treated factor IX. When she attended the meeting at Pelican House the position, as she understood it, was that she either left patients untreated or used BTSB unheat treated factor IX. She said she was not in a position to refuse the BTSB product. She said it was her view that what she had suggested to the BTSB was outrageous in their view. She also said that some Irish patients were reluctant to part with the unheat treated factor IX from the BTSB in favour of heat treated commercial factor IX, on the basis that the Irish product may be safer. Mr. Finlay put it to Dr. Daly that, if she had asked for commercial heat-treated factor IX only, in light of her visit to Pelican House and Dr. O'Riordan and Mr. Hanratty, it would have been a momentous decision for her to take. Dr. Daly said she was not in a position to take such a decision against the BTSB.

Mr. Finlay suggested to Dr. Daly that it would have been possible for her to order more factor IX from commercial sources, or commercial heat treated factor IX from the BTSB. Dr. Day said the matter had been effectively taken out of her hands when it was agreed by the BTSB and Prof. Temperley that heat-treated factor IX would be made available from the start of November 1985.

In addition to her concerns over the heat treatment of factor IX with respect to HIV, Dr. Daly also contacted Dr. O'Riordan concerning an outbreak of Hepatitis C, which she traced to a BTSB batch. Dr. Daly said she got no response from Dr. O'Riordan. Dr. Daly said that during August 1985, St. James's Hospital took delivery of more than six times the previous monthly average of unheat-treated factor IX from the BTSB. Dr. Daly said there was no particular reason, from her point of view, why so much factor IX would be needed at St. James's Hospital. Dr. Daly said for the duration of her locum at St. James's, she modified the treating practice to some extent in order to minimise the exposure of patients to unheat-treated factor concentrates and cryoprecipitate.

Dr. Daly said she was not aware of any trial conducted on BTSB factor IX at St. James's Hospital in October of 1985. Dr. Daly said she had completed her locum at that stage. However, she would be surprised if such a trial could take place without some patient involvement.

Dr. Daly said that one of the tasks she undertook on her arrival in St. James's in the summer of 1985, was to inform people about HIV antibody tests which had then been performed, and the results of which were available. Dr. Daly

said she was handed a list of patients whose results, positive or negative, were recorded. Dr. Daly said she counselled a total of 93 persons, who consisted of patients and non-patients. On the list that she had available, 81 were yet to be consulted when she ended her locum at the end of September 1985. Dr. Daly said she counselled proportionately more positive than negative patients. Dr. Daly said that she informed people when they attended the clinic and set up extra clinics to inform them of their HIV status. Dr. Daly said in-patients would be told their results unless they were so ill they could not be so told.

Dr. Daly agreed that counselling was not really part of her brief, and that of all the tasks that she had to perform during the locum, Paediatric Haematology was her major concern. Dr. Daly described how she would actually impart information to people with HIV. She said she would emphasise the dangers of sexual transmission. She said that when she had completed counselling individuals, a representative of the I.H.S. was on hand to distribute condoms. She said the majority of patients availed of this offer. Dr. Daly said that the only knowledge that people appeared to have prior to her counselling them was from the media. She said this was not a good source of information. Dr. Daly said the prognosis offered at the time may have been vague, and this was because it was simply not known as to how AIDS would develop. Dr. Daly said it was generally expected that an optimistic scenario would unfold. However, she said this was unjustified optimism as it turned out.

With respect to informing Mr. Raymond Kelly as to the HIV status of his son John, she said she would have conveyed the impression to him that it was very unlikely that his son would go on to develop AIDS.

Dr. Daly was examined by Mr. Raymond Bradley for the Irish Haemophilia Society. Dr. Daly said that when she arrived in Ireland in 1985, she was contacted by a member of the Irish Haemophilia Society who told her that most people who had been tested for HIV had not been given their results. Dr. Daly said that after the 13th August 1985 meeting with the BTSB, she implemented substantial cut-backs in the use of cryo. She reduced the use of unheat treated material and changed over to heat-treated product where possible. However, she continued to use small amounts of cryo after this date. Dr. Daly said her difficulty was she had no cast iron reason for refusing non-heat treated BTSB factor IX. She was aware that it had been recommended that the use of non-heat treated products be discontinued. She had read the Bloom article of June 1985, but she said she was not in a position to follow its advice. Dr. Daly said no sense of urgency seemed to exist within the BTSB to change the product, and as she had no proof against the BTSB's non-heat treated factor IX at that time it was difficult for her to overcome the BTSB's resistance to her request. She said the attitude appeared to be that Irish product was safe.

PROCEEDINGS: Friday 4th May 2001 - Day 125

Mr. Raymond Bradley continued his cross-examination of Dr. Helena Daly. Dr. Daly said that in August 1985 the BTSB, in refusing to supply her with heat treated factor IX, restricted her clinical choice in the treatment of her patients. She said she was unable to provide the therapy she wanted and the BTSB's denial of her request seemed to be based on the idea that Irish product was safe.

Dr. Daly rejected the suggestion that the period from the commencement of her locum in July 1985 until the meeting in August 13th 1985, constituted a delay on her part in acting on behalf of her patients. Dr. Daly said the BTSB controlled the choice of product available to her. She said that while some heat-treated product was available, a proportion was unheat-treated. Dr. Daly said that the November 1st deadline for the introduction of heat-treated factor IX was decided between Prof. Temperley and the BTSB; she did not participate in this decision-making process. This was despite the fact that she was the locum consultant and technically in command of the treatment of people with haemophilia at the time.

Dr. Daly said that with respect to counselling, the type of counselling that she engaged in went beyond mere medical counselling and telling people that they were positive or negative. She said it was basic counselling, but it was of a very comprehensive nature and offered the information as to HIV status, the dangers of transmission, and reassurance to the patient.

Dr. Daly said she also set out the need for further counselling in her letter to Mr. Fitzpatrick. She said she had set out her opinion in this letter and assumed it would be acted upon. Dr. Daly said that when she finished her work at St. James's Hospital she passed the entire information on to Dr. Jackson. She said she met him at the Central Pathology Laboratory and set out what she had done. She described this process as a fairly detailed hand-over to Dr Jackson. She left with the impression that counselling would continue in her absence.

Dr. Daly was further cross-examined by Ms. Deirdre Murphy for St. James's Hospital, Mr. O Brolchain for the Southern Health Board and Mr. Frank Clarke for the BTSB. Mr. Clarke directed Dr. Daly to her observations that BTSB factor IX orders for August 1985 increased six fold. Dr. Daly said that whatever the reasons for the BTSB supplying six times the normal amount of factor IX, there was no need for 100,000 units of factor IX concentrate at St. James's Hospital in 1985. Mr. Clarke pointed out that the BTSB would only have delivered the amount of factor IX that was ordered by the hospital. He also put it to Dr. Daly that the BTSB had at no time denied any request that she had made for concentrates. Dr. Daly said that she asked for heat-treated factor IX, and the answer she received was no. Mr. Clarke said that no order had been made for heat-treated factor IX. Dr. Daly said that she made a very firm request and was refused.

Dr. Daly was also cross-examined by Mr. Brennan for the Department of Health and Mr. Finlay for the Tribunal.