

IRISH HAEMOPHILIA SOCIETY

TRIBUNAL NEWSLETTER

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7th June 2001

TRIBUNAL OF INQUIRY

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

PROCEEDINGS: Tuesday 15th May 2001 - Day 128

Mr. Paul Barron of the Department of Health and Children gave evidence to the Tribunal. Mr. Barron pointed out that he had no personal involvement in the matters under investigation, but had familiarised himself with the papers and with the State's discovery.

Mr. Barron was examined in his evidence by Mr. Durcan for the Tribunal. He told the Tribunal that the function of the Department was to ensure that services were provided in respect of health care in the State. Mr. Barron agreed with Mr. Durcan that the Minister carried political responsibility and authority for the activities of the Department. He agreed that the buck stopped with the Minister, but pointed out that this operated at a macro level and not an individual level.

Mr. Barron set out the various legislation by which organisations such as the BTSB and the Irish Medicines Board were established. He agreed that the Department of Health controlled the BTSB insofar as it appointed the board of the BTSB and examined the annual report and accounts. He said that the BTSB was unusual in that it was expected to pay its own way by selling products such as blood and blood products. Previously capital funding had not been made available. Mr. Barron said this was not now the case.

Mr. Barron said that Department officials were appointed to the board of the BTSB. He said such officials were expected to assist the BTSB with respect to the Board's approach to different issues. However, it was not part of their function to report back to the Department. He agreed that information concerning the activities of the Department, and the activities of the BTSB, flowed both ways through the activities of these officials.

Mr. Barron said that with respect to blood products, the BTSB was an independent statutory organisation and conducted its affairs on this basis. He agreed that the Department of Health had a function in making policy, but said it did so at different levels. Mr. Barron said the Department was involved in the BTSB's self sufficiency project in that it had an input into this policy and expected to have an input. Mr. Barron said this policy was derived from the Council of Europe recommendations.

Mr. Durcan referred Mr. Barron to NHSCC documents, whereby the NHSCC requested the Department to provide approval for the BTSB to proceed with factor VIII production. The documentation shows that the Department's view was that it should not get involved in these activities, or in approving such activities for the BTSB. Mr. Barron agreed that the thrust of the communications between the BTSB and the Department was to keep the Department out of the BTSB's production discussions. He agreed that the Department appeared to back away from this issue. He said this was a matter for the BTSB; they were the experts and they were in the position to decide.

With respect to Dr. O'Riordan's attendance at the Committee of Experts of the Council of Europe, Mr. Barron said that Dr. O'Riordan was there as a representative of Ireland and not just the BTSB. The recommendations coming from the Council of Europe were addressed to the State. The committee of ministers referred to in the Council of Europe documentation was a committee of foreign ministers. Mr. Barron said that the public health committee of the Council of Europe was the level at which the health

ministers and the experts representing the health ministers came in. Dr. O’Riordan was one of these experts during the 1970s and 1980s. Dr. O’Riordan assisted in putting the recommendations together, and the recommendations were forwarded to the ministers from the experts. Mr. Barron said that Council of Europe recommendations were taken seriously and were adopted as policy by the Department of Health.

Mr. Durcan asked Mr. Barron if the Department adopted Council of Europe recommendations as policy, was it not important to see that the policy was implemented? Mr. Barron said that this was the responsibility of the BTSB. He agreed with Mr. Durcan that there was no evidence in the documentation that any step was taken to ensure that the Department’s policy was implemented in this regard. Mr. Barron agreed that if the Department had a policy, it should have taken steps to implement the policy.

With respect to the implementation of Council of Europe recommendation R(83)8, Mr. Barron said that the Department relied on the BTSB to implement the policy. Implementation was done by way of a leaflet prepared by the BTSB. However, the leaflet only partially implemented the recommendation. It specifically excluded the recommendation with respect to persons with haemophilia.

Mr. Barron agreed that by August 1983 the Department was aware that blood products were a source of infection. The note contained in the Department’s discovery from the authorities in Britain, warns that a supply of pre-March 1983 U.S. concentrate could find its way to Ireland. Mr. Barron agreed that no step was taken to notify persons with haemophilia of the dangers posed by this concentrate. No step was taken to inform persons with haemophilia by the Department as set out in the recommendations of the Council of Europe at R(83)8. Mr. Barron said that the NHSCC could have informed the persons with haemophilia of the risks. However, he agreed that this important information was not disseminated as per the Council of Europe recommendation. He agreed that no evidence of any step being taken was contained in the documentation whereby the U.S. information was conveyed to people with haemophilia.

With respect to the preparation of information for parliamentary questions in November 1985, Mr. Barron said that the information that heated blood products only were in use from 1st January 1985, was factual information obtained from the BTSB. He agreed that this information was incorrect. He was aware that it was incorrect by virtue of information which had come to light during the course of the Tribunal. Mr. Barron also agreed that a speech delivered by the Minister, Mr. Desmond, on 25th October 1982, also contained incorrect information. Mr. Barron said this information would have been drafted by an official but he [the official] was not the source of the information. Mr. Barron agreed that it would appear from the records of the BTSB that board members were told of HIV seroconversions in June 1986 at a BTSB board meeting. He agreed that Mr. McCartney, a Department of Health official, was on the board at this time. However, no record of this information is contained in the Department, he said.

Mr. Barron agreed that during the time under investigation, the number of haematologists available to the BTSB was reduced from four to one. With respect to staffing at the NDAB, Mr. Barron said that from 1974 onwards, the NDAB was always looking for more staff. He agreed that they appeared to fall further and further behind with respect to product authorisations, and at one point a backlog of five years had accumulated at the NDAB. Mr. Barron said that during this time the Department was instructed to reduce staff across the health services, and this is what they did. He agreed that there was a 17 month delay in answering a request from St. James’s Hospital for the appointment of a senior social worker.

Mr. Barron was cross-examined for the Irish Haemophilia Society by Mr. Martin Hayden. Mr. Barron said he had prepared for the Tribunal by making enquiries among various colleagues. Mr. Barron said he was aware in general terms of the financial crisis faced by the BTSB in the early 1980’s, and was aware that the Department had provided funding of £1.9 million to the board following its move to Mespil Road.

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Mr. Hayden continued his examination of Mr. Paul Barron of the Department of Health. Mr. Hayden referred Mr. Barron to a B.T.S.B. board minute of February 15th 1989, wherein it is recorded that the Minister was fully advised on the situation with regard to B.T.S.B. products infecting people with HIV. Mr. Barron indicated that this matter would be dealt with by his former colleague, Mr. Lyons. Mr. Barron told Mr. Hayden that, with respect to HIV infections arising from the use of cryoprecipitate, he had never heard or read of this prior to the last few weeks when it emerged at the Tribunal. He said such information was not contained in the Department.

With regard to the B.T.S.B.'s financial crisis and the Department's knowledge of issues arising for the B.T.S.B. between 1982 and 1986, Mr. Barron said that the Department stepped in when the B.T.S.B.'s financial situation required. Money was provided at the end of the day, he said. However, he pointed out that the B.T.S.B. was responsible for its own funds and management, and that the Department would generally only intervene in a crisis situation or when the public interest demanded it. He said it was apparent that the Department was aware that difficulties existed at the B.T.S.B. management level, and that it considered Dr. O'Riordan's dual role unsuitable. However, it took a number of years to effect any change at the B.T.S.B., said Mr. Barron.

With regard to the implementation of R(83)8, Mr. Barron said that the official dealing with Council of Europe matters at the Department, Mr. Kelly, was a higher executive officer. As such, he was not among the top management of the Department. Mr. Barron said that Mr. Kelly would have provided the administrative back-up. The upper management at the Department was equally well versed in the Council of Europe requirements.

Mr. Hayden referred Mr. Barron to the B.T.S.B.'s financial situation. Mr. Barron said this matter would be dealt with by Mr. Smith. However, the general procedure for approving revenue and capital expenditure was addressed. Mr. Barron said the estimate would be negotiated, the Government would allocate the funds, and the Dail would approve the Government's allocation or otherwise. Disbursement would then take place by the Department.

Mr. Barron said from 1987 onwards mid-year adjustments were recorded in the Departmental budget. In the late 1980s this adjustment often took the shape of a downward adjustment. The Department's resources were finite, said Mr. Barron. In the mid to late 1980s the health services were hit by general financial stringency and cut-backs. With respect to dispute on the payment of blood products between St. James's Hospital and the Eastern Health Board, Mr. Hayden noted that the sum at issue rose from £300,000.00 to £700,000.00 over a five year period. Mr. Barron said that the Department could deal with small amounts, but for large financial matters the Department of Finance had to be consulted in order to effect necessary cut-backs. A 1:3 policy for filling vacancies was adopted. With respect to a social worker for St. James's Hospital, Mr. Barron said that the Department's hands were tied by the requirements to reduce the number of staff and Government policy to reduce the health services' work force.

Mr. Barron was then cross-examined by Mr. Nicholas Butler for Prof. Temperley, Dr. Daly and Dr. Jackson. He agreed that the situation on AIDS was monitored closely, particularly by Dr. Walsh. However, he said that the Department did not accept that AIDS represented a health care crisis. It was a threatening situation and was monitored. Mr. Barron said that during the 1980s, keeping the health service going was the major priority.

Mr. Barron was cross-examined by Mr. Clarke for the BTSB. With respect to the document containing U.S. regulations and the warning on pre-March blood still in circulation. Mr. Clarke put it to Mr. Barron that such a document was never in the BTSB. He also asked Mr. Barron, was there any evidence of communication between the Department of Health and the BTSB in respect of the parliamentary question answered by Mr. Desmond in late 1985? Mr. Barron agreed that heat treatment was in place in January 1985.

Mr. Barron was cross-examined by Mr. Brennan for the Department.

Ms. Grainne Clohessy then examined Mr. Dermot Smith for the Department of Health on behalf of the Tribunal. Mr. Smith is a Director at the Department of Health, working in the Finance Unit since mid-1987. He said that during the 1980's the system was under massive stress. The priority was to maintain services and to avoid any additional expense. Mr. Smith said the Department now had multi-annual programmes, which covered periods of greater than one year. The first of these was introduced in 1998.

Mr. Smith said that a number of financial adjustments were made on behalf of the BTSB in the early 1980's. During this time, financial decisions were made by the Secretary of the Department and the Finance Unit. Mr. Smith said that during this time, 25 per cent of bed numbers were cut. He said this was the biggest health spending cut in an OECD country. More than 3,000 beds were removed from the system between mid-1987 and mid-1988. He said that the BTSB was funded by way of a bank overdraft. The BTSB's chief source of income was the sale of blood and blood products. Mr. Smith said a lot of overtime was worked at the BTSB. Costs were met from revenue raised by the sale of blood.

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Ms. Clohessy continued her examination of Mr. Dermot Smith of the Department of Health, Mr. Smith dealing with financial matters on behalf of the Department.

Mr. Smith agreed it was evident from the report of Mr. John McStay that the BTSB's financial position was difficult and remained difficult during the 1980's. Mr. Smith said that the BTSB, in common with other parts of the health service, was under great pressure during the time. He said that the Department responded by bringing persons with business skills and acumen onto the board, and the appointment of a chief executive officer.

Ms. Clohessy asked Mr. Smith, given the figures as revealed in Mr. McStay's report, could it be said that the BTSB was a self-financing organisation? With respect to the overdraft it was running, Mr. Smith said he did not think one could say it was self-financing with that kind of overdraft level. Mr. Smith agreed that the BTSB appeared to be financing its cash flow by way of overdraft, and paying interest upon this facility. Mr. Smith said that despite the fact that the BTSB was under serious financial pressure, it provided a service throughout the period in question.

Ms. Clohessy referred Mr. Smith to the situation in 1986 when the BTSB sought recoupment of losses incurred by withdrawing non-heated and non-tested blood products. The BTSB was at a loss of some £80,000 and requested the Department to make good the loss. The Department's response was to tell the BTSB to take care of the loss in their accounts. Mr. Smith said that a price increase was granted to the Department later that year. A 5 per cent increase was allowed in November 1986. Mr. Smith said that the Department itself did not have the funds to meet the BTSB's request at this time.

With respect to ALT testing, Mr. Smith said that the efficacy of ALT testing was never questioned by the Department. Mr. Smith said that the medical aspect of the ALT testing was never considered by the Department. It was considered simply on the financial issue.

Ms. Clohessy asked Mr. Smith, how did the Finance Unit become involved in such decision-making? Mr. Smith said that such applications would be considered by the medical side of things in the first instance; thereafter Finance would get involved. Mr. Smith said the Finance Unit became involved early in this application because of the effect of a price increase on the system. Any price increase proposed by the BTSB would have the effect of increasing costs to the hospitals. Mr. Smith said the analysis of both cost and efficacy was undertaken with respect to the ALT application. Mr. Smith said that issues such as the application for ALT testing had to be considered in light of the fact that the Department's global budget was cut from 1987 to 1988. Regardless of any meetings which may have taken place between the Department and the BTSB at the time, said Mr. Smith, there was no funding available to meet the BTSB's requirements with respect to ALT testing at this time.

Mr. Smith was then cross-examined by Mr. Martin Hayden for the Irish Haemophilia Society. Mr. Hayden questioned Mr. Smith on the Department's financial position. With respect to the BTSB in the early 1980's, Mr. Smith agreed with Mr. Hayden that the Department of Health and its officials were in no doubt as to the cash flow difficulties that the BTSB were suffering throughout the years 1981 through to 1986. Mr. Smith said this was so, but these difficulties took place against the background of price increases awarded and internal control weaknesses.

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Mr. Martin Hayden continued his cross-examination of Mr. Smith of the Department of Health.

With respect to the issue of self sufficiency, Mr. Hayden asked Mr. Smith, up until 1987 who would have made the decision as to whether an application would be accepted, and the percentage price increase allowed? Mr. Smith said such a decision would have been taken by the Finance Unit by the assistant secretary. Up until 1987 the assistant secretary was Mr. McCartney. Mr. Smith agreed that with Mr. McCartney on the board, the Department could not have been better informed as to the effect of price increases or the lack of price increases on the B.T.S.B. The impact of decisions taken in the Finance Unit, and the consequences of these decisions, were therefore known to the Department through Mr. McCartney. Mr. Smith said that once the decision was made whether or not to grant a price increase, it was for the B.T.S.B to implement whatever policies were in existence. Mr. Smith said that the Department would try to get financing into line, but the implementation of policy remained a matter for the agency concerned.

Mr. Smith said that throughout the 1980s the B.T.S.B continued to get price increases, unlike other agencies. Mr. Smith said the B.T.S.B got the price increases it was looking for during the period. Mr. Smith agreed that during the 1980s the B.T.S.B was in severe financial difficulties. Mr. Smith said that this was the case, but it was also made clear to the B.T.S.B that no blank cheque would be issued in order to alleviate such difficulties.

Mr. Smith was examined by Mr. Brennan for the Department of Health on the issue of when the Finance Unit would consider an application for ALT testing. Mr. Smith said, in clarification of his previous evidence, such applications would be considered in the first instance by the line division of the Department of Health. Such division would examine the costings, and if the request withstood such analysis it would then be passed to the Finance Unit of the Department.

Mr. Gerry Durcan for the Tribunal then examined Mr. Michael Lyons, formerly of the Department of Health. Mr. Durcan referred Mr. Lyons to the leaflet concerning a warning about blood products from the U.S. Mr. Durcan asked Mr. Lyons who else would have had sight of this document. Mr. Lyons said he was with the international division of the Department in 1983, and as such worked for the co-ordinating division of the Department for Council of Europe matters.

Mr. Durcan referred Mr. Lyons to a document previously referred to Mr. Barron, entitled Council of Europe Partial Agreement Public Health Committee Acquired Immune Deficiency Syndrome, United Kingdom note on Acquired Immune Deficiency Syndrome in accordance with Appendix C. Mr. Lyons said his handwriting was appended to this note. The note was circulated to him as part of the process of fulfilling the co-ordination role for the international division within the Department. Mr. Lyons said that the document was clearly circulated to him for information purposes. Mr. Lyons said that if a follow-up was required it would have been put on the document at the time. The notation on the document in question did not indicate a follow-up. Mr. Lyons said to the best of his recollection, the Department official on the Public Health Committee was Dr. Humphries. He said that the existence of the document had come as a surprise to him, and other than having sight of it in the last few days he could not remember its existence from 1983.

Mr. Durcan referred Mr. Lyons to a meeting he attended with the Irish Haemophilia Society in early 1988, where he was informed that claims for compensation from people infected with HIV were likely.

Mr. Durcan referred Mr. Lyons to a document prepared by the Irish Haemophilia Society entitled "AIDS, Haemophilia and the Government", dated April 1988, the thrust of which was to establish a recompense

fund. A note from Mr. Collins to Mr. Lyons contains the Department's response to this request by the Irish Haemophilia Society. A side note by Mr. Lyons records that, in the Department's view, persons with haemophilia have no case and no compensation has been paid in any jurisdiction other than the UK. Based upon this viewpoint various briefing documents were prepared to be submitted to the Minister, and in turn presented to the Government.

Mr. Durcan referred Mr. Lyons to a meeting between the Irish Haemophilia Society and the Minister for Health on February 10th 1989. At this meeting, the Irish Haemophilia Society set out its case for recompense. However, the response of the Minister was to offer £50,000.00 for counselling purposes, and to point out to the Irish Haemophilia Society that the Department and the BtSB did not consider that they bore any moral or legal responsibility for the infection of people with haemophilia with HIV.

In late April 1989 Mr. Lyons prepared a document wherein the Minister's response to Parliamentary questions was contained. Mr. Lyons agreed that the whole issue of haemophilia and HIV infection was generating a lot of interest at this stage, and ultimately a General Election ensued in and around this time. Mr. Lyons set out for Mr. Durcan the method by which he would compile information upon which the Minister would answer Parliamentary questions. Mr. Lyons said his sources in this instance were the Department of Health, the BtSB, the NDAB and the Society. Mr. Lyons said his sources at the BtSB were Mr. Hanratty and Mr. Kelly. His source at the NDAB was Dr. Scott.

Mr. Lyons said no minutes existed of his meeting with Mr. Hanratty and Mr. Kelly of the BtSB. However, he said he would not have gone into detail and would have benchmarked the information with other sources within the Department. Mr. Lyons said as a result of his conversations and investigations, he was left with the impression that significant strides had been made towards the achievement of self sufficiency. Mr. Lyons agreed that his document indicated that the BtSB placed heavy reliance on the use of cryoprecipitate to avoid HIV infection. He also agreed that the I.H.S. had mentioned that two factor IX patients had developed AIDS. Mr. Lyons agreed that this was a matter of concern, but said he did not discuss this matter with the BtSB as his contact with the I.H.S. followed his contact with the BtSB. Mr. Lyons said to the best of his information, there were no Irish blood-donor-related HIV or AIDS cases. No donation related case of HIV had been recorded by the BtSB. However, he said that this related to whole blood and not blood products. He was aware that heat treated product was only available to the BtSB from 1985. However, Mr. Lyons said that his understanding was that this was a reference to factor VIII only.

Mr. Lyons agreed with Mr. Durcan that the information compiled by him and upon which the Minister based his view was incomplete and inaccurate. He further agreed that not only was his document used to brief the Minister, it went on to become the basis of a briefing document for Counsel in respect of claims being made by people with HIV against the Department and other defendants. Mr. Lyons agreed that the information to Counsel was also incomplete and inaccurate, given that it was based on the same sources of information and the same documentation as had been put to the Minister.

Mr. Lyons said that throughout all of this period, when dealing with persons with haemophilia and the issue of HIV, the Department's primary motivation was to discharge a humanitarian function. Mr. Lyons agreed with Mr. Durcan that at the time, he thought everything was properly done, but would now accept that the information upon which the State based its view and informed the Dail and advised the Government was incomplete and inaccurate.

Following the General Election, which took place in June of 1989, the new Government set up a trust fund of £1 million for persons with haemophilia infected with HIV. At this time, various people with haemophilia who had been infected with HIV were pursuing litigation against the State and various other

defendants. In 1991 discussions took place with the Society and the Government with a view to settling the litigation. The Society made a claim for £15.5 million.

In May 1991 the Government established a compensation fund. Mr. Durcan referred Mr. Lyons to a cutting from the Irish Times of June 1986, where the questions of HIV factor IX infections with B.T.S.B product was raised. Mr. Lyons said that this documentation may have been circulated during the course of the settlement negotiations. Mr. Lyons said that in 1991, the newspaper cutting did not set off any alarm bells with him. His objective at the time was to finalise the settlement. Mr. Lyons agreed that a lot of information would have been available at this time by virtue of the fact that parties to the litigation had made discovery. However, a scheme was agreed, and the I.H.S. eventually accepted a settlement.

Mr. Durcan referred Mr. Lyons to a document from the then Minister for Finance, Mr. Reynolds, where the Government's final offer of £8 million is set out. The Minister for Health is advised that this represents the final offer by the Government, and if it is not acceptable to persons with haemophilia then they would have to take their chances in court. Mr. Lyons said that at all times humanitarian considerations prevailed in the Department of Health.

Mr Lyons was cross-examined by Mr Martin Hayden for the I.H.S.

With respect to the briefing document prepared by Mr. Lyons for the February 1989 meeting, Mr. Lyons said that these were his reasoned views to the secretary general of the Department. He said he had come to those views by virtue of having been with the Department for 20 years at that time and having made extensive enquiries among his colleagues. He said he did not have recall having made such enquiries with Dr. Walsh. Mr. Hayden put it to Mr. Lyons that his view had been formed in November 1988 that no liability attached to the Department. Mr. Lyons said he put the memo together for the February 1989 meeting. He checked the information with the B.T.S.B and with Department sources. Mr. Lyons said that it was his understanding at the time that the Council of Europe recommendations were implemented, and Ireland was the first country in Europe to do so.

Mr. Lyons' cross-examination continued on Monday May 21st.