REDRAFT June2nd[t] ,2000

STATEMENT I OF BRIAN O'MAHONY

SELF SUFFICIENCY

I reside at GRO-C .I have severe Haemophilia B and I am currently Chairman of the Irish Haemophilia Society and President of the World Federation of Haemophilia. Between both positions I am devoted full time to the care and promotion of the interests of persons with Haemophilia. Although both organisations are voluntary in nature, the commitment required to manage and supervise these organisations is considerable and my role in relation to the World Federation of Haemophilia is to promote access to Haemophilia care on a global basis and most particularly in developing countries.

I attach as exhibit 1 to my Statement my Curriculum Vitae

I have been an Executive Member of the Irish Haemophilia Society since October 1982 to date. I was appointed Honorary Secretary of the Society between October 1983 to October 1985. From October 1985 to October 1986 I was Vice Chairman of the Society and from October 1986 to October 1987 I was an ordinary Executive Member. From October 1987 to date I have been Chairman of the Irish Haemophilia Society on a continuous basis.

The Irish Haemophilia Society was founded in 1968.The membership was composed of people with Haemophilia and parents.The organisation was started mainly by parents of people with Haemophilia,and at the time I became involved in late 1982,the Executive committee was a mixture of parents and people with Haemophilia.The 5 people with Haemophilia who were on the Executive at the end of 1982 (including myself) were all in their 20's The balance of Executive members comprised 2 parents and the fiancee of one of the young men with Haemophilia.

The Society was a small voluntary organisation with very limited.resources.The organisation had no office or permanent address (the home address of the Honorary secretary at any given time was the mailing address used.).The organisation had no staff and no secretarial assistance (getting our correspondence typed was a major challenge)

It is important to realise that when I joined the Society in October 1982 that the Society was a voluntary organisation with limited resources and limited objectives.

The annual budget of the Society was in the sum of £4,000 and this did not comprise any funding from any Health Board, Department of Health or other State Entity. Raising funds was difficult and time consuming. Raffles,church gate collections and flag days were all utilised.

The Society had been instrumental during the 1970's in helping to contact people with Haemophilia,putting them in touch with each other and in helping to obtain and advance Haemophilia care through the establishment of the National Haemophilia Treatment Centre. The Persons who were primarily involved in this process from the Society's perspective were Jack Downey, Bill O'Sullivan and Eithne Scallon. Other Persons instrumental in advancing Haemophilia care during the course of the 1970's were Dr Jack O'Riordan, Dr Ian Temperley and Sean Hanratty.

The Irish Haemophilia Society in the early 1980's had to some extent entered a phase in its history where its obligations were less onerous that in the past. People with Haemophilia at that time were receiving treatment for their condition and the support offered by the Society was very personal in nature. Executive Committee Members would visit persons with Haemophilia in Hospital, liaise with Parents down the Country in relation to difficulties in obtaining treatment, education or even financial assistance. The emphasis was on maintaining personal contacts within the Haemophilia Community and in addition, providing approximately two publications per annum. Even in relation to such publications the Committee would discuss over the course of a number of meetings as to the content of each Newsletter. The discussions of the Committee were often

protracted and were focussed to some extent an occasion for maintaining social contacts. In addition to these areas the priorities of the Executive would have been making representations on the services offered by the treatment centres,and dealing with requests for assistance form individual members.Areas of treatment such as the Dental and Orthopedic services were problematical and were priorities.The physical structure of the National treatment centre and the deficiencies in the services provided were priorities and were discussed when the opportunity arose with Prof. Temperley and with the NCC.(also referred to as the NHSCC)

The Society or the Members of the Executive Committee of the Society had no role in any decision making process in relation to the provision of Haemophilia treatment or Haemophilia care. The Members of the Executive Committee were parties to a culture of paternalism propounded by the medical community which was the normal course in relation to the provision of medical care at that particular time.Decisions on the replacement therapy used to treat people with Haemophilia were taken by Prof. Temperley in consultation with the other centre Directors and the BTSB.The Society were notified of the decisions by our attendance at the meetings of the NCC.Seperate meetings were held on an ad-hoc basis with Prof. Temperley or with Sean Hanratty or other representatives of the BTSB (.There were clearly tensions between Prof.Temperley and the BTSB with regard to which of them had the control over decision making in this area and I now believe that they both tried to "use" the society to further their own case.) The society endevaoured to get Prof. Temperley to be more proactive in notifying people with Haemophilia of developments with regard to treatment and AIDS.We did not have any role in the decision making process in relation to the treatment used.We did not have the level of knowledge required to authoritavely challenge the decisions made and we did not have regular contacts with experts from abroad who could have assisted us with advice.In addition,there was a high level of trust in Prof. Temperley and in the BTSB .(The prospect of even questioning medical decisions they had made was a new and not entirely welcome development to some on the Executive)

As the Society entered the year 1982, more particularly when I became a member of the Executive Committee in October 1982, the organisational structure was undoubtedly amateurish The Executive Committee, although well intentioned and using their best

endeavours, were working in circumstances where resources were limited and their continuous endeavours were to obtain some resources from fund raising.

In October 1982, the Irish Haemophilia Society minutes indicate, in accordance with my recollection, that the primary consideration was to obtain a better National Haemophilia Treatment Centre and additional resources therein. such as a better Dental and orthopaedic service.

1. **November 1982:**

I attended my first Executive Committee meeting of the Irish Haemophilia Society in November 1982. Yet, I noted from the Minutes and most particularly the verbal report of the delegates from the Irish Haemophilia Society to the NCC, that in September 1980 the NCC indicated that the BTSB were working towards self sufficiency. One further year on in November 1981 the NCC meeting stated that the BTSB aspired to make Ireland self sufficient in Factor Replacement Therapy for people with Haemophilia. Yet by the commencement of 1982 matters had not significantly progressed.

2. **January 1982:**

A report to the IHS Committee was forthcoming of an NCC discussion re Pelican House Factor VIII Production. It was indicated that the product was to undergo a trial within three months. It was aspired that the introduction of Irish Factor VIII Concentrate would occur within six months of January 1982. The Irish Haemophilia Society offered to help with the equipment necessary and required in accordance with the capital investment programme envisaged in respect of the introduction of FVIII concentrate derived from Irish donor plasma..

The delegates to the NCC reported to the IHS Executive Committee on September 24th that the lab trials in relation to Factor VIII production were complete. Sean Hanratty had reported to the NCC that the Department of

Health were to be asked for capital funding so that the BTSB could commence Factor VIII production The Minutes indicate that if the Department would not fund the provision of this equipment that it would still make a viable commercial enterprise.

In addition our Minutes indicate that the BTSB were working on Factor VIII Concentrate production on October 30th 1982 and that this home produced product would save money by decreasing the need for imports or foreign derived products at a time financial constraints. As stated, in November 1982 I attended my first Executive Committee Meeting.

3. **1983:**

On the 10th May 1983 I had a conversation with Sean Hanratty, Chief Technical Officer of the BTSB and expressed the Society and its Member's concerns over AIDS and the need to continue the push for self sufficiency. Arising from this meeting I took a minute and same is attached herewith as **Exhibit 2.** I informed Mr Hanratty of the Irish Haemophilia Society Committee's concern over AIDS and the use of imported American Blood Products which we believed at that time could lead to cases of AIDS in Ireland. Mr Hanratty agreed that American Blood Products were of inferior quality to products which could be produced from Irish plasma. because of the fact that US donors were paid and this tended to attract unsuitable donors.

Arising from this admission, I asked whether there was any reason why we could not use Irish Products exclusively. Mr Hanratty was of the opinion that the use of American Products was pushed by the Irish Haemophilia Society Committee because of their greater suitability for home therapy. But at this time, Mr Hanratty indicated there was no difficulty in providing all our national needs for Factor IX Replacement Therapy immediately. Furthermore, the BTSB were developing a Factor VIII Concentrate Product that would be a significant improvement on Cryoprecipitate .However, the work in relation to the development of this product was

proceeding much more slowly than originally envisaged. Mr Hanratty requested that we would exert whatever pressure was necessary on Professor Temperley to expedite the provision of Factor VIII Replacement Treatment. Also, I was recommended by Mr Hanratty to discuss the matter with Professor Temperley but not to quote him in relation to said discussions.

4. **May 27th 1983:**

The Honorary Secretary of the Society wrote to Mr David Watters indicating the Society was concerned about the risk of AIDS to people with Haemophilia and requesting information and names of persons who could keep the Society informed of developments.

Furthermore, the letter indicates that the Society was under the impression that the risk of AIDS was being played down. Also it was indicated that pressure was to be exerted to ensure the introduction of a self sufficiency policy in relation to Blood Products so that there would be a decrease in risk to people with Haemophilia.

5. **31st May 1983:**

The Honorary Secretary, Shay Farrelly, wrote to Professor Ian Temperley expressing the concerns of the Society regarding AIDS. The particular concern related to the use of American Blood Products especially in circumstances where there was a high incidence of AIDS in the United States. Furthermore, Mr Farrelly outlined that it was the Committee's understanding that the risk of contracting AIDS and/or Hepatitis could be decreased by using home produced products.Also,the society sought details of what steps were being taken to supply people with haemophilia with Irish blood products and what steps(if any) the Society could take to assist with this matter.

6. **July 28th, 1983:**

At an IHS Committee Meeting I expressed concern over transmission of AIDS and Hepatitis from US Blood derived Products. In addition, I sought to ascertain as to whether a reply had been received from Professor Temperley to our letter of the 31st May 1983 concerning AIDS. I also pointed out to the meeting that both Germany and Switzerland had already banned US Products. I emphasised that we should exert pressure to have home produced products used in all instances

Arising from my contention, it was indicated that the Secretary of the Society was to get in contact with Professor Temperley's Secretary and seek a reply to our letter. A reply to our letter of the 21st May 1983 was received on the 9th August 1983. Professor Temperley separated AIDS from Hepatitis and indicated that both BTSB and commercial products had been associated with Hepatitis.

In relation to the AIDS issue, Professor Temperley emphasised that the policy of Directors of the Regional Haemophilia Centre in UK was to allay fears and to continuing using all concentrate products both national and commercial until more evidence regarding the incidents in Haemophilia subjects and the nature of the condition becomes available.

Professor Temperley indicated that his policy was to support the BTSB production of Concentrates, but he did not believe that the issue of AIDS should be used to make an injudicious decision. He emphasised that there were many problems regarding BTSB versus Commercial Products and AIDS was only one.

Also he emphasised that the BTSB could not guarantee that its products would not transmit AIDS.

At the end of his letter, he indicated the importance that every person with Haemophilia would ultimately be assessed throughout the next year or so

presumably in retrospect in relation to a physical examination of their lymph glands.

7. **10th November 1983:**

A special meeting was arranged with Mr Sean Hanratty to discuss the situation with regard to production of Factor Replacement Therapy at the BTSB.

The Minutes of this meeting are self explanatory. It is important to emphasise that we received no answer for the delay in respect of the introduction of a self sufficiency policy and it was decided to draw up a plan of campaign to promote home produced Factor Concentrates which was as follows:-

(a) A Submission to be prepared for the following NCC Meeting in February 1984.

(b) I, as Honorary Secretary, was instructed to write to Dr O'Riordan requesting information on current and projected future situation re Factor Therapy.

(c) That the Committee must have two representatives at the forthcoming NCC Meeting. If any member was unable to attend a substitute was to be selected.

I wrote to Dr O'Riordan on the 24th November 1983 indicating that the Committee of the Irish Haemophilia Society would be grateful if he would provide them with the following information regarding the implementation of foreign Factor Replacement Therapy:-

(a) The number of Units of Factor VIII used in the last year.

(b) The number of Factor VIII Units imported.

(c) The cost of imported Factor VIII.

(d) The number of Units of Factor IV used in the last year.

(e) The number of Units of Factor IV imported.

(f) The cost of imported Factor IV.

In addition we requested information regarding the production of Factor VIII and Factor IX to satisfy national requirements on whether same was a feasible proposition.

8. **December 1st, 1983:**

The IHS Minutes referred to the reply received from Dr J. P. O'Riordan to the aforementioned letter, the nature of which was a phone call. Dr O'Riordan indicated that he was not prepared to send us the details requested in relation to Factor Therapy but, that he would deal with the issue of Factor VIII in a forthcoming meeting with Professor Temperley and he (Prof.Temperley) would subsequently be in contact with us in relation to same.

9. **February 25th, 1984:**

I attended, for the first time, a meeting of the NCC on the 3rd February 1984 as a substitute for John Scallon. The production of BTSB Factor VIII Concentrate was on the Agenda. I pointed out that this matter had been on the Agenda for a period of two years and queried the lack of progress made.

10. **February 25th, 1984 – IHS Meeting:**

I delivered a report on the NCC Meeting to the Irish Haemophilia Society Executive Committee. On the issue of production of Blood Products, we had been informed that all clinical trials were satisfactory and that the BTSB were to provide detailed costings for the next meeting on;

(a) Collection of Plasma for home production.

(b) Production of home product.

In addition, it was indicated that a submission was to be made to the Department of Health on the options of;

(i) Home production of Factor VIII

(ii) Collection of Plasma here and contract production.

From my own handwritten notes of this meeting, I note that arrangements for 1984 in relation to the provision of Factor VIII Concentrates had already been made. The suppliers were to be Armour and Cutter. In addition, every patient was to receive one specified batch of Factor VIII for the entire year. Treatment was also to be provided in hospitals in the form of freeze dried Cryoprecipitate but home Therapy was in the form of Factor Concentrates from Armour or Cutter.

In relation to the production of Irish Factor Concentrates, the NCC were informed that the final clinical trials results were satisfactory. There were two stages in the production:-

(a) To obtain sufficient Plasma.

(b) To produce Factor VIII from it.

It was indicated that Plasma was required to be fresh, i.e., used within six hours of donation. I asked if there was necessity for an increased number of donors to be needed for home Production of Factor VIII. Mr Hanratty replied no, but that some donors would be put on Plasmapherises. In addition he indicated that the Society should become further involved in relation to the recruitment of such donors.

Also the clinical trials showed a return of Factor VIII greater than that achieved in commercial Factor VIII Concentrates. Unfortunately the half life was somewhat less. In relation to BTSB products it was 7/8 hours whereas for commercial products it was 12 hours.

Mr Hanratty indicated to the NCC that there were two alternatives now available due to the emergence of monoclonally produced Factor VIII (which was indicated should be available in or around five years from 1984);

(a) Proceed with home production to meet national requirements.

(b) To get Factor VIII produced on a contract basis for using Irish Plasma. Mr Hanratty indicated that this would involve less risk of having obsolete equipment when monoclonal product became available.

At this instance, I asked Mr Hanratty if he agreed that five years was too long to be dependent on commercial products. Mr Hanratty agreed that it was too long.

At this juncture I asked if there was any chance of Factor VIII being produced here during 1984 as the contract had already been signed with Fractionators for the purchase of all requirements for the year 1984.

Professor Temperley indicated that there would be no production of home produced Factor VIII concentrate in the year 1984.

It was decided to proceed and to detail costings on both alternatives and same were to be submitted by the NCC to the Department of Health as soon as possible. At this juncture I outlined from the NCC Minutes the dearth of progress over the past two years on this particular issue and urged the Committee to go ahead with the introduction of a self sufficiency policy as expeditiously as was possible.
This was the last NCC meeting I attended until 1986.

At a later date the official Minutes of the NCC Committee Meeting indicated that home product had been produced sufficient to treat 8 patients covering surgery and various types of trauma. These Minutes also highlight that in the short term it would be in the best interests of "everybody to develop a system to obtain sufficient Plasma from the Irish donor population to produce Factor VIII. Also the question of purchasing a plant to produce the material could be left in abeyance until more is known about the success of cloning and genetic engineering which are currently at an experimental stage".

12. **November 16th, 1984**

John Scallan reported back to the IHS Executive Committee that Mr Hanratty indicated that the production of home product was well advanced but that he may have difficulty with the Minister for Health in employing three additional staff. Consequently it could be mid 1985 before Factor VIII would be produced for Home Therapy.

13. **January 1st, 1985:**

Heat treated imported Factor VIII and Factor IX Concentrates were introduced. These Products were manufactured by Cutter. Also non-treat heated Irish Factor 9 continued to be used.

14. **February 15th, 1985:**

On the 15th February 1985 the NCC met and the IHS were represented by John Scallan and Shay Farrelly.At the meeting it was reported that the Minister for Health had approved a programme in respect of home produced Factor VIII Replacement Therapy. A capital grant of £150,000 plus 8 additional staff were allocated to the programme. The NCC took a vote in relation to contact fractionation of Irish derived Plasma and a motion was passed by 14 votes to 2. The two dissenting voters were Professor Temperley and Dr Paule Cotter.

The Minutes of the NCC referred to the Board being in discussions with the users in relation to detailed specifications and quality of the Product if it was to be made available for the treatment of people with Haemophilia. The users referred to are the Medical Directors and the Irish Haemophilia Society were not consulted in relation to this particular aspect.

The official Minute indicates that Professor Temperley expressed reservations about the programme and these reservations mainly concerned the freedom of choice and the costs of the product.

It was noted that the Directors of the Haemophilia Service voted against the proposal and the NCC being Professor Ian Temperley and Dr Paule Cotter.

15. **February 28th, 1985:**

The IHS Committee met to discuss the issues including self sufficiency and more particularly the NCC meeting of earlier in February.

The Irish derived product would be made by Contract Fractionation and Professor Temperley was to be allowed the freedom to choose which Company was to provide such product. In addition, if he was not pleased with the service he could change to another Fractionator.

It was pointed out to the Executive Committee that both Professor Temperley and Dr Cotter were oppposed to the project. Professor Temperley was against the project as:-

(a) There was insufficient involvement of the Treaters.
(b) The cost of the provision of treatment could be excessive due to lack of competition.

John Scallon in his report indicated that there may be some other reason why Professor Temperley was against home derived blood products but that maybe Professor Temperley couldn't mention it at the NCC meeting. Arising from this information, Paul Sheridan proposed that the NCC Representatives would write to Professor Temperley and request him to clarify his position and then subsequently write to the BTSB indicating the Society's position. A sub-committee was formed,comprising myself, Paul Sheridan and Pamela Aldrich.in addition to the NCC representatives,to progress matters.

On March 28th a letter was received from Professor Temperley suggesting a meeting with several members of the Committee as he could not put his views in writing. I attended with John Scallon and Shay Farrelly and our purpose was to ascertain Professor Temperley's opposition to the BTSB home produced blood products. Professor Temperley felt that he was not properly consulted in relation to the entire project. Most interestingly he indicated that he wasn't concerned about the quality of the blood product but was concerned as to whether the BTSB would increase the price significantly in circumstances where there was no competition as they had done with other blood products such as Platelets.

He also wished that the BTSB would proceed with the project but he required an input into the programme and he wanted the Society's support in this regard. He indicated it was important that he would actually be involved as opposed to being kept informed about happenings.

In addition, he informed us that he was taking a sabbatical to the Royal Free Hospital for a period of six months. In his absence three Locum Consultant Hematologists were to take over his responsibilities during said period.

In addition, he delivered worrying information by telling us that 80% of the HTLV III blood tests undertaken on our members showed a positive result. In addition he indicated that he expected that there would be one more case in Ireland of AIDS according to the US findings/statistics.(the first case had occoured the previous December.)

16. **May 10th, 1985 – NCC Minutes – Report by Shay Farrelly for IHS Executive Committee Members:**

Factor VIII Product derived from Irish Plasma would be available for distribution from the 1st January 1986 and the cost will be lower than commercial product and the quality would be as stipulated by the Centre Directors.

17. **July 25th, 1985:**

I attended an IHS Executive Committee Meeting at which Shay Farrelly proposed a meeting with Sean Hanratty, Dr O'Riordan and Dr Helena Daly, to discuss the delays in initiating Irish Products and AIDS developments.The suggestion for this proposed meeting was triggered by a "World in Action" TV documentary which had been screened on July 22.The program implied that 50% of people with Haemophilia in the UK may develop AIDS.

It was decided that if we received no satisfaction arising from this meeting, the following course of action would be considered:-

(a) Seek a meeting with the Minister for Health.

(b) Give Interviews to the News Media outlining the problem.

18. **August 13th, 1985:**

I attended a meeting together with other Executive Committee Members being, Shay Farrelly, Pamela Aldrich, John Scallon, Dr Helena Daly, Dr J. P. O'Riordan and Mr Sean Hanratty, in relation to the availability of Irish Plasma derived from Factor VIII concentrates. We received assurances that said Products would be available from the 1st January 1986. Furthermore, these Products were to meet 80% of the Haemophilia population needs. The remaining 20% would be met by Cryoprecipitate.

19. **March, 1986:**

There was a discussion at an IHS Executive Committee Meeting in regard to the procurement of additional donors for the BTSB's Plasmapherises Programme.

20. **June 6th,7th,1986**

I attended a 2 day seminar in UCD organised by the Academy of Medical Laboratory Sciences. One of the lectures was on the topic "AIDS and Haemophilia".This was delivered by Prof.Temperley I attended this particular lecture due to my personal interest in Haemophilia. I had expected that he would outline the history and give figures for the number of people with haemophilia who had been infected with HIV up to 1985.I was shocked when he informed the meeting that 5 or 6 people with Haemophilia B had been infected with HIV.This had just come to light and was probably linked to the use of products made by the BTSB.This was the first I had heard of this.I was appalled by the fact that the initials of the individuals concerned were displayed on a transparency at the meeting.I

imparted this information to the IHS Committee at the meeting on June 18th.

Signed:_____

BRIAN O'MAHONY
Chairman,
Irish Haemophilia Society,
1987 to Date